SUMMER – 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

Subject Name: Pharmacy Law and 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	**Give the procedure for preparing First register and What qualifications required for entry for First register as per pharmacy Act. 1948?** **Marking scheme: Procedure 2.5 marks, Qualification 2.5 marks** **Answer: Procedure for First Register Preparation (2.5 M)** **1. Constitution of Registration Tribunal** For the purpose of preparing the first register, State Government shall by notification in the Official Gazette constitute a Registration Tribunal consisting of three persons and shall appoint a registrar who shall act as Secretary of Registration Tribunal. **2. Appointment of date for the application** State Government shall by same or similar notification appoint a date on or before which the application for registration accompanied with the prescribed fees shall be made to the Registration Tribunal. **3. Scrutiny** Registration Tribunal shall examine each and every application received on or before the appointed date. If it is satisfied, the applicant is qualified and his name will be directly entered in the first register. **4. Appeal** First register so prepared shall be published in such manner as the State Government may direct and if any person who is aggrieved with the decisions of Registration Tribunal may appeal within 60 days of such publication to the authority appointed	**5M**

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		thereupon above. **5. Issue of a certificate of registration** Registrar of State Council shall keep the register in accordance with the orders made by and shall thereupon, issue to every person a certificate of registration in the prescribed form. **6.** Upon the constitution of State Council, the register shall be given into its custody and the registration fees shall be paid to the credit of State Pharmacy Council. **Qualifications for entry for First register as per pharmacy Act. 1948 (2.5 M)** A person, who has attained his 18 years of age, resides or carries on his profession or business of pharmacy and has been paid the prescribed fees for the registration, shall be entitledto have his/ her name to be entered on the first register and if he/she- a) holds a degree or diploma in pharmacy or pharmaceutical chemistry or 'Chemists and Druggists' diploma of an Indian University or any other prescribed qualification granted by an authority outside India. b) holds a degree other than degree in pharmacy or pharmaceutical chemistry of a recognized University with not less than three years' experience in compounding of drugs in a hospital or at any other place where drugs are dispensed on the prescription of Registered Medical Practitioner. c) has passed an examination recognized as an adequate by State Government for the Compounders and Dispensers. d) is engaged in compounding and dispensing of drugs for a total period of not less than five years in a hospital or dispensary where drugs are dispensed regularly on the prescriptionof Registered Medical Practitioner.	
1	b	**Write the qualification for Drug inspector and give the procedure of drug inspector in taking samples.** **Marking scheme: Qualification 2 marks, Procedure 3marks** **Answer: Qualifications required for Drug Inspector (2M)** A person to be appointed as drug inspector should be graduate in pharmacy or pharmaceutical chemistry or medicine with specialization in Clinical Pharmacology or Microbiology from recognized University established in India. Provided that- 1. a person who have not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C; or 2. who have not less than 18 months experience in testing of at least one of the substances specified in schedule C; or 3. who have not less than 3 years experience in inspection of firms manufacturing at least one of the substances specified in Schedule C.	**5M**

Q. No.	Sub No.	Answers	Marking Scheme

Procedure of Inspectors in taking samples (3M)

1. Where an Inspector takes the sample of drugs, he shall pay the fair price of it and maygive written acknowledgment thereof.
2. Where a price is refused or where an Inspector seizes the stock of drugs, he shall give receipt of it in Form 16.
3. Where an Inspector takes the sample of drug for test or analysis he shall intimate such purpose in Form 17 in writing to a person from whom he takes it.
4. In presence of such person, unless he wilfully absents himself, the drug inspector shalldivide the sample into four portions, effectively seal and mark them and allow that person to add his own seal and mark.
5. Where an Inspector takes the sample of drug or cosmetic from manufacturing premises sample should be divided into three portions only.
6. Where a drug or cosmetic is made up in small volume containers and if drug is likely todeteriorate or damage by exposure, drug inspector shall take three or more containersafter suitably marking the same and sealing them.
7. Drug inspector shall give one portion of sample to a person from whom he takes it anddivide the remaining three portions as follows

a. He shall give one portion of sample to a person from whom the sample is taken.
b. He shall send second portion to the Government Analyst for test or analysis.
c. He shall produce third portion in the court before which proceeding have been instituted.
d. He shall send forth portion to warrantor whose name, address and other particulars havebeen disclosed.

8. The portion of sample or container shall be sent by registered post or by hand. A copy of memorandum and specimen impression of seal used to seal the packets shall be sent separately by registered post.
9. Where an Inspector seizes the register, records or other document and samples of drugsor cosmetics he shall inform Judicial Magistrate and take his order of custody.

Q. No.	Sub No.	Answers	Marking Scheme
1	c	**Define the term under D and C Act. 1940** **i) Adulterated Drugs** **ii) Misbranded Drugs.** **Give the functions of CDL as per D and C Act. 1940.** **Marking scheme: Each definition 1.5 marks, Any 2Functions 2Marks** **Answer: i) Adulterated Drug (1.5 M)** A drug shall be deemed to be adulterated if- a) it contains in whole or in parts of filthy, putrid or decomposed substances; or b) it is prepared, packed or stored under unsanitary conditions whereby it may have been contaminated with filth or which may render the contents injurious to the health, or c) its container is composed in whole or in parts of poisonous or deleterious substance which may render the contents injurious to the health; or d) it contains or bears for the purpose of coloring only, a color other than those prescribed;or e) it contains harmful or toxic substances which may render it injurious to health; or f) any substance has been mixed therewith so as to reduce its quality or strength. **ii) Misbranded Drug (1.5 M)** A drug shall be deemed to be misbranded if – a) 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 b) it is not labelled in the prescribed manner; or c) 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. **Function of CDL (Any 2 functions, 2M)** 1. To analyze or test such samples of drugs as may be sent to it by the Custom Collectors or Courts. 2. To carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board. 3. In case of sera, vaccines, toxins, antigens, antisera, solution of serum proteins for injections, sterilized ligature and suture and bacteriophages, the functions of CDL iscarried out at the Central Research Institute, Kasauli and such functions are exercised bythe Director of the said institute. 4.The functions regarding Oral Polio Vaccine testing are exercised by the Deputy Director and Head of the Polio Vaccine Testing Laboratory of Central Research Institute, Kasauli.	5M

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		5. In case of antisera, vaccines, diagnostic antigens and toxoids for veterinary use, the functions of CDL are carried out at the Indian Veterinary Research Institute, Izatnagar orMukteshwar and such function are exercised by the Director of the said institution. 6.In case of condoms, the functions of CDL are carried out at Central Indian Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by Director ofthe said laboratory. 7. In case of VDRL (Venereal Disease Reference Laboratory) antigens the function of CDL is carried out at the Laboratory of Serologist and Chemical Examiner to Government ofIndia and such functions are exercised by Serologist and Chemical Examiner of the said laboratory. 8. In case of IUCD (Intrauterine Contraceptive Devices) and felope rings, the functions of CDL are carried out at Department of Biochemical engineering, Indian Institute of Technology, New Delhi and such functions areexercised by Head of said department.	
1	d	**State in detail provisions "Schedule N" of D and C Rules 1945.** **Marking scheme: Schedule Statement (1M), Description on sub points (4M)** **Answer: Schedule N** It prescribes the list of minimum equipment, requirements of premises for the effective running of a pharmacy. **1. Entrance:** The entrance of a pharmacy shall bear an inscription "Pharmacy" in front. **2. Premises:** The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The areas of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters. The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices. A pharmacy shall be provided with an ample supply of good quality water. The dispensing department shall be separated by a barrier to prevent the admission of the public. **3. Furniture and apparatus-** The furniture and apparatus of a pharmacy shall be adopted to the uses for which they are intended and correspond to the size and requirements of the establishment. Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them. Drawers,	5M

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

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

A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.

A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the word 'POISON' in red letters on a white background. Containers of all concentrated solutions shall bear special labels or marked with the words "To be diluted"..

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

Apparatus:-

Balance, dispensing, sensitivity 30 mg.
Balance, counter, capacity 3 Kg M., sensitivity 1 gm.
Beakers, lipped, assorted sizes.
Bottles, prescription, ungraduated assorted sizes.
Corks assorted sizes and tapers.
Cork, extracter.
Evaporating dishes, porcelain .
Filter paper.
Funnels, glass.
Litmus paper, blue and red. Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml.
Mortars and pestles, glass.
Mortars and pestles, wedgwood.
Ointment pots with bakelite or suitable caps.
Ointment slab, porcelain
Pipette graduated, 2 ml, 5 ml and 10 ml. Ring, stand (retort) iron, complete with rings.
Rubber stamps and pad Scissors
Spatulas, rubber or vulcanite
Spatulas, stainless steel.
Spirit lamp
Glass stirring rods.
Thermometer, 0°C to 200°C.
Tripod stand.
Watch glasses.
Water bath.
Water distillation still in case Eye drops and Eye lotions are prepared.
Weights, Metric, 1 mg, to 100 gm.
Wire Gauze.
Pill finisher, boxwood.
Pill Machine.

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		Pill Boxes. Suppository mould. **Books:** The Indian Pharmacopoeia (Current Edition). National Formulary of Indian (Current Edition). The Drugs and Cosmetics Act, 1940. The Drugs and Cosmetics Rules, 1945. The Pharmacy Act, 1948. The Dangerous Drugs Act, 1930. **4. General provisions-** A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises. The Pharmacist shall always put on clean white overalls. The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean. All records and registers shall be maintained in accordance with the laws in force. Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person. Medicaments when supplied shall have labels conforming to the provisions of laws in force.	
1	e	**Give the objectives of DPCO, 2013 and define the term under this Act -** **i) Active Pharmaceutical Ingredients** **ii) Formulation** **iii) Maximum Retail price** **Marking scheme: Objectives 2marks, Each definition 1mark** **Answer: Objectives of DPCO2013 (2M)** The various objectives of this order are- a. to make the essential medicines available at reasonable prices. b. to provide sufficient opportunity for innovation and competition to support the growth of industry. c. to meet the goals of employment and shared economic growth of all. d. to achieve adequate production. **Definition: i) Active Pharmaceutical Ingredients (1M)** It means any pharmaceuticals, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopoeias or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation .	**5M**

Q. No.	Sub No.	Answers	Marking Scheme
		ii) Formulation(1M) It means any medicine processed out of or containing one or more drug/drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease but shall not include - a) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines b) any medicine included in the Homeopathic system of medicine c) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 do not apply. **iii) Maximum retail price (1M)** It means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack.	
1	f	**Give two points of difference in law and ethics. Explain the duties of a pharmacist in relation to his trade.** **Answer: Marking scheme: Difference- any 2points (2M), Duties- 3marks**	5M

Sr. No.	Law	Ethics
1	It is an authorative instrument that rules over the society.	It is a way of conducting life laid down by the society to help the individuals to decide what is right and wrong.
2	Laws are a set of rules and regulations enforced by the Government or authorities.	Ethics are morals and principles adapted by society from the environment.
3	Law can prevent the illegal practice of pharmacy.	It can prevent unethical practices of pharmacy that can cause grave risk or danger to the life of individual or patient.
4	Failure to follow laws can result in penalties and punishment	Ethics do not attract penalties and punishment.
5	Laws are made by lawyers and legislature	Ethics are made by religious leaders, philosophers and elders in the family.
6	Laws are compulsory and must to be followed	Ethics are values to be considered to be a positive attitude to follow.
7	Laws are in a written document	Ethics are not written
8	Laws tend to be the same in a country.	Ethics tend to vary from one city to another.
9	Law can prevent the sale of substandard quality drugs but cannot prevent selling of drug at cheaper rate.	The sale of substandard quality drugs at cheaper rate is restricted by the code of ethics.

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		Duties of a pharmacist in relation to his trade (3M) a) Pricing of drugs Pricing of drugs and pharmaceuticals should be fair. The overcharging of the productsshould be avoided. A suitable price structure should be adopted for pricing of drugs. He should calculate the retail price of his formulation according to the formula prescribed under Drugs andPrice Control Order. While calculating the price he should consider the material cost, packaging charges, cost of packaging material, etc. b) Fair trade practice Pharmacist should not make any attempt to capture the business of fellow pharmacist bycutthroat competitions that is by offering gifts or reducing prices to the patient, etc. Trade marks,signs and symbols of another pharmacist should not be copied. c) Purchase of drugs Pharmacist should purchase drugs of standard quality only. He should not purchase substandard quality, adulterated drugs or misbranded drugs. He should purchase drugs under cash or credit memo from a duly licensed manufacturers and dealers. d) Hawking of drugs Hawking of drugs should be prohibited under the code of pharmaceutical ethics to prevent self-medication and mismedication. e) Advertising and display Advertisement and display of drug should also be prohibited under the code of pharmaceutical ethics to prevent self-medication and mismedication. Advertisements of drugsmaking a false claim or which gives misleading information about the drug should be prohibited.	
1	g	**Explain the steps involved in New Drug Development.** **Marking Scheme:** Each step in drug development Process -1Mark **Answer: Steps Involved in Drug Discovery and Development Process includes** **Step 1: Discovery and Development** 1. Discovery and development: The identification of drug candidates, synthesis, characterization, screening, and tests for therapeutic efficacy are all parts of the drug development process. A compound will be subjected to the process of medication development after clinical trials when these investigations yield satisfactory results. Due to the high costs of research and development and clinical trials, developing new drugs is an expensive process. From the time a new medication molecule is discovered until it is sold to patients, it takes about 12 to 15 years to develop.	5M

Q. No.	Sub No.	Answers	Marking Scheme
		Step 2: Preclinical Research The two types of preclinical research are: in vitro and in vivo. Usually, preclinical studies are not very large. Preclinical trials of drug development are conducted on animals to collect the information on Safety, Efficacy. However, these studies must provide detailed information on dosing and toxicity levels. After preclinical testing, researchers review their findings and decide whether the drug should be tested in people. **Step 3: Clinical Research** "Clinical research" refers to studies, or trials, that are done in people. As the developers design the clinical study, they will consider what they want to accomplish for each of the different Clinical Research Phases. Clinical trials include Phase I,II,III IV and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins. **Step 4: FDA Drug Review** If a drug developer has evidence from its early tests and preclinical and clinical research that a drug is safe and effective for its intended use, the company can file an application to market the drug. The FDA review team thoroughly examines all submitted data on the drug and makes a decision to approve or not to approve it. **Step 5: FDA Post-Market Drug Safety Monitoring** Even though clinical trials provide important information on a drug's efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval. Despite the rigorous steps in the process of drug development, limitations exist. FDA reviews reports of problems with prescription and over-the-counter drugs, and can decide to add cautions to the dosage or usage information, as well as other measures for more serious issues. Committee of Safety of Medicine (CSM) receives the information of all studies and if it is satisfied the product license is issued. Medical practitioners report the efficacy and toxicity of product which is reviewed by the Committee of Review of Medicines. The committee may renew or cancel the licence of product.	
2		**Answer any TEN of the following:**	**30 M**
2	**a**	**Explain the general principles of law.** **Marking Scheme: Any three principles- 3marks** **Answer: General principles of law (Any three, 3 M)** 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	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		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, 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 discriminations. **4. Principle of justice** The principle of justice obliges us to equitably distribute benefits, risks, costs, and resources. 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. 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	**b**	**Define Drug and New Drug as per the D and C Act.1940.** **Marking Scheme: Each definition- 1.5 marks** **Answer: (i) Drug (1.5marks)** a) 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; b) 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 human beings or animals. c) All substances intended for use as components of a drug including empty gelatin capsules; and d) Such devices intended for internal or external use in the diagnosis, 'treatment, mitigation or prevention of disease or disorders in human beings or animals.	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		(ii) New Drug (1.5 marks) **a)** A new substance of chemical, biological or biotechnological origin in bulk or prepared dosage form used for prevention, diagnosis or treatment of disease in man or animals, which except during local clinical trials has not been used in the country to any significant extent and which, except during local clinical trials has not been recognised in the country as effective and safe for the proposed claims. **b)** A drug already approved by the Licensing authority for certain claims, which is now proposed to be marketed with modified or new claims namely indications dosage, dosage form and route of administration. **c)** A fixed dose combination of two or more drugs, individually approved earlier for certain claims which are now proposed to be combined for the first time in a ratio or if the ratio of ingredients in an already marketed combinations is proposed to be changed with certain claims viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration.	

Q. No.	Sub No.	Answers	Marking Scheme
2	c	**List licences (with form numbers) for sale of drugs under D and C Act,1940** **Marking Scheme: Licenses for sale -3marks** **Answer:** **Issue of Licence (3M)**	**3M**

Licence Issued	Issue of Licence (Form No.)		
	Drugs other than Sch.C, C1 & X	Drugs in Sch. C & C1	Drugs specified in sch.X
Retail	20	21	20F
Wholesale	20B	21B	20G
Restricted	20A	21A	—
Wholesale or Distribution from Motor Vehicle	20BB	21BB	—-

2	d	**Define Repacking of Drugs and state any six conditions for grant of repacking license.** **Marking Scheme: Definition- 1mark, Conditions-2marks** **Answer: Repacking of drugs (1M)** It is the process of breaking up any drug from a bulk container into small packages and the labelling of each such package with a view to its sale and distribution. But, it does not include the compounding, dispensing or the packing of any drug in the ordinary course of retail business. **Conditions of repacking Persons licensed to repack drugs should observe the following conditions (2M)** 1) Adequate space & equipment for the repacking operations which must be carried out under hygienic conditions & under supervision of Competent Person. 2) License should maintain adequate arrangement for analysis and testing of each batch of raw material and repacked drugs or by testing approved institutions, maintain record	**3M**

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		for the period of 3 years from date manufacturing and in case of drugs with expiry date at least for 3 months from such date. 3) The drugs repacked should, in addition to other particulars, bears the no. of license preceded by the words 'Rpg. Lic. No.' on their label. 4) Application for the grant or renewal of such license shall be made in Form 24-B & the license shall be issued in Form 25-B. 5) License required for the repacking of drugs other than those specified in schedule C and C1. 6) The factory premises should comply with requirement specified as per schedule M, the licenses should make adequate arrangement for the storage of drugs 7) Licensee shall allow Inspector to inspect records and registers maintained under these rules. Also allow any Inspector to enter with or without notice, in any premises, where packing of drugs is carried on and to inspect premises and to take samples of repacked drugs. 8) The licensee shall maintain an Inspection book in Form 35 to enable Inspector to record his impression and the defects noticed. 9) Any change in the competent staff named in the license should be forthwith notified to the licensing authority. 10) The license should comply with the provision of the Act and the Rules and with such further requirement of which he has been not less than 4 months' notice by the licensing authority.	
2	**e**	**Define 'Illicit traffic's under NDPS Act.1985.** **Marking Scheme: Definition-3marks** **Answer: Illicit traffic (3M)** It includes**:** i) Cultivating any coca plant or gathering any portion of coca plant ii) Cultivating the opium poppy or any cannabis plant iii)Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use of consumption, interstate import, inter- state export, import into India, export from India or transhipment, of narcotic drugs or psychotropic substances. iv) Dealing in narcotic drugs, psychotropic substances. v) Handling or letting any premises for use for any of the purposes referred in (i) to (iv) vi) Financing any activity by himself or through any other person in the furtherance or in support of doing any of the aforesaid acts. vii) Harbouring persons engaged in any of the activities specified in (i) to (vi) or viii) Abetting or conspiring in the furtherance or in support of doing any of the aforesaid	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		acts except to the extent permitted under the Narcotic Drugs and Psychotropic Substances Act, 1985, or any rule or order made, or any condition of any license, permit or authorisation issued, thereunder.	
2	f	**Give offences and penalties under Drugs and Magic Remedies (OA)Act, 1954** **Marking Scheme: Offences & penalties-1.5 marks for each** **Answer:** **Offences & Penalties under Drugs & Magic Remedies (O.A.) Act, 1954 (3M)** 1) Contravention of any of the provision of this Act or Rules thereunder shall be punishable with imprisonment six month or with fine or with both on first conviction. - Punishable with imprisonment one year or with fine or with both on subsequent conviction. 2) In case of contravention of the provisions of the Act by a company, every person who at the time of the commission of the offence, was in-charge of & was responsible for the conduct of company business shall be deemed to be guilty & liable for the punishment. However, such person is not liable for the punishment if he proves that the offence was committed without his knowledge or he has taken all the precautions to prevent that the commission of such offence.	**3M**
2	g	**Give provisions for sale and possession of poison under poison under poison Act, 1919.** **Marking Scheme: Provision for sale-2marks,any 4points & possession-1mark** **Answer: Possession & sale of specified poisons: (any 4 points, 2 marks)** 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 labeling 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	**3M**

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		Possession of any poison (1M) 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 insuch local area where such occurrences are very frequent.	
2	h	**Write the experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act,1971.** **Answer: Experience and training of Registered Medical Practitioner (RMP) required for termination of pregnancy as per MTP Act,1971 (3M)** The Medical Termination of Pregnancy Rules 1975 prescribe the experience or training in gynaecology and obstetrics that a registered medical practitioner should have to terminate any pregnancy. **a**) A medical practitioner registered in a state Medical register immediately before the commencement of the Act should have not less than three year's experience in the practice of gynacecology and obstetrics. **b**) A medical practitioner, registered in a state Medical Register on or after the date of the commencement, can terminate the pregnancy, **i)** If he has completed six months of house surgency in gynaecology and obstetrics or **ii)** If he has experience at any hospital for a period of not less than one year in the practise of obstetrics and gynaecology, or **iii)** If he has assisted a registered medical practitioner in the performance of twenty five cases of medical termination of pregnancy in a hospital established or maintained ,or training institute approved by the Government, for this purpose. **c**) In case of a registered medical practitioner who holds a post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma is considered.	**3M**
2	i	**Explain the documentation, license and renewals in pharma manufacturing.** **Marking scheme: Documentation-1M, Licenses-1M, Renewals-1M** **Answer: 1) Documentation: (1M)** Manufacturer should maintain record as per Schedule U. He should obtain the required manufacturing licences from licensing authority. He should maintain the Product Master Records, Batch Manufacturing Records, Material/ components control record and Personnel record. He should have adequate testing facility. Also, he should maintain equipment log books, cleaning log books. He should also maintain the records of distribution of each batch of products, records of returns/recall & customer contents. He should maintain the validation records	**3M**

Q. No.	Sub No.	Answers	Marking Scheme
		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 25 b. Grant of a licence to manufacture drugs specified in schedule C, C1, excluding those specified in schedule X- Form 28 b. Grant of a licence to manufacture for sale drugs specified in schedule X - Form 25 F **3) Renewal of licences (1M)** The granted licences are valid upto 5 years and should be renewed before expiry.	
2	**j**	**Write the difference between branded and generic drugs (any six)** **Answer: Difference between branded and generic drugs (6 points - 3 M)**	**3M**

	Branded Drugs	Generic Drugs
1.	Branded drugs are Developed and manufactured by an innovator company only.	Generic drugs are manufactured by several pharmaceutical companies after patent expiration of the relevant brand name drugs.
2.	Brand name drugs are Patent protected	Generic drugs are not patent protected.
3.	Preclinical studies, clinical trials and post marketing surveillance are essential.	Preclinical studies, clinical trials are not required.
4.	New drug development is time consuming and very expensive	New drug development process is not required.
5.	Huge expenses are made on drug development, sales promotion and marketing	No such expenses are usually made.
6.	Branded products are patentable, capable of protection and registration	Generic drugs are non-patentable, need no registration for unbranded drugs.
7.	Branded drugs are costlier	Generic drugs are cheaper.
8.	Brand names are easy to pronounce, identify, remember and very useful in sales promotion and marketing	Generic names are usually complicated, difficult to remember and hardly play any role in sales promotion and marketing.

Q. No.	Sub No.	Answers	Marking Scheme
		9 | Examples: Crocin, Calpol | Example: Paracetamol	
2	k	**Explain the procedure for registration of the clinical establishment.** **Marking scheme: Procedure for registration- 3marks** **Answer: Registration Procedure of the clinical establishment** Registration of clinical establishment is required as per the provisions of Clinical Establishment Act, 2010. 1) For registration and continuation, every clinical establishment shall fulfil the following conditions, namely - (i) Prescribed minimum standards of facilities and services (ii)Prescribed minimum requirement of personnel (iii)Prescribed provisions for maintenance of records and reports (iv) Such other conditions as may be prescribed. (2) Medical examination facilities for staff (3) Maintenance of record There are two types of registrations A] Provisional Registration: In this, authority grants approval without inspection. Registration will get within 10 days from the date of application and valid upto 12 months. The provisional registration shall be renewed before 30 days of expiry B] Permanent Registration: According to application format for permanent registration, applicant has to provide information such as details of establishment, types of services, system of medicines, etc. For the permanent registration of the establishment, the applicant has to apply with proof to comply with minimum standard. He shall display the standards for information to public. The registration is valid for 5 years from date of issue. Application should be submitted to District Registering Authority in person or by post or online along with necessary fee.	**3M**
3		**Answer ALL questions:**	**20M**
3	**a**	List of diseases and ailments which a drug may not claim to prevent or cure is covered under ……. schedule **Answer: J**	**1M**

SUMMER – 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

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

Q. No.	Sub No.	Answers	Marking Scheme
3	b	As per D and C rules schedule R prescribe…… **Answer**: Standards for condoms made up of rubber latex intended for single use and other mechanical contraceptives.	1M
3	c	Which of the following is prohibited to be imported? i)Toilet preparations ii) Ayurvedic Drugs iii) Misbranded Drugs iv) Schedule C, G Drugs **Answer**: iii) Misbranded Drugs	1M
3	d	CPCSEA stands for …… **Answer: C**ommittee for the **P**urpose of **C**ontrol and **S**upervision of **E**xperimentation on **A**nimals	1M
3	e	Define captive animal as per prevention of cruelty to Animal Act, 1960 **Answer:** **captive animal** - means any animal (not being a domestic animal) which is in captivity or confinement, whether permanent or temporary, or which is subjected to any appliance of contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed;	1M
3	f	Out of 22 members of the Food Authority, the proportion of women is …….. i) Half ii) One-Third iii) One- Fourth iv) Two- Third **Answer:** ii) One-Third	1M
3	g	Which act's prime objective is to make sure that the essential drugs are available to all at a reasonable price. **Answer:** Drugs Price Control Order (DPCO) 2013	1M
3	h	For calculation of price of bulk drugs a return of 12% is allowed on ……costing i) Short term marginal ii) Long term marginal iii) Periodic iv) Intermediate **Answer:** ii) Long term marginal	1M
3	i	Code of pharmaceutical ethics developed by …….. **Answer: P**harmacy Council of India	1M

SUMMER – 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

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

Q. No.	Sub No.	Answers	Marking Scheme
3	j	Define the term minor **Answer:** Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.	1M
3	k	The CDSCO is a ……..body. **Answer:** National Regulatory	1M
3	l	Which authority issue the drug manufacturing license……. **Answer:** Central Drugs Standard Control Organization (CDSCO)	1M
3	m	Minimum haemoglobin value required for a donor to donate blood is …….gm/dl **Answer:** 12.5 gm/dl *Note- any value between 12 to 13 gm/dl may be considered.	1M
3	n	Medical devices rules were established in the year……. i) 1971 ii) 1917 iii) 1997 iv) 1979 **Answer:** **Note* - All above options are not correct so don't give any marks for this question.**	
3	o	Head office of National Institute of Disaster Management (NIDM) is situated in which city? **Answer:** New Delhi	1M
3	p	Consumer protection Act is significant to ? i)All goods and services ii) Immovable goods iii)Movable goods iv) Selected goods and services **Answer:** i) All goods and services	1M
3	q	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.	1M
3	r	As per Bioethics, Enlist the principle of justice.	1M

SUMMER – 2023 EXAMINATION

Model Answer – Only for the Use of RAC Assessors

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

Q. No.	Sub No.	Answers	Marking Scheme
		Answer: Any one Principle 1.Equal opportunity 2. Eliminate discrimination in biological studies and healthcare 3. No differentiation in research based on age, sex, races, religious beliefs	
3	**s**	Moral rules to protect and defend the right of patient is mentioned under…….. principle of bioethics. **Answer:** Beneficence	**1M**
3	**t**	Animal anatomical waste are categorised under which category of biomedical waste. **Answer:** Yellow	**1M**