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.

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any *Eight* of the followings:**	**16M**
1	**a)**	**Why gargles are submitted in concentrated form?** Gargles are submitted in concentrated form because, • The quantity of solution require for doing one time gargle is around 20 ml. • Therefore if it is dispensed in dilute form it requires the large quantity which is practically impossible to dispense. • Therefore they are dispensed in concentrated form.	**2M**
1	**b)**	**What is double wrapping? Where it is useful?** When wrapping is done in white glazed paper which is lined with waxed paper is called as double wrapping. The lining is cut a few mm smaller than the white glazed paper and is quite satisfactory to fold both papers together. It is **useful** for wrapping of volatile, hygroscopic and deliquescent substances.	**2M (1MDefination, 1M use)**
1	**c)**	**Discuss the drawbacks of cocoa butter as a suppository base.** Following are drawbacks of cocoa butter as a suppository base- • Exhibits marked polymorphism. • Rancidity. • Stick to mould. • Leakage from body cavity. • Costly. • Immiscibility with body fluid. • Chloral hydrate or lactic acid liquefies it. • Melts in warm weather	**2M (0.5 x 4 = 2M)**
1	**d)**	**Give the metric equivalent of the following:** **i)** **1 pound –** 450 gram **ii)** **1 grain –** 64.8 mg/60mg **iii)** **1 dessert spoonful –** 8.00 ml **iv)** **15 minim –** 0.06 x 15 = 0.9 ml	**2M (0.5 X4 = 2M)**

1	e)	**List reasons causing therapeutic incompatibility.** Following are reasons causing therapeutic incompatibility • Error in dosage. • Wrong dose or dosage form. • Synergism and Antagonism drug. • Contraindication. • Drug interactions	**2M (0.5 X4 = 2M)**
1	f)	**Define with example (any one)** **i) Douches** – Douches are medicated soln. for rinsing body cavity mostly for bladder, vagina, rectum, nasal cavity**.** **E.g.** Potassium permanganate douche solution, Isotonic sodium chloride solution etc. **ii) Gargles** – Gargles are clear aqueous solutions used to prevent or treat throat infections. They are brought into intimate contact with the mucous membrane of the throat and are allowed to remain in contact with it for few seconds, before they are thrown out of the mouth. **E.g.** Potassium chlorate and Phenol gargles B.P.C, Phenol gargles , Potassium chloride and phenol gargle **iii) Inhalations –** Inhalations are solutions or suspensions of volatile, aromatic substances administered by the nasal or oral respiratory route in the form of vapour inhaled from the surface of hot water. **Eg.** Eucalyptus oil Inhalations	**2M (1M Def., 1M e.g.) Any one example of each can be considered**
1	g)	**What is HLB? Give it's significance.** Griffin devised useful method for calculating balanced mixtures of emulsifying agents to provide a particular type of emulsion.in which every emulsifying agent has given number ranging from 1-18 .It is called as HLB or (Hydrophilic – Lipophilic Balance System	**2M (1 +1)**

		Significance – It is very difficult to select a proper emulsifying agents for the preparation of a stable emulsion from large number of emulsifying agents. No single emulsifying agent possess all the properties required for preparation of stable emulsion. So sometimes it is necessary to use two or more than two emulsifying agents instead of one to prepare stable emulsion.	
1	**h)**	**Give any four qualities of a good suspension.** The qualities of Ideal suspension- • It should settle slowly • It should be readily re-dispersed on gentle shaking of the container. • It should pour readily and evenly from its container. • It should be chemically inert. • The suspended particle should not form a cake. • It should be free from large particles which spoils its appearance & give gritty taste to oral preparation and also cause irritation to sensitive tissues when applied externally.	**2M** **(0.5 X4 = 2M)**
1	**i)**	**Define antiperspirants and deodorants.** **Antiperspirants:** These are the agents used to prevent the flow of perspiration to overcome bad smell which is due to bacterial decomposition Eg. Aluminium salts **Deodorants:** Deodorant inhibits the formation of bad odour in perspiration by suppressing the growth of bacteria or masks the unpleasant odour Eg Salicyclic acid, boric acid, zinc stearate	**2M** **(1 +1)**
1	**j)**	**Give the reasons, "glycerine is choice of vehicle for throat paints."** Glycerine is used as vehicle in throat paint because- • Glycerine is viscous in nature and adheres to the throat • Increases contact time and prolong the action • It is also act as soothing agent.	**2M**

1	k)	**White Vaseline is not used in ophthalmic ointment. Why?** White Vaseline is obtained from yellow soft paraffin by bleaching. White Vaseline is not used in ophthalmic ointment because it may contain small traces of bleaching agent which are left over after bleaching the yellow soft paraffin. Hence white Vaseline may cause irritation to eye.	**2M**
1	l)	**What are the advantages of parenteral products?** Advantages of parental products - • Rapid onset of action. • Immediate therapeutic action is possible. • Each dose can be administered accurately. • When oral route is not possible in unconscious and non-co-operative patient. • When drugs get inactivated in GIT tract • Prolong action can be possible by this route. • Absorption of the drug faster compare to other route.	**2M (0.5 X4 = 2M)**
2		**Attempt any FOUR of the followings**	**12M**
2	a) **Ans:**	**Write the advantages and disadvantages of powder as a dosage form.** **ADVANTAGES** • Faster dispersal of medicament compared to tablet, capsules • Convenient for dispersing bulky drug. • Dry therefore stable, less incompatible , rapid onset of action. • Convenient for children & elderly patients. • Economical. **DISADVANTAGES** • Drugs having bitter, nauseous, unpleasant taste cannot be dispensed in powder form. • Deliquescent & Hygroscopic drug cannot be given in powder form. • Drugs affected by atmospheric condition cannot be given in powder form. • Dispensing is time consuming • Weighing difficulty (qty. Less than 100mg.)	**3M (0.5 X3= 1.5 M + 0.5 X 3= 1.5M)**

2	b)	**Define incompatibility. What is tolerated and adjusted incompatibility?**	**3M**
	Ans:	**Incompatibility:-** Incompatibility occurs as a result of mixing two or more antagonistic substances & an undesirable product is formed which may affect the safety, efficacy & appearance of the pharmaceutical preparation. **1. Tolerated incompatibility -** In this type of incompatibility, chemical reaction can be reduced by mixing the solutions in dilute forms or by changing the order of mixing but no alteration is made. Example (any one example) Rx Sodium bicarbonate …… 1g Borax …….. 1 g Phenol ……. 0.5g Glycerine …….. 20 ml Water …….upto…….. 90 ml Make a spray solution, When sodium bicarbonate, borax and glycerine are mixed together in the presence of water, a reaction takes place with the evolution of carbon dioxide. If the mixture is dispensed as such, there are chances of bursting the bottle. Therefore, mix these ingredients in an open vessel until the evolution of carbon dioxide ceases add phenol and transfer the mixture to a bottle. **2. Adjusted incompatibility -** In this type of incompatibility, change in the formulation is needed with a compound of equal therapeutic value e.g. in the mixture of caffeine citrate and sodium salicylate, caffeine citrate is replaced with caffeine. Example (any one example) Rx Caffeine citrate …… 1g Sodium salicylate ……. 3g Water ……. 90ml Caffeine citrate is a mixture of equal weights of caffeine and citric acid. the citric	**(1+1+1)**

<table>
<tr><td></td><td></td><td>acid present in caffeine citrate reacts with sodium salicylate to liberate salicylic acid which get precipitated. If caffeine is used instead of caffeine citrate it forms a soluble complex with sodium salicylates. Hence substitute caffeine citrate with half as much caffeine as that of caffeine citrate to form a clear mixture.</td><td></td></tr>
<tr><td>2</td><td>c)</td><td>Explain the term superscription, inscription and subscription.
Superscription: It consist of symbol Rx which is instruction to pharmacist. Rx stands for Latin word recipe meaning ‘ you take’ and Rx represents sign of Jupiter meaning God of healing. This is for praying quick recovery of patient.
Inscription: This is main part of prescription order , contains name and quantities of the prescribed ingredients.
Subscription: It contain direction to the pharmacist for preparing prescription which is usually ‘Mix’,‘ Send tablets’, or ‘capsules’ etc.</td><td>3M (1+1+1)</td></tr>
<tr><td>2</td><td>d)
Ans:</td><td>What are elixirs? How do they differ from syrup?
Elixirs - Elixirs are clear, sweetened and flavoured hydro alcoholic liquid preparation intended for oral use.

<table>
<tr><th>Elixirs</th><th>Syrups</th></tr>
<tr><td>Elixirs are clear, sweetened and flavoured hydro alcoholic liquid preparation intended for oral use.</td><td>Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7% w/w of sugar</td></tr>
<tr><td>Uses:
Can be used as Antibiotic Antihistaminic Sedative purpose</td><td>Uses:
Can be simple syrup use for sweetening and flavouring purpose and medicated syrup for therapeutic purpose</td></tr>
<tr><td>More viscous than elixir and less viscous than linctus</td><td>less viscous than syrup</td></tr>
<tr><td>Ex Tolu syrup, ginger syrup ect.</td><td>Ex chloral hydrate elixir ect</td></tr>
</table>
</td><td>3M (1 + 0.5x4=2)</td></tr>
</table>

2	e)	**Describe layout of sterile product area.**	**3M** **(1 + 2)**

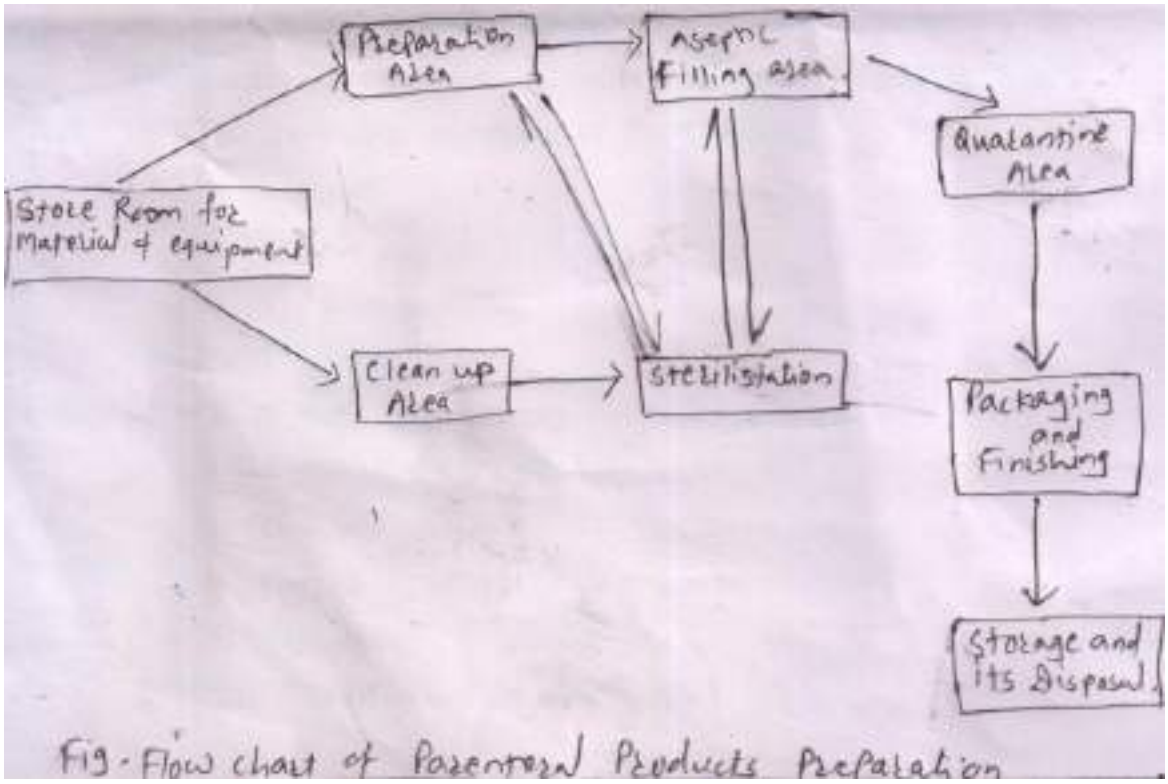


Fig - Flow chart of Parenteral Products Preparation

Clean up area:-In such area cleaning and steaming of packing materials and utensils is done therefore the walls and ceiling are constructed in such a way, that they withstand the effects of steam and chemicals. Generally, epoxy or vinyl paint is coated to solve the purpose. This area must be kept clean by washing it regularly. Precaution must be taken to prevent the growth of microorganism and collection of dust.

Compounding area:-It is nothing but a "preparation" area, where the formula is compounded, and not necessarily aseptic. There should be strict control it that these should not catch dust. The cabinets and counters should be of stainless steel. Ceiling wall and floor should be sealed and can be coated with Epoxy paint. Adequate sink and counter space should be provided.

Aseptic Area: - It is an entirely sealed area from outside atmosphere to keep aseptic environment free from physical and biological contamination. Therefore, at the time of designing and constructing the aseptic area civil work can compose to HVAC (High ventilating and air conditioning) system including the electrical wire fittings and switches.

		The walls facing outside should have double walled glass partition. Epoxy paints should be used.to prevent wall, ceiling ,and floor from the accumulation of dust and microorganisms The air in the aseptic area should be free from fibers ,,dust and microorganism. This can be achieved by the use of high efficiency particulate air filers (HEPA) which can remove particles upto 0.3 um. HEPA filters are fitted in laminar air flow system in which air free from dust and microorganism flows with uniform velocity.The air is supplied under positive pressure which prevents particulate contamination from sweeping from adjoining areas .Ultraviolet lamps are fitted to maintain sterility. . The personnel enter in this area through air lock door. Movement should be minimum and restricted during filling procedure . **Quarantine area:-** Approved batches from QC department can be kept here before labelling and packing.It must contain space that separates 'Approved batches' and 'In process batches'.This area is only restricted to a responsible person. **Labelling and packing area:-**Adequate space is required for installation of printing devices and packaging machines In this area, label printing and labelling can be take place. **Storage and its disposal:-** The finished product are stored under specified storage condition and dispensed off.	
2	**f)** **Ans:**	**Translate the following terms in English:** **i) Capiendus –** To be taken **ii) Guttae –** A drop, **iii) Hora somni –** Every hour iv) **Trochiscus –** A lozenge **v) Unguentum –** An ointment **vi) Dolere urgente –** When the pain is severe	**3M** **(0.5 X 6 = 3M)**
3		**Attempt any FOUR of the followings**	**12M**
3	**a)**	**Report the incompatibility in following prescription how will you correct it ?** **Rx** **Quinine sulphate ……1.5 gm**	**3M** **(1.5+1.5)**

		Dilute sulphuric acid …..4ml **Potassium iodide …….8gm** **Water 9.5 ……200 ml** **Fiat Mistura** **Signa- Cochleare amplum quartis horis summendum** **Identification of incompatibility:** Dil. sulphuric acid is added to dissolve the quinine sulphate, but potassium iodide present in formulation react with dil. sulphuric acid to form hydroiodic acid further it gets oxide to form free iodine, free iodine, hydroiodic acid and quinine sulphate together form iodosulphide of quinine called "herapathite" It form olive green scales after three days stay. **Correction** 1. Dispense it for three days. **2.** Dispense in two different bottles one bottle containing dil. sulphuric acid with quinine sulphate and in another bottle potassium iodide and water. Instruct the patient to mix them before the dose actually taken.	
3	**b)**	**Define mixture and draught. Give different types of vehicle used in preparation with examples.** **<u>Definition:</u>** **Mixture**: A mixture is a liquid preparation meant for oral administration in which medicament or medicaments are dissolved, suspended or dispersed in a suitable vehicle. **Draught**: These are the liquid preparation where whole dose has to be taken at once. **<u>Vehicle used:</u>** **Water:** Purified water is used. **Aromatic waters** like camphor water, chloroform water, peppermint water. **Medicated vehicle**: vehicles having therapeutic value such as compound gentian infusion, orange peel infusion, infusion of senega.	**3M (1x2=2M Def., 0.5x2= 1M vehicle)**
3	**c)**	**Define cachets? Write the advantages and disadvantages of cachets as dosage form.** **Definition**: - Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used	**3M (1 Def.+ 0.5x2=1**

		to enclose nauseous or disagreeable powders and are available in different sizes to hold drugs from 0.2 to 1.5 gm of powders. **Advantages**: 1) It can be made easily , no complicated machines required 2) They disintegrate quickly in stomach 3) The drug can be easily dispense 4) Large doses of drug can be swallowed by using cachets. **Disadvantages**: 1) They have to be soften before swallowing 2) They are easily damaged 3) They cannot protect drug from light and moisture 4) The shell is very fragile 5) They cannot be manufactured on large scale	**+ 0.5x2=1)**
3	**d)**	**Write the dose of the following drugs.** **i) BCG Vaccine :** 0.1 ml **ii) Aspirin:** 0.6g to 1gm **iii) Sodium bicarbonate:** 5% **iv) Frusemide:** 40 to 120 mg **v) Streptomycine:** 0.5 to 1.0 g **vi) Castor oil:** 1 to 15 ml	**3M (0.5x6)**
3	**e)**	**What is emulsion? How emulsion prepared by dry gum method?** **Definition:** An Emulsion is a biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other. The liquid which Is converted into minute globules is called the "dispersed phase" and the liquid in which the globules are dispersed is called the "continuous phase " **Dry gum method for preparation of emulsion.** 1. Measure the required quantity of oil in a dry measure and transfer it into a dry mortar. 2. Add the calculated quantity of gum acacia into it and triturate rapidly so as to form a	**3M (1+2)**

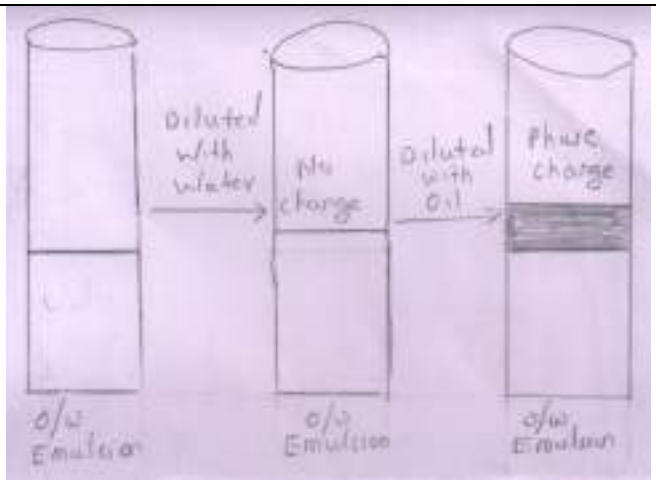
		uniform mixture. 3. Add required quantity of water and triturate vigorously till a clicking sound is produced and the product becomes white or nearly white due to the total internal reflection of light. The emulsion produced at this stage is known as primary emulsion. 4.If any other ingredient present in the formulation has to be added by dissolving in the vehicle 5. Add more of vehicle to produce required volume.	
3	**f)**	**Give in brief account on Contact lens solutions.** Contact lens solutions **For Hard contact lenses** two solutions are there 1) **Wetting solution** is use for treating the lenses before insertions since these are poorly wetted by lachrymal secretions. Hence the contact lenses require moistening with a wetting agent to make the insertion easy and comfortable. The formulation of contact lens solutions contains a wetting agent. Thickening agent (cellulose derivative), antimicrobial agent (benzalkonium chloride) Isotonicity adjustments (sodium chloride). **2) Storage solutions**: It is used for overnight cleansing, soaking and storage. They are stored in storage solution to prevent dehydration. The formulation of storage solutions contains non-ionic surfactant which helps in cleansing the contact lenses.it also contains preservative to prevent microbial growth. **For Soft contact lenses** These are cleansed by heating in 0.9% sodium chloride solution. The wetting of soft contact lenses is not problem because of the hydrophilic nature of the lenses. The storage solution should be sterile.	**3M** **(2+1)**
4		**Attempt any FOUR of the following.**	**12M**

4	**a)**	**What is importance of date and age of patient in prescription writing?** **Date**: It helps a pharmacist to find out the date of prescribing and date of presentation for filling the prescription. The prescription which prescribed narcotic and other habit forming drugs must bear the date so as to avoid the misuse of prescription if it is presented by the patient, a number of times for dispensing. **Age of the patient**: Age of the patient must be written in the prescription because it serves identity of the prescription. In case, if it is missing in the prescription, the same may be included by the pharmacist after proper enquiry from the patient. Age of the patient, especially in case of children, help the pharmacist to check the prescribed dose of medication.	**3M** **(2 x1.5)**
4	**b)**	**Name the additives used in suspension. Discuss the significance of wetting and flocculating agent.** Following additives used in formulation of suspensions**.** Flocculating agents: Thickening agents Wetting agents Preservatives Organoleptic additives **Wetting agents-** These are the substances which reduce the interfacial tension between solid particles and liquid medium, thus producing a suspension of required quality. For examples, alcohol in tragacanth mucilage, glycerine in sodium alginate or bentonite dispersion and polysorbate in oral and parenteral suspensions. **Flocculating agents**: The flocculating agent act by reducing the surface tension and There by improving dispersion of solids and minimise flocculation. eg. Sodium Lauryl Sulphate, tweens, spans and carbowaxes.	**3M** **(1+1+1)**

4	c)	**Define "displacement value". Write its Importance in suppository.** **Definition:** Displacement value of a medicament is defined as "The quantity of the drug which displaces one part of the base." **Importance**: The volume of suppository from a particular mould is uniform but its weight will vary because the densities of medicaments usually differ from the density of the base with which the mould is calibrated . For preparation of uniform suppositories, accurate weight, allowance must be made for the change in density of the mass due to added medicament. For this purpose displacement value of the medicament is taken into consideration.	**3M (1+2)**
4	d)	**What are Shampoos Mention desirable properties of shampoo?** **Definition:** Shampoos may be define as preparation containing surface active agents which are used to remove dirt, grease and debris from the hair scalp without affecting the natural gloss of hair **Qualities of an ideal shampoo.** • It should be capable of removing grease, dirt, and skin debris from the hair and scalp. • It should be non-toxic. • It should be non-irritant. • It should provide sufficient fragrance to the hair after its use. • It should be effective in small amounts • It should get easily removed by washing with water. • It should produce sufficient foam, both in hard soft water. • It reduces the fluffiness and smoothens the hair shafts. • It makes the hair soft and shiny.	**3M (1+0.5x 4=2)**

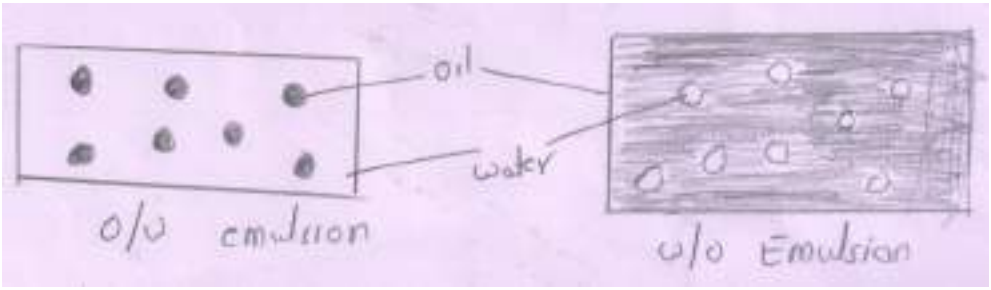
4	e)	**Name the various facial cosmetics. Describe in short rouges.** **Facial cosmetics:** a) Face powder b) Compact Face powder c) Rouge d) Cold cream e) Cleansing cream f) Vanishing cream g) Foundation cream h) Moisturising cream i) Preparation for Eye makeup j) Lipstick k) Bleaches l) Shaving media **Rouges :** Rouges are the cosmetic preparations which are applied on cheeks for enhancing the face beauty. It also impart and stimulate the rosy freshness of the young and healthy skin . It is used by ladies to add to their beauty. The colour of rouge may vary from pink to red or reddish brown colour. The shade of the rouge depends on the type and quantity of colour mixed with it. Rouges` are available in solid, liquid and cream form. The dry compact rouge is applied by means of a puff. FORMULA FOR DRY ROUGE Talcum Powder 80.0 g Zinc Oxide 5.0 g Zinc Stearte 5.0 g Rice Starch 10.0 g Perfume Sufficient quantity	**3M** **(1+2)**

		Colour Sufficient quantity	
4	**f)**	**What are ointments? Write the desirable properties of ointment base.** **Definition :** Ointments are semisolid preparations meant for external application to the skin or mucous membrane. They usually contain medicament or medicaments dissolved ,suspended or emulsified in an ointment base **Properties of ointment base.** **1)** It should be inert, odourless and smooth **2)** It should be physically and chemically stable **3)** It should be compatible with skin and with the incorporated medicaments **4)** It should be of such a consistency that it spreads and softens when applied to the skin with stress **5)** It should not retard healing of the wound **6)** It should not produce irritation or sensitisation of the skin	**3M** **(1+ 0.5x4=2)**
Q.5		**Answer any FOUR of the following:**	**12M**
Q.5	**a.**	**Describe the test for identification of type of an emulsion** **Tests for identification** 1) Dilution Test 2) Dye Test 3) Conductivity Test- 4**)** Fluorescence Test 5) Cobalt Chloride Test **1) Dilution Test** - • Emulsion diluted with water i)Emulsion remains stable then it is o/w emulsion ii)Emulsion break it is w/o emulsion • Emulsion diluted with oil i)Emulsion remains stable then it is w/o emulsion ii)Emulsion break it is o/w emulsion	**3M** **(0.5+0.5 X5)**



2) Dye Test-

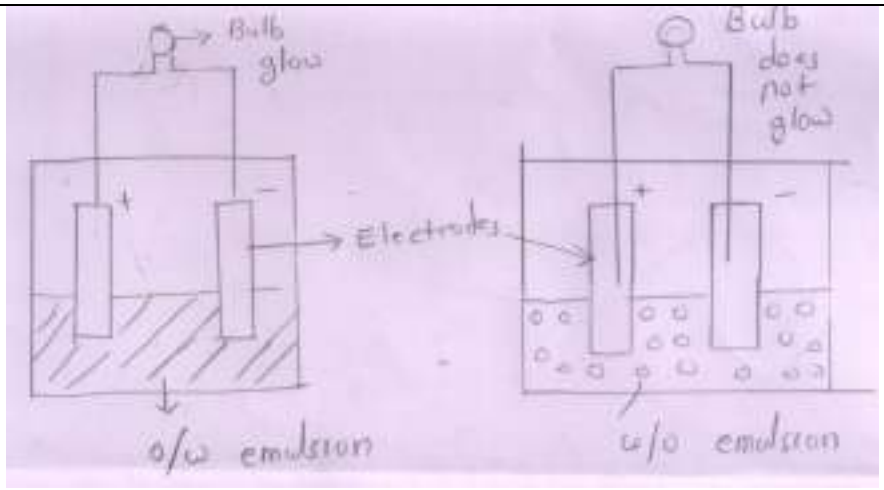
- Emulsion diluted with scarlet red dye i)Dispersed globules appear red & background is colourless then it is o/w type ii) Dispersed globules appear colourless & back ground is red then it is w/o type.



3) Conductivity Test-

This type of emulsion show bulb glowing on passing electric current.

- If bulb glow the emulsion is o/w type
- If bulb does not glow the emulsion is w/o type



4) Fluorescence Test:

- If an emulsion on exposure to ultra-violet radiations shows continuous fluorescence under microscope, then it is w/o type
- If it shows only spotty fluorescence, then it is o/w type.

5) Cobalt Chloride Test:

When a filter paper soaked in cobalt chloride solution is dipped in to an emulsion and dried, it turns from blue to pink, indicating that the emulsion is o/w type.

Q.5	**b.**	**What is face powder write desirable properties of face powder** **Face powder** is a cosmetic preparation meant for improvement of overall attractiveness of the face. It is applied to the face by means of powder puff, It provides a visual covering to skin and impart smooth finish to it **Ideal properties of face powder** 1. It should be very fine and should not have any gritty particles. 2. It should be non-toxic. 3. It should be non-irritant to the skin. 4. It should look natural. 5. It should not remove from the skin immediately after its application. 6. It should be stable both physically and chemically. 7. It should have good absorbing property. 8. Its ingredients should be evenly distributed. **9.** It should remove shine from the face. **10.** It should stick to the face and should not dust off in a few minutes	**3M** **1+0.5x4 =2)**

Q.5	**c.**	**Comment 'aqueous solutions are usually not preferred for ear drops".List formulation ingredients for ear drop** Aqueous solution are not preferred as secretion in the ear are mainly fatty or oily in nature and therefore aqueous solutions do not mix easily with them. **Formulation of Ear drop** • The main solvent used in ear drop includes glycerine propylene glycol and water. • The viscous glycerine solution permits the drug to remain in ear for longer time. • The viscous liquids such as glycerine or propylene glycol are used either alone or in combination with surfactant to aid in the removal of ear wax Example **(any one example can be considered)** Soda glycerine ear drop Rx Sodium carbonate 5.0gms Glycerine 30.0ml Purified water q.s 100.0ml	**3M** **(1.5+1.5)**
Q.5	**d.**	**Define Posology .Calculate the dose of acetaminophen for a child of six months, if adult dose is 500mg.** **Posology: It** is derived from Greek words 'posos' meaning how much and 'logos' meaning science. Posology is branch of science which deals with dose or quantity of drugs which can be administered to a patient to get desired pharmacological actions. According to fried's formula: Dose of the child=Age in months X Adult dose 150 = 6 X500 150 = 20.0mgs	**3M** **(1+2)**

Q.5	**e.**	**What are the various approaches to overcome incompatibility due to liquification** **Liquification**: When certain low melting point solids are mixed together they form a new chemical compound which has melting point lower than room temperature, therefore they become liquid at room temperature. Example: Rx Menthol ---------- 5g. Camphor ---------- 5g. Ammonium chloride ---------- 30g. Light magnesium carbonate ---- 60g. Send five powders The combination forms eutectic mixture. **The substance can be dispensed by any one of the following methods;** i) Triturate together to form liquid and mixed with an absorbent like light kaolin or light magnesium carbonate to produce free flowing powder. ii) The individual medicaments are powdered separately and mixed with absorbent and then combined together lightly and filled in suitable container	**3M** **(1+2)**
Q.5	**f.**	**What are intravenous fluids, write their uses** Large volume of parenteral solutions intended to be administered by intravenous route are commonly called intravenous fluids. The median basilic vein near the anterior surface of the elbow is usually selected. **Uses**: 1. To correct electrolyte imbalances. 2. To deliver medications, 3. For blood transfusion. 4. For Fluid replacement, for example, dehydration. 5. Used for chemotherapy.	**3M** **(1+0.5X 4=2)**

		6. To deliver Blood substitute. 7. To provide total parental nutrition 8. As a vehicle for other drug substances.	
Q.6		**Answer any FOUR of the following:**	**16M**
Q.6	**a.**	**Describe modern methods of dispensing the prescription** • Now a days role of pharmacist is to hand over the ready made preparations to the patients and provide advice if demanded regarding its mode of administration, dose schedule, drug interactions etc. • In present day set up, the writing of prescription is more significant. The prescription should be precise, accurate, clear and easily readable. As far as possible Latin terms should be avoided. The drugs should be prescribed by its official (generic) name not by its proprietary or trade name. **Advantages** of prescribing the drugs by its proprietary names 1) Easy to remember 2) Easy to communicate with the patient. 3) The continuity can be maintained by prescribing the same proprietary name every time. 4) Only those proprietary drugs can be prescribed which have better bioavailability. **Disadvantages** of prescribing the drugs by its proprietary names 1) It is cheaper to prescribe the drugs by its official name. 2) It becomes difficult for a pharmacist to dispense the substitute of the drugs which is not available in the stock..	**4M** **(1.5+1.5 +1)**
6	**b.**	**Classify the various methods and give the formulae for the calculation of paediatric doses** **Methods of calculation of doses:** • Dose proportionate to age • Dose proportionate to body weight. • Dose proportionate to body surface area. **Formula for the calculation of paediatric dose**	**4M** **(1+1x3)**

		1.Depending on age: Dillings formula: Child Dose = Age in years X Adult dose 20 Young's formula: Child dose =Age in years X Adult dose Age in years +12 Frieds Formula: Child Dose =Age in month X Adult dose 150 **2.Depending on weight.** Clarks formula: Child Dose = weight in pound X Adult dose 150 **3.Depending body surface area:** Body surface area formula: Child Dose = body surface area of child in m^2 X Adult Dose. 1.73 m^2	
6	**c.**	**What are liniment and lotion? Write the composition of Turpentine liniment and Calamine Lotion** **Liniment**: Are liquid or semi liquid preparation meant for application to the skin Applied with friction, Vehicle is mostly oily or alcoholic, These are used for application to the unbroken skin and applied directly. **Lotions** : Are liquid or semi liquid preparation They are used for topical effect such as local cooling, soothing protective & emollient effect, applied without friction, Vehicle is mostly aqueous, Lotions are applied on broken skin, they are applied with cotton gauze. **Composition of Turpentine liniment** Rx Soft soap 90.0gms	**4M** **(1+1+1+1)**

		Camphor 50.0gms Turpentine oil 650.0ml Purified water q.s 1000.0ml **Composition of Calamine Lotion** Rx Calamine 150.0gms Zinc oxide 50.0 gms Bentonite 30.0gms Sodium Citrate 5.0gms Liquified Phenol 5.0ml Glycerin 50.0ml Rose water q.s 1000.0ml	
6	**d**	**Define eye drops. Mention the terminal sterilization process of eye drop** **Eye drops:** Eye drops are sterile aqueous or oily suspension of drugs, that are instil into the eye with the dropper they usually contain drugs having antiseptic, anaesthetic, anti-inflammatory, mydriatic or meiotic properties. **Terminal sterilization process: They can be sterilize by moist heat sterilization or by heating with bactericide** **Moist heat sterilization -Autoclaving:** **This is most reliable method and is used whenever the medicament is sufficiently stable.** In this method preparation is filled in final container and then sterilised by autoclaving at desired temperature and pressure i.e. 10 lbs/sq inch with corresponding temp 115 ^{0}C or 15 lbs/sq inch with corresponding temp 121 ^{0}C After the stated period, switch off the autoclave. Allow it to cool to about 40^{0}C before opening the vent. When whole of the steam is removed, the lid is opened and the sterilized material is taken out. **Heating with bactericide**: It is used particularly for solutions containing medicaments	**4M** **(1+2x1.5)**

		that can be degraded by autoclaving but can withstand temp of 98-100 ^{o} C suitable preservative in required concentration are added to the eye drops for e.g cholrocresol, phenyl mercuric nitrate etc. and the container is sealed and kept in the water bath at 98-100^{o} C for half an hour and than the preparation is cooled	
6	**e.**	**Give significance of particulate matter and mention different method in its detection** **Significance:** Presence of particulate matter in IV solutions may lead to septicemia, fever and blockage of small blood vessels. The presence of undissolved particles create doubt about the quality of product Methods: 1)Visual method 2) Coulter counter method 3) Filtration method 4) Light blockage **Visual Method:** It is an old but reliable method. The filled containers are examined against strong illuminated screen by holding the neck and rotating it slowly or inverted it to exclude the possibility of foreign particles. If any particulate matter is visible, that container is rejected. **Coulter Counter Method:** The method is based on the principle that increase in resistance is observed between two electrodes, as the particle approaches and passes through the orifice. An electrolyte is required to be included in the preparation before its evaluation. The particles with diameter below 0.1 /um can be detected by this method. **Filtration method:** The liquid sample is passed through a filter and the material collected on the surface of the filter. It is examined under microscope. **Light blockage method:** It allows a stream of the fluid under test to pass between a bright white light source and photodiode sensor. It is possible to detect cross sectional area in this instrument because it blocks the path of light and size of the particle is consider as a diameter of a circle of equivalent area.	**4M** **1+1 x3**

6	**f.**	**Describe various methods for the preparation of ointment** **Ointments can be prepared by any one of the following methods** • **Trituration method** • **Fusion method** • **Chemical reaction method** • **Emulsification method** **Trituration method:** This method is used when the base is soft and the medicament is insoluble in the base 1.Finely powder the solid medicament 2.Weigh the required amount of base and place it at one end of the ointment tile and place the medicament at the opposite end of the tile 3.Take the proportionate amount of base and the drug in the centre and uniformly mixed them with the help of the ointment spatula 4.Continue the process until whole of the drug is uniformly mixed with the base. **Fusion method:** This method is used when the base contains number of solid ingredients 1.Melt the solid bases in their decreasing order of their melting points i.e the high melting point solids has to melted first in the porcelain dish followed by next in the order 2.When the base has been melted than medicament is incorporated and uniformly mixed and cooled till it solidifies 3.In case any liquid ingredient or aqueous substance has to be incorporated than it has to be heated at same temperature as that of the base and than it has to be mixed with the base and stir continuously till it solidifies. **Chemical reaction method:** **Ointment containing free Iodine**	**4M** **(1+1+1+1)**

Iodine is slightly soluble in most fats and vegetable oils. But it is readily soluble in concentrated potassium iodide solution in water ,due to formation of polyiodides. These polyiodides are readily soluble in water ,alcohol and glycerine .The liquid selected should ensure proper distribution of medicament and should be non-volatile otherwise distributed medicament may crystallise when the solvent evaporates .

Ointment containing combined Iodine

Certain chemical reactions are involved in preparing certain ointments

for e.g non staining Iodine ointment :

Fixed oils contains unsaturated fatty acids which reacts with iodine and iodine gets attached to either side of double bond, therefore free iodine is not available in the preparation

$CH_3.(CH_2)_7.CH=CH.(CH_2)_7.COOH + I_2 \longrightarrow CH_3.(CH_2)_7.CHI.CHI.(CH_2)_7,COOH$

Oleic acid di-iodo stearic acid

Emulsification method:

1. In this method the fat, oil and waxes are melted together on a warm bath and temperature is maintained at 70^oC .The aqueous solution containing all water soluble component is also heated at the same temperature
2. Aqueous solution is added to the melted oily base little by little with continuous stirring till emulsification takes place and the ointment solidifies.

WINTER– 19 EXAMINATION

Subject Title: PHARMACEUTICS-ll Subject Code: 0811

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.

<table>
<tr><th>Q. No.</th><th>Sub Q. N.</th><th>Answer</th><th>Marking Scheme</th></tr>
<tr><td>1</td><td></td><td>Answer any Eight of the followings:</td><td></td></tr>
<tr><td>1</td><td>a)</td><td>Define emulsion. Write its significance.
Definition: Emulsion is a biphasic liquid preparation containing two immiscible liquids which are made miscible by adding emulsifying agent.
Significance: (0.5 X 2 = 1M)
❖ Mask the Unpleasant taste.
❖ Improved Bio-availability (Griseofulvin).
❖ Sustained Release Medication (depot).
❖ Nutritional supplement.
❖ Diagnostic purpose (x-rays examination).
❖ External use preparation (cream lotion foam aerosol).</td><td>(2M = 01 +01)</td></tr>
<tr><td>1</td><td>b)</td><td>Differentiate between liniments and lotions.
<table>
<tr><th>Liniments</th><th>Lotion</th></tr>
<tr><td>1. They are used for counter irritant, rubefacient, soothing or stimulating purpose.</td><td>1. They are used for topical effect such as local cooling, soothing protective & emollient effect.</td></tr>
<tr><td>2.Applied with friction</td><td>2. Applied without friction.</td></tr>
<tr><td>3.Vehicle is mostly oily or alcoholic</td><td>3. Vehicle is mostly aqueous.</td></tr>
<tr><td>4. These are used for application to the unbroken skin.</td><td>4. Lotions can be applied on broken skin.</td></tr>
<tr><td>5.Applied directly</td><td>5. Applied with cotton gauze</td></tr>
<tr><td>6. alcohol is added to improve penetration power</td><td>6. Alcohol is added for cooling action.</td></tr>
<tr><td>7.These are semi-liquid preparations</td><td>7.These are liquid preparation</td></tr>
<tr><td>8.Turpentine liniment</td><td>8 .Sulphur lotion.</td></tr>
</table></td><td>(2M = 0.5 X 4)</td></tr>
</table>

1	c)	**Translate the following Latin terms in English.** **Jantaculum -**Breakfast **Capiendus-** To be taken **Haustous:** A droughts **Hora Somni:** at bed time or before sleep.	**(2M = 0.5 X 4)**
1	d)	**Why most of emulsion appears white or opaque.** Emulsions usually appear cloudy or white because light is scattered off the phase interphases between the components in the mixture. If all of the light is scattered equally, the emulsion will appear white.	**2M**
1	e)	**Give any four properties of suppositories base.** ● It must retain the shape and size. ● It should melt at body temperature. ● It should shrink sufficiently to remove from mould. ● It should permit incorporation of drug. ● It should be physically stable on storage. ● It should not be soften or harden on storage. ● It should be compatible with variety of drugs. ● It should not interfere in release or absorption of drug. ● It should be non-irritant.	**(2M = 0.5 X 4)**
1	f)	**How will you dispense a powder containing eutectic mixture?** When two or more substances are mixed together they liquefy due to the formation of new compound which has a lower melting point than room temperature such substances are called as eutectic mixtures. The can be dispensed in separate packets or equal quantity of inert solid is mixed. Rx Menthol 5 parts Camphor 5 parts Ammonium chloride 30 parts Magnesium carbonate 60 parts	**2M**

1	g)	**Give stokes equation for creaming in emulsion.** $V = \frac{2r^2 (d_1 - d_2)}{9\mu} g$ Where, V= Rate of creaming. r = Radius of globules. d_1-d_2 = Density of dispersion medium/dispersing medium. μ = Viscosity. g = Gravitational constant	**2M**
1	h)	**White Vaseline is not used in ophthalmic ointment.** • White Vaseline is semi-solid hydrocarbon obtained by bleaching (de-colourization) of yellow soft paraffin. • White Vaseline not used in the preparation of ophthalmic ointment because it may contain the traces of bleaching agent which may produce the irritation.	**2M**
1	i)	**What is rouge? Name the types of rouges.** **What is rouge: (1M)** • Rouges are the cosmetic preparations which are applied to the cheeks for enhancing the face beauty. • It also imparts and stimulates the rosy freshness of the young and healthy skin. **Types: (0.5 X2 =1M)** • Solid. • Liquid. • Cream form.	**(2M= 1+1)**
1	j)	**What is LAL test?** **LAL test** is used for the detection and quantification of bacterial endotoxins: Limulus amebocyte lysate (LAL) is an aqueous extract of blood cells (amoebocytes) from the horseshoe crab, Limulus polyphemus. LAL reacts with bacterial endotoxin or lipopolysaccharide (LPS), which is a membrane component of Gram negative bacteria.	**2M**

		The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polymhemus). The result of the reaction is turbidity or precipitation or gelation of the mixture.	
1	**k)**	**What precautions needed to be taken in storage of eye drop?** Following precautions taken during storage of eye drops: i. If the dropper is separate, always hold it with its tip down. ii. Never touch the surface of dropper iii. Never rinse the dropper iv. Never used eye drops that have changed color v. When the dropper is at the top of the bottle, avoid contaminating the cap when removed. vi. Use within one month after opening the container. vii. If colour of preparation changes discard it. viii. Store in cool place protected from light. ix. Do not freeze it.	**(2M= 0.5 X 4)**
1	**l)**	**The adult dose of phenobarbitone is 15 mg. What is the dose for a child weighing 40 pound?** **Data given:** Child weight=40 pound Adult dose = 15 mg Clarks formula, Child dose = weight in pound /150 X adult dose Child dose = 40/150 X 15 Child dose = 4 mg	**2M**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Define and explain the various parts of prescription.** **Prescription:** Prescription is a written order given by registered medical practitioner, any other licensed person, veterinarians or dentist to pharmacist to dispense proper medication to patient. **Parts of prescription:** 1. **Date**: It is important to avoid misuse of prescription if it is presented by the patient,	**(3M = 1 + 2)**

		a number of times for dispensing. 2. **Name, age, sex & address of the patient:** The Name, age, sex & address of the patient is important for proper handling of prescription & also identification of patient .Age & sex is important especially for children to check prescribed dose of medication. 3. **Superscription:** Rx stands for Latin word recipe meaning 'you take'. It is the symbol in the name of god of healing called Jupiter to pray for quick recovery of patient. 4. **Inscription:** This is main part of prescription contains Base, Adjuvant and vehicle or name & quantities of the prescribed ingredients. 5. **Subscription:** Direction to the pharmacist for preparing dosage form as instructed with quantity. Ex. 'Mix', 'Send tablets', or 'capsules' etc. 6. **Signatura :** It consist of the direction to be given to the patient regarding administration of the drug. 7. **Renewal instructions :** The prescriber indicate on every prescription order whether it may be renewed & if so, how many times. It is important particularly in the prescription containing the narcotic & other habit forming drugs to prevent misuse. 8. **Signature, address & registration number of the prescriber:** The prescription bears signature, address & registration number of the prescriber. It is important particularly in the prescription containing the narcotic & other habit forming drugs to prevent misuse.	
2	**b)**	**Define elixir and discuss various formulation aspects of elixir.** **Definition:** Elixir: Elixirs are clear, sweetened, aromatic, hydroalcoholic liquids preparation intended for oral use. **Formulation:** 1. Vehicles: • Vehicle should be free from volatile and non-volatile impurities. • They are added for production of clear solution, for improving solubility and stability.	**(3M= 1 + 2)**

		• E.g. Water, Alcohol, syrup, glycerin, sorbitol and propylene glycol 2. Adjuncts: Used to improve Safety, efficacy and palatability. • Chemical Stabilizer: protecting the drug for oxidation and reduction. • Citric acid added in Neomycin Elixir to prevent the darkening of it. • Disodium EDTA as sequestering agent for metal ions which catalyzes decomposition of antibiotics. • Preservative: These are added to prevent growth of microorganisms. • 20% alochol, syrup and methyl paraben and propyl paraben • Colouring Agent: these makes the preparation attractive. • Coal tar dyes, amaranth solution, titanium dioxide etc. • Flavouring agent: these are added to improve the taste of the formulation. • Black current syrup, raspberry syrup, lemon syrup and orange syrup etc.	
2	**c)**	**Write a short note on poultice.** **Definition: (1M)** Poultices are soft, viscous wet masses of solid substances applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as a counter-irritant. **Ingredients: (1M)** Rx Heavy kaolin finely sifted and dried at 100^0C ----- 527 g Boric acid ---------- 45 g. Thymol ---------- 0.5 g. Peppermint oil ---------- 0.5 ml Methyl salicylate ---------- 2 ml. Glycerin ---------- 425 g. Send 20 gm Direction: to be used as directed. **Method of Preparation: (1M)** • Sieve kaolin & Boric acid through a sieve no. 180.	**(3M= 1+1+1)**

		• Mix the Heavy kaolin & Boric acid with glycerin to form a smooth paste in a mortar. • Transferred to a heat resistant glace jar protected suitable and heat at 120^0C for one hour in hot air oven with occasional stirring. • Dissolve thymol in methyl salicylate and Peppermint oil. • Add this solution to cooled mixture and mix thoroughly. • Transfer it to suitable container closes it tightly and labels it.	
2	**d)**	**Name the various ophthalmic products. Give there essential characteristics.** **Ophthalmic products: (0.5 X 3=1.5M)** ☐ Eye drop ☐ Eye lotion ☐ Eye ointment ☐ Eye suspension ☐ Contact lens solution **Essential characteristics: (0.5 X 3=1.5M)** ☐ It should be free from foreign particle. ☐ It should be Isotonic with lachrymal secretion. ☐ Viscosity must be high. ☐ It should have pH matching with lachrymal secretion. ☐ It should be sterile. ☐ Surface activity: wetting	**(3M= 1.5 + 1.5)**
2	**e)**	**Classify suppositories bases. Explain oleaginous bases.** **Classification: (0.5 X 3 =1.5M)** A. Oleaginous bases: 1. Cocoa butter. 2. Emulsified cocoa butter. 3. Hydrogenated oils. B. Hydrophilic bases/ aqueous bases: 1. Glycero-gelatin base. 2. Soap-glycerin base.	**(3M=1. 5+1.5)**

3. Polyethylene glycol.

C. Emulsifying/Synthetic bases:

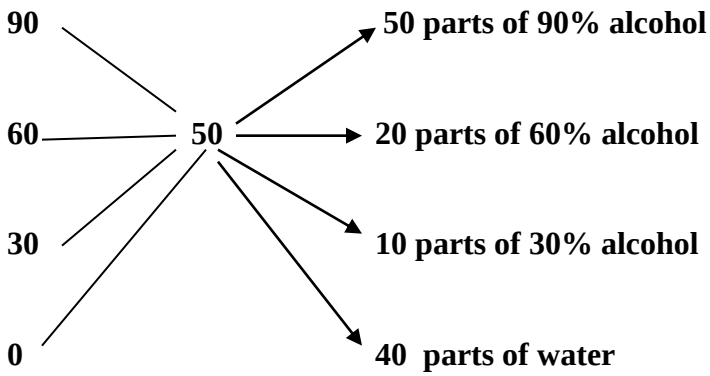
1. Witepsol
2. Massa estarinum
3. Massuppol.

Oleaginous bases/Fatty bases: (0.5 X3=1.5M)

Cocoa butter:

- **Source:**
  - Cocoa butter is fat obtained from the roasted seed of Theobroma cocoa.
- **Properties:**
  - At room temperature it is a yellowish, white solid having a faint, agreeable chocolate like odour.
  - Chemically, it is a triglyceride (combination of glycerin and one or different fatty acids) primarily of oleopalmitostearin and oleodistearine.
  - It melts at 30 - 35^0C,
- **Advantages**:
  - Melting just below the body temperature.
  - Maintaining its solidity at usual room temperatures.
  - Readily liquefy on heating and solidify on cooling.
- **Disadvantages:**
  - Exhibits marked polymorphism.
  - Rancidity.
  - Stick to mould.
  - Leakage from body cavity.
  - Costly.
  - Immiscibility with body fluid.
  - Chloral hydrate or lactic acid liquefies it.

		Emulsified theobroma oil: • It is used as base when large quantities of aqueous solution are to be incorporated. • The use of glyceryl monostearate5%, 10% lenette wax, 2-3% cetyl alcohol, 4% bees wax and 12% spermaceti is recommended to prepare emulsified theobroma oil suppositories. **Hydrogenated oils:** • These are obtained by hydrogenation of various vegetable oils. • These include hydrogenated vegetable oils, such as coconut, palm kernel, cottonseed, peanut, fractionated palm kernel oil etc. • **Advantages:** • Hydrogenation increases resistance to oxidation. • Increases chemical inertness, • Lubrication not required. • **Disadvantages:** • Become brittle on rapid cooling. • Sedimentation of added substance take place.	
2	**f)**	**Define displacement value. Explain with the help of an example how displacement value helps in formulation of suppositories.** **Definition:** It is the amount of drug required to displace one part of base. **Displacement value helps in formulation of suppositories for determine the quantity of base required.** **Example: (any example by students can be granted full marks)** Rx, Zinc oxide .....500mg Theobroma oil ... QS Prepare 6suppositories of 2gm each. Displacement value of zinc oxide = 5. **Calculation:** Calculate for 2 extra suppositories	**3M=1+ 2)**

		Weight of **Theobroma oil** for one suppository= 2 gm Weight of **Theobroma oil** for 08 suppositories = 2x 08=16g Weight of **Zinc oxide** for one suppository=500 mg = 0.5gm Weight of **Zinc oxide** for 08 suppositories= 0.5 g X 8 = 4gm Displacement value of **Zinc oxide** = 5.0 The quantity of **Theobroma oil** required = Total amount of base -Total amount of drug/Displacement Value = 16 – 4/5 = 16 – 0.8 = 15.2gm **Formula for 08 suppositories is as under** **Rx,** **Zinc oxide ..... 4gm** **Theobroma oil ... 15.2gm**	
3		**Attempt any FOUR of the followings**	
3	**a)**	**Find out amount each of 90%, 60% and 30% alcohol and water required to produce 500ml of 50% alcohol.**  **120 parts of water** Therefore, when 50 parts of 90% alcohol,20 parts of 60% alcohol,10 parts of 30% alcohol and 40 parts of water are mixed together, the resulting solution will produce 50 % alcohol.	**3M**

		i) Volume of 90% alcohol required = 120 parts : 500 ml :: 50 parts : V $V = \frac{500 \times 50}{120} = \frac{2500}{12} = 208.33$ ml ii) Volume of 60% alcohol required =120 parts : 500 ml :: 20parts : V $V = \frac{500 \times 20}{120} = \frac{1000}{12} = 83.33$ ml iii) Volume of 30% alcohol required =120 parts : 500 ml :: 10parts : V $V = \frac{500 \times 10}{120} = \frac{500}{12} = 41.67$ ml iv) Volume of water required = 500- (208.33+83.33+41.67) = 166.67 ml	
3	**b)**	**What are principle behind sterility test? Explain the official method of sterility test.** The test for sterility is done by detecting the presence of viable forms of bacteria, fungi & yeast in parental preparations. **Principle:** The test is based on the principle that if bacteria or fungi are placed in a medium which provides nutritive material & water & kept a favourable temperature the organism will grow & their presence can be indicated by turbidity in the clear medium. Sterility Testing Methods: **I) Membrane filtration method:-** The membrane filtration method is performed in following cases : • An oil or oily preparation. • An ointment that can be put into solution.	**(3M=1 mark principle and 2 marks for 2 methods)**

		• A soluble powder or a liquid that possess bacteriostatic & fugistatic properties. • Liquid products where the volume in container is 100 ml or more. ➢ It involves the filtration of sample under test through a membrane filter having porosity of 0.45 u & diameter 47 mm ➢ After filtration, membrane is removed aseptically & divided into 2 parts. ➢ The first part is transferred into 100ml of culture media meant for fungi & incubated at 20^{o} to 25^{o}C for not less than 7 days. ➢ The other half part is transferred into 100ml of fluid thioglycollate medium & incubated at 30^{0} to 35^{o}C for not less than 7 days. ➢ Observe the growth in media. **II) Direct Inoculation Method:** • In this method the specified quantity of sample under test is drawn aseptically from the container & transferred into a vessel of culture medium. (Fluid Thioglycolate and Soybean Casein Digest medium.) • Mix the liquid with the medium & incubate for not less than 14 days. • Observe the growth of microorganisms in the medium.	
3	**c)**	**Discuss the various additives in formulation of suspensions.** Following are various additives in formulation of suspensions 1. Thickening agent. 2. Flocculating agents 3. Wetting agents. 4. Preservatives 5. Organoleptic additives **1. Thickening agent.** The thickening agent used to stabilize the Suspension are classified into 3 major group **1) polysaccharides : Two types** **a) Natural polysaccharides:** **i) Gum acacia:** It is a good protective colloid & suspending agent. It is more effective when it is used as compound tragacanth powder which is used in concentration of 2 g per 100 ml of mixture when the vehicle is other than water & chloroform water.	**(3M= any 3 additives ,)**

ii) Tragacanth : It is used as compound tragacanth powder or tragacanth mucilage.

Tragacanth mucilage is used when the vehicle is water or chloroform water in the concentration of ¼ th of the total volume of the mixture.

iii) Starch: It is sometimes used with other suspending agents because of the high viscosity of its mucilage.

iv) Sodium alginate: It forms a viscous solution when dissolved in water.

b) Semisynthetic :

i) Methyl cellulose: It is generally used in the concentration of 0.5 to 2% both in external and internal preparation

ii) Sodium carboxymethylcellulose : It is used in 0.25 to 1% in preparations meant for oral, external and parenteral use.

iii) Microcrystalline cellulose: It is prepared from wood cellulose by acid hydrolysis.

2) Inorganic agents –

a) Clay: Bentonite & aluminum magnesium silicate is very commonly used as thickening agent.

b) Aluminum hydroxide: It is used as a suspending agent in suspension containing Barium sulphate, calamine, sulphonamide & sulphur.

3) Synthetic compounds :

a) Carbomer: (carboxy vinyl polymer): It is used as a thickening agent in the concentration of 0.1 to 0.4 percent for internal & external preparations.

b) Colloidal silicon dioxide : It is white powder & act as a suspending agent in the concentrations of 1.5 to 4 %

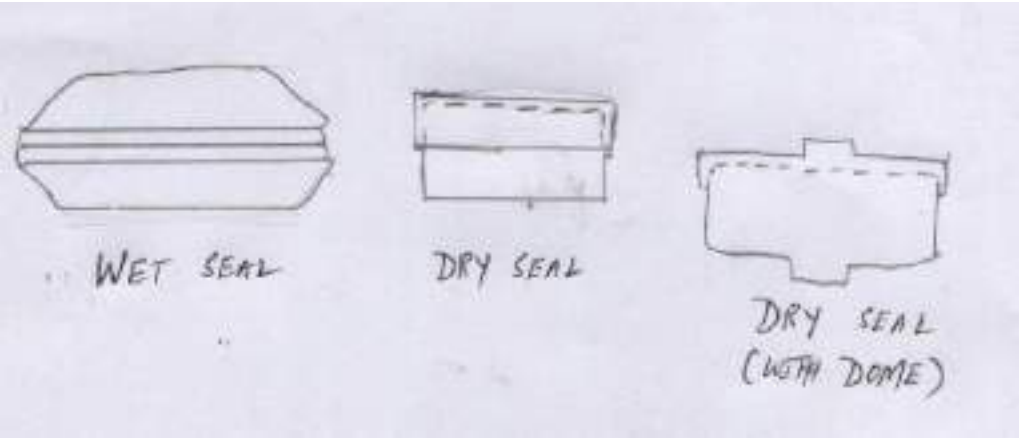
2. Flocculating agents

The flocculating agent act by reducing the surface tension and Thereby improving dispersion of solids and minimise flocculation.

eg. Sodium Lauryl Sulphate, tweens, spans and carbowaxes.

3. Wetting agents.

These are the substances which reduce the interfacial tension between solid particles and liquid medium, thus producing a suspension of required quality. For examples, alcohol in tragacanth mucilage, glycerine in sodium alginate or bentonite dispersion and polysorbate

		in oral and parenteral suspensions. **4. Preservatives** Used to preserve suspensions against bacterial growth. e.g. Benzoic acid, sodium benzoate, methyl paraben, propyl paraben **5. Organoleptic additives-** It includes colouring agents, sweetening agents and flavouring agents generally incorporated in oral suspensions.	
3	**d)**	**Write a note on cachets. (Students can write any three heads like definition, types, advantage or disadvantages etc.)** **Definition:-** Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used to enclose nauseous or disagreeable powders. **Types:** **Wet seal:** A wet seal cachet is made up of two similar convex halves having flat edges. The weighed quantity of powdered drug is placed in one half, the edges of the other half are moistened with water and placed exactly over the first half containing the drug. The flat edges of both the halves are pressed together in order to seal it perfectly. **Dry seal:** Dry seal cachets consists of two halves, the upper half and the lower half. The diameter of the upper half is slightly larger than the lower half. The powdered drug is filled in lower half and upper half is fitted over it. The filled cachets are then sealed in a machine by pressing the two halves, removed and packed in boxes.  	**3M**

		Advantages:- 1) They can made easily because no complicated machinery is required. 2) They disintegrate quickly in the stomach 3) The drug can be easily dispensed in cachets. 4) Large dose of drug can be swallowed by using cachets. **Disadvantages:-** 1) They must be softened before swallowing 2) They are easily damaged 3) They can't protect the enclosed drug from light & moisture 4) The shell of cachets are fragile, so the drug can't be compressed in cachets 5) Not suitable for filling the drug by large scale machinery. 6) They occupy more space than the corresponding sizes of capsules & tablets.	
3	**e)**	**Mention the different methods of removing unwanted hairs.** Following are different methods of removing unwanted hairs- **1) Epilation:** It is mechanical removal of hair by method like plucking, waxing, electrolysis. It is painful & may cause skin damage. Chances of skin secretion can be increased. Contains rosin, Beeswax along with vegetable oil, cooling agent, local anaesthetic & antibacterial agent. **2) Depilation:** It involves chemical breakdown of the hair without injury to skin. They are alkaline reducing agents which cause the hair fiber to swell & produce a cleavage of disulphide or cystein bridges between adjacent polypeptide chains & degrade the hair. **3) Electrolysis:** The method involves the inserting of needle into the hair follicle and hair root is completely destroyed by means of weak D.C. current. The hair is removed permanently. The method is very expensive and time consuming. But once the treatment is given successfully the hair does not grow again.	**(3M=1 mark for each method)**
3	**f)**	**Describe the method for the preparation of mixtures containing indiffusible solids.** **Method for the preparation of mixtures containing indiffusible solids-** **1st Method:- When Tragacanth Powder is used** 1) Finally powder diffusible, indiffusible solid and soluble solids mixed them with tragacanth powder	**(3M= each method 1.5 marks)**

		2) Measure 3/4th of the vehicle triturate it with apportion of it till there is formation of cream. Then add remaining of the vehicle. 3) Examine the contents for foreign particles present filter through muslin cloth. 4) Add any liquid ingredients if present. 5) Transfer the mixture to a measuring cylinder and make up the volume. 6) Transfer to suitable container and label **2nd Method:- Tragacanth mucilage is used when vehicle is water or chloroform water.** 1) Finally powder indiffusible solid and add soluble solids and diffusible solids mixed them 2) Triturate the material with tragacanth mucilage (1/4th of the volume) to form smooth cream. 3) Then gradually dilute with ½ of the vehicle. 4) Examine the contents for foreign particles present filter through muslin cloth. 5) Add any liquid ingredients if present. 6) Transfer the mixture to a measuring cylinder and make up the volume. 7) Transfer to suitable container and label	
4		**Attempt any FOUR of the following.**	
4	**a)**	**Define therapeutic incompatibility. What are the various types and causes of therapeutic incompatibility?** **Therapeutic Incompatibility**:- When the intensity or nature of action drug is different from that intended by prescriber, then such effects are termed as therapeutic incompatibility. **Various types and causes of therapeutic incompatibility-** **1. Error in dosage:-** • It is error in writing or interpreting the prescription order. • The most serious type of dosage error in the dispensing is overdose of a medication. • So it is the duty of a pharmacist to check the prescription before dispensing it. E.g.	**(3M= 1mark def., 2 marks types causes)**

Rx

Atropine sulphate -------0.006gm

Phenobarbitone----------0.015gm

Asprin ----------0.300gm

Prepare 10 capsule

In this prescription, the quantity of atropine sulphate in each capsule is more than its minimum recommended dose of 2mg. So the prescription is referred back to the prescriber to correct the overdose of atropine sulphate.

2. Wrong drug or dosage form:-

- There are certain drugs which have quite similar name & there is always a danger of dispensing of wrong drug.
- For e.g. Prednisone & Prednisolone, Digoxin & Digitoxin
- Sometimes many drugs are available in different dosage forms & hence dosage form should be clearly mentioned on prescription.

3. Contra-indicated drugs:

- There are certain drugs which may be contra-indicated in a particular disease or particular patient who is allergic to it. For e.g. Corticosteroids are contraindicated in patients having an active peptic ulcer.
- Penicillin & sulpha drugs are contra-indicated to the patients who are allergic to it.

4. Synergistic & antagonistic drugs:-

Many drugs exhibit synergism & antagonism when administered in combination.

- Synergism:- When two drugs are prescribed together, they increase the activity of each other. For e.g. a combination of aspirin & paracetamol increases the analgesic activity.
- Antagonism:-When two drugs having the opposing pharmacological effects are prescribed together antagonism occurs. For e.g. Acetyl acetic acid & probenecid are used in the treatment of gout, the combination of these lead to neutralization.

5. Drug interaction:-

- The effect of one drug is altered by prior or simultaneous administration of another drug or any food items & it is corrected by proper adjustment of dosage, or

		appropriate directions. For e.g. Rx Tetracycline HCL---------- 250mg Send 10 capsules. Direction: Take 1 capsule every 6 hours with milk. In this tetracycline is inactivated by calcium which is present in milk. So tetracycline capsule should not be taken with milk. So prescription may by refer back to the physician.	
4	**b)**	**Write a note on dentifrices.** **Definition**- Dentifrices are the preparations meant to be applied to the teeth with a help of tooth brush for the purpose of cleaning the accessible surface of the teeth. **Qualities of good Dentifrices-** 1) It should be economical. 2) It should be non toxic. 3) It should be properly sweetened and flavoured. 4) It should give fresh and clean sensation. 5) It should be efficient in removing food substances, plaque and other foreign particles. 6) It should clean the teeth. **Formulation-** **1. Abrasive agents:** • The abrasive agents such as calcium sulphate, magnesium carbonate, sodium carbonate and sodium chloride are used in fine powder. • A strong abrasive substance should however not to be used as it may damage the tooth structure. **2. Detergents:** • They contain a suitable detergent or soap. • Soap removes the debris from surface of tooth by the mechanism of emulsification	**(3M=1 mark def., 1 mark qualities, 1 mark formulation)**

3. Humectants:

- Humectants are added to prevent the drying of preparation.
- Ex. Glycerin, propylene glycol, etc.

4. Sweeteners:

- Sweeteners are added to change the taste of the formulation and to avoid the bitter taste of the ingredients.
- Ex. Saccharine sodium, sucrose, etc.

5. Colours: Colour is added to improve appearance of preparation to make it attractive.

Ex. Coal tar dyes,

6. Flavours:

- Flavours are added to improve the taste of the formulation.
- Ex. Peppermint oil, cinnamon oil, etc.

4 c) Differentiate between flocculated and non flocculated suspensions. **(3M any 6 points for 3 marks)**

Flocculated suspension	**Non flocculated suspension**
1)Particle form loose aggregates & form network like structure.	1) Particle exist as separate entities
2) The rate of sedimentation is high	2)The rate of sedimentation is slow
3) Sediment is rapidly formed.	3) Sediment is slowly formed
4)Sediment is easy to redisperse	4)Sediment difficult to redisperse
5)Sediment is loosely packed & does not Form a hard cake.	5)Sediment is very closely packed & a hard cake Formed.
6)Supernatant liquid is clear.	6)Supernatant liquid is not clear
7)The floccules stick to the sides of bottle	7)The floccules do not stick to the sides of bottle.
8)Suspension is not pleasing in appearance.	8)Suspension is pleasing in appearance.

4	d)	**Write the various methods and give the formulae for the calculations of doses.** **1) Proportionate to age-** **1. Young's formula:** $\text{Dose for a child} = \frac{\text{Age in years}}{\text{Age in years} + 12} \times \text{Adult dose}$ **2. Dilling's formula:** $\text{Dose for a child} = \frac{\text{Age in years}}{20} \times \text{Adult dose}$ **3. Fried's formula:** $\text{Dose for a child} = \frac{\text{Age in months}}{150} \times \text{Adult dose}$ **2) Proportionate to body weight-** $\text{Dose for a child} = \frac{\text{Weight of the child lb}}{150} \times \text{Adult dose}$ **3) Proportionate to body surface area-** $\text{Dose for a child} = \frac{\text{Surface area of child}}{\text{Surface area of Adult}} \times \text{Adult dose}$ The average body area for an adult is = $1.73m^2$ Hence, $\text{Dose for a child} = \frac{\text{Surface area of child}}{1.73m^2} \times \text{Adult dose}$	**(3M=1 mark for each method)**

4	**e)**	**Describe the tests to differentiate types of emulsions.** **1) Dilution Test -** I. Emulsion diluted with water - i)Emulsion remains stable then it is o/w emulsion ii)Emulsion break it is w/o emulsion II. Emulsion diluted with oil- i)Emulsion remains stable then it is w/o emulsion ii)Emulsion break it is o/w emulsion **2) Dye Test-** I. Emulsion diluted with scarlet red dye – i)Dispersed globules appear red & background is colourless then it is o/w type ii) Dispersed globules appear colourless & back ground is red then it is w/o type. II. Emulsion diluted with amaranth dye – i)Dispersed globules appear red & background is colourless then it is w/o type ii) Dispersed globules appear colourless & back ground is red then it is o/w type. **3) Conductivity Test-** This type of emulsion show bulb glowing on passing electric current. I. If bulb glow the emulsion is o/w type II. If bulb does not glow the emulsion is w/o type **4) Fluorescence Test**: I. If an emulsion on exposure to ultra-violet radiations globules shows continuous fluorescence under UV light, observed under microscope, then it is o/w type II. If it shows only spotty fluorescence, then it is o/w type. **5) Cobalt Chloride Test**: When a cobalt chloride test paper dipped in to an emulsion, if it turns from blue to pink, indicating that the emulsion is o/w type.	**3 M= any 3 tests.**
4	**f)**	**What are pastes? Give its classification.** **Definition:** Paste are semisolid preparation intended for external application to the skin as protective, antiseptic, or soothing dressing. **Types of bases for pastes-** 1) **Paste with gelatin base** -A hot 2% gelatin solution is used which becomes jelly on	**(3M=1 mark def., 2 marks classific**

		cooling, to this 10-15% glycerin is added which act as preservative and emollient and in this solution solid substances are incorporated example Unnas paste 2) **Paste with starch base** (gelatinized or ungelatinised) In case of gelatinized paste 10% starch solution is prepared and gelatinized by heating and then glycerin is added in this solution solid substances are added, in case of ungelatinised paste large portion of starch powder is mixed with other solid ingredients and water to form the paste. 3) **Paste with tragacanth base** also called as Bassorin pastes In this the tragacanth powder is mixed with alcohol and triturated briskly followed by addition of glycerin and water. 4) **Paste with cellulose derivatives**- cellulose are dissolve in cold water and allowed to stand overnight it forms jelly and in this solid substances are incorporated. 5) **Paste with pectin base**- Pectin is triturated with medicament and glycerine followed by addition of salon solution to form paste. 6) **Paste with colloidal base aluminum hydroxide and bentonite** are used as colloidal base. The colloidal base is triturated with solid substances followed by addition of glycerin and water.	**ation)**
Q.5		**Answer any FOUR of the following:**	
Q.5	**a.**	**Define antiperspirants and deodorants. How do they function?** **Antiperspirant:** It prevents the flow of perspiration to overcome bad smell which is due to bacterial decomposition. Antiperspirants contain a substance having **astringent** action on reacting with skin proteins it causes coagulation which is accompanied by swelling at the opening of sweat glands. This blocks opening of sweat gland preventing flow of sweat. Eg. Aluminium chlorohydrate, any marketed preparation students may write. **Deodorant:** Deodorant inhibits the formation of bad odour in perspiration by suppressing the growth of bacteria or masks the unpleasant odour. Eg. Salicyclic acid, boric acid, zinc stearate, talc and starch powder, any marketed	**(3M = 1+1+1)**

		preparation. **How do they function:** They inhibit the flow if perspiration where and deodorants inhibit formation of bad odor in perspiration by suppressing the growth of bacteria or mask the unpleasant odor.	
Q.5	**b.**	**Define ointments. Give its classification with examples.** Ointments are semisolid preparations meant for external application to the skin or mucous membrane. They usually contain a medicament dissolved, suspended or emulsification of ointment Classification of ointment: **1)Therapeutic properties based on penetration** 1. Epidemic ointments 2. Endodermic ointments 3. Diadermic ointments **a) Epidermic ointments:** These ointments are meant for action on epidermis & produce local effect. They are not absorbed. Used for protective, antiseptic, local anti-infective effect. **b) Endodermic ointments**: These are meant for deeper layers of cutaneous tissues. They are partially absorbed & act as emollients, stimulants & local irritants **c) Diadermic ointments** : Meant for deep penetration & release the medicament that pass through the skin & produces systemic effects. **2) Therapeutic uses** 1. Antibiotic ointments 2. Antifungal ointments 3. Anti-inflammatory ointments 4. Antipruritic ointments 5. Astringent ointments 6. Anti-eczematous ointments 7. Keratolytic ointments 8. Counter irritant ointments 9. For Dandruff treatments 10. For Psoriasis 11. Parasiticide ointments 12. Protectant ointments	**3M = 1+2)**

Therapeutic uses

1. Antibiotic ointments :

Used to kill micro organism.

Eg. Bacitracin , neomycin , Chlorotetracycline

2. Antifungal ointments:

inhibit or kill fungi

eg.Benzoic acid, salicylic acid , & nystatin

3. Anti-inflammatory ointments:

Used to relieve anti inflammatory ,allergic , & pruritic conditions of skin.

Eg. Betamethasone valerate, hydrocortisone.

4. Antipruritic ointments

Used to relieve itching

Eg. Benzocain & coal tar.

5. Astringent ointments

Causes contraction of skin & decreases discharge.

Eg. Calamine , zinc oxide, acetic acid & tannic acid.

6. Anti-eczematous ointments

Used to prevent oozing & excrection from vesicles on the skin

Eg Hydro cortisone, coal tar &

7. Keratolytic ointments

Used to remove & soften horny layer of skin

Eg. Resorcinol ,salicylic acid , & sulphur.

8. Counter irritant ointments

Applied locally to irritate the skin , thus reducing or relieving another irritation or deep sited pain.

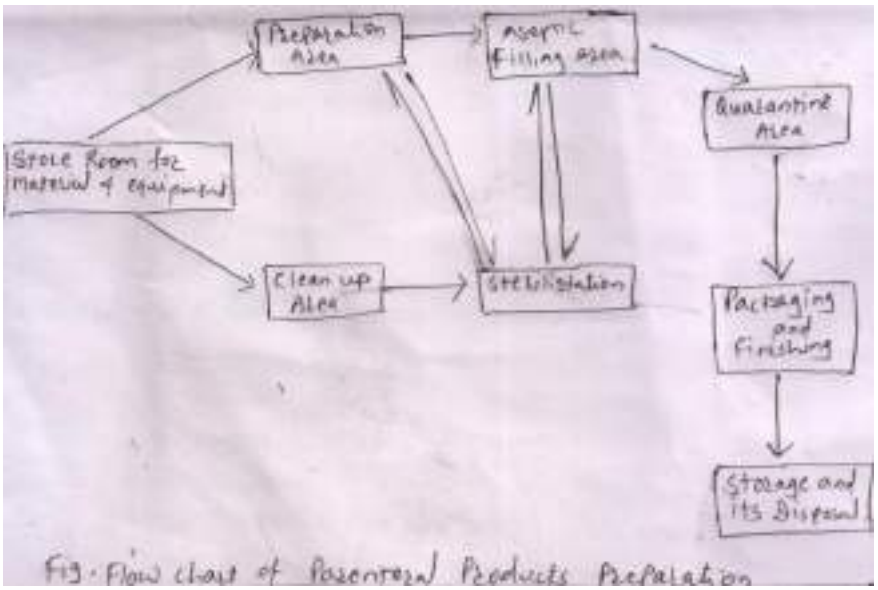
9. For Dandruff treatments

To get relief from dandruff . eg.salicylic acid, cetrimide.

10. For Psoriasis

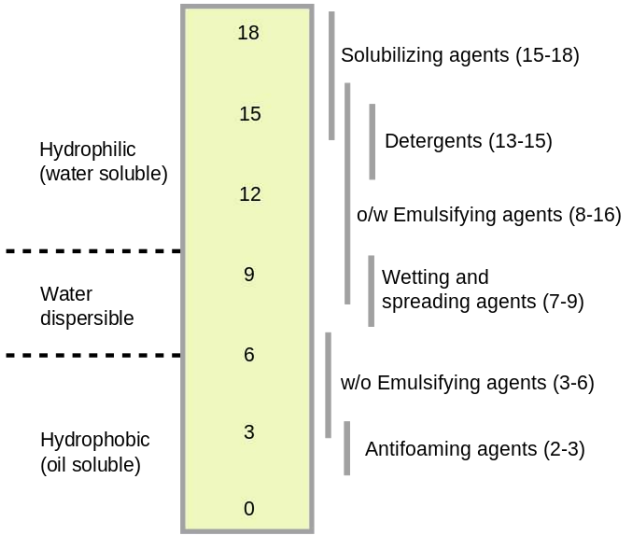
Coal tar ,corticosteroids, dithranol ,& salicylic acid .

11. Parasiticide ointments

		Destroy or inhibit living infestation, such as lice & ticks. Eg.benzyl benzoate, hexachloride , sulphur. 12. Protectant ointments Protect skin from moisture , air, sun rays. Eg. Calamine ,zinc oxide , silicones , titanium dioxide.	
Q.5	**c.**	**Describe the layout of sterile area**  Fig. Flow chart of Parenteral Products Preparation **Clean up area:-**In such area cleaning and steaming of packing materials and utensils is done therefore the walls and ceiling are constructed in such a way, that they withstand the effects of steam and chemicals. Generally, epoxy or vinyl paint is coated to solve the purpose. This area must be kept clean by washing it regularly. Precaution must be taken to prevent the growth of microorganism and collection of dust. **Compounding area:-**It is nothing but a "preparation" area, where the formula is compounded, and not necessarily aseptic. There should be strict control it that these should not catch dust. The cabinets and counters should be of stainless steel. Ceiling wall and floor should be sealed and can be coated with Epoxy paint. Adequate sink and counter space should be provided. **Aseptic Area: -** It is an entirely sealed area from outside atmosphere to keep aseptic environment free from physical and biological contamination. Therefore, at the time of designing and constructing the aseptic area civil work can compose to HVAC (High	**3M= 1M for layout,(0.5x4=2 M for explana tion**

		ventilating and air conditioning) system including the electrical wire fittings and switches. The walls facing outside should have double walled glass partition. Epoxy paints should be used.to prevent wall, ceiling ,and floor from the accumulation of dust and microorganisms The air in the aseptic area should be free from fibers ,,dust and microorganism. This can be achieved by the use of high efficiency particulate air filers (HEPA) which can remove particles upto 0.3 um. HEPA filters are fitted in laminar air flow system in which air free from dust and microorganism flows with uniform velocity.The air is supplied under positive pressure which prevents particulate contamination from sweeping from adjoining areas .Ultraviolet lamps are fitted to maintain sterility. The personnel enter in this area through air lock door. Movement should be minimum and restricted during filling procedure **Quarantine area:-** Approved batches from QC department can be kept here before labelling and packing.It must contain space that separates 'Approved batches' and 'In process batches'.This area is only restricted to a responsible person. **Labelling and packing area:-**Adequate space is required for installation of printing devices and packaging machines In this area, label printing and labelling can be take place. **Storage and its disposal:-** The finished product are stored under specified storage condition and dispensed off.	
Q.5	**d.**	**Report the incompatibility in the following prescription with method to correct it.** **Rx** **Codeine phosphate -0.5 gm** **Prepare 10 powders** **Label-one to be taken at bed time.** **Solution:** Its Therapeutic incompatibility of error in dose. Therapeutic dose of Codeine phosphate is 5mg, prescriber has written 0.5gm which is 500 mg. **method of correction:** Refer back prescription to prescriber for correction of dose	**3M= 2+1)**

Q.5	**e.**	**What are additives employed in the formulation of effervescent granules?Give their functions.** **Additives employed in the formulation of effervescent granules** 1)Sodium bicarbonate : 2) Citric acid. 3)Tartaric acid : 4)Sodium sacchrine: **functions.** 1)Sodium bicarbonate : It reacts with acid when preparation is added to water. The evolved carbon dioxide produce the effervescence 2) Citric acid a)To release water of crystallization & to create conditions for release of more water . b)Partial neutralization of bicarbonate. 3)Tartaric acid : Only for neutralisation 4)Sodium sacchrine: sometime added as sweetning agent.	**3M=1+2)**
Q.5	**f.**	**What is HLB value? Give its importance in formulation of Emulsion.** The HLB scale means (Hydrophilic – Lipophilic Balance) System and has an arbitrary scale of 1-18 HLB numbers are experimentally determined for different emulsifiers in laboratory.	**3M = 1+2)**



Role of HLB in formulation of Emulsion:

HLB scale is useful for calculating balanced mixture of emulsifying agent. It is very difficult to **select proper emulsifying agent** from different emulsifying agent to prepare stable emulsion, therefore sometimes it is necessary to use two or more than two emulsifying agent. No single emulsifying agent possesses all the properties required for preparing stable emulsion.

Q.6		**Answer any FOUR of the following:**	
Q.6	**a.**	**Describe the various types of ingredients used in formulation of shampoo.** **Various additives used in formulation of shampoos** **1)Conditioning Agent:-** used to lubricate the hair & improve the texture of hair & it reduces the fluffiness & make the hair soft & shiny. e.g. Lotion & its derivatives, Glycerin, PG **2)Thickening Agents:-** Use to increase the viscosity of shampoo & provide desired consistency.e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate **3)Solubilizig Agent :-** Used to solubilize poorly soluble subs.e.g. ethyl alcohol, glycerol, PG. **4)Opacifying Agents:-** used to make shampoo opaque. e.g. glycerol, glyceryl stearate, stearyl alcohol. **5) Preservatives:-** used to preserve the shampoo against bacteria or mould. e.g. Methyl	**4M = 1X 4)**

		Paraben, Propyl Paraben**.**	
6	**b.**	**Explain cracking of Emulsions.** The following factors results in the cracking of emulsion. • Decomposition of the emulsifying agent • Addition of a solvent which dissolves both the phases • High temperature and change in pH. • Addition of opposite types of emulgents • Growth of micro – organism • Extensive creaming. **Decomposition of emulsifying agent:** • When acid is added to alkali soap emulsion it causes decomposition of emulsifying agent & thus leading to cracking of emulsion. **Addition of common solvent:** • Addition of common solvent in which both disperse & continuous phase are soluble forms one phase system & destroys the emulsion. • Eg. Turpentine, soft soap & water are soluble in alcohol. **Change in Temperature:** • Increase in temperature leads to reduction in viscosity; encourage creaming thus leads to cracking. Low temperature causes freezing of water content. **Addition of emulsifying agent of opposite type:** • **Soaps of monovalent** metal produces **o/w** emulsion,& Soaps of **divalent metal** produces **w/o** emulsion. But addition of monovalent soap to divalent soap emulsion & vice versa may leads to cracking. **Growth of microorganism:** • Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking. **Extensive creaming:** Extensive creaming leads to cracking.	**4M=1X 4)**

6	c.	**Comment;(any one)** **(i) Total parenteral nutrition** (ii) **Bacterial Endotoxin test for parenteral.** **Definition:** **Total <u>parenteral</u> nutrition** (TPN), is the practice of feeding a person intravenously, bypassing the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. **Need:** o When the gastrointestinal tract is nonfunctional because of an interruption in its continuity or because it's absorptive capacity is impaired. o To treat people suffering the extended consequences of an accident or surgery or digestive disorder. o Needed for children born with non-existent or severely deformed guts. **Requirement:** o Normal calories required for an adult is approximately 2500 kcal /day which can be supported by injecting dextrose 25%. o TPN requires water (30 to 40 mL/kg/day), **energy (30 to 60 kcal/kg/day, depending on energy expenditure)**, amino acids (1 to 2.0 g/kg/day, depending on the degree of catabolism), essential fatty acids, vitamins, and minerals **OR** **Bacterial Endotoxin test for parenteral:** **Bacterial endotoxin test is used for pyrogen testing (LAL test)** • An extract from the blood cells of the horse shoe crab contains enzyme and protein system that coagulates in the presence of low level of lipopolysaccharides. • This discovery led to the development of the limulus ameboytes lysate LAL test for the presence of bacterial endotoxin The advantage of this test is that it is more sensitive test then the rabbit test use for detection of pyrogen. The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polymhemus). The result of the reaction is	**4M**

		turbidity or precipitation or gelation of the mixture. This is used as a quantitative measure to estimate the endotoxin content. The rate of reaction depends upon conc. of endotoxins, pH, temperature and presence of clotting enzyme system and clottable proteins from lysate	
6	**d.**	**Describe general method for a preparation of suppositories.** **General method for a preparation of suppositories: (Fusion Method)** 1. Calculate the qualities required taking displacement value into the account. An excess must be made(two extra suppository)because of unavoidable wastage during preparation . 2. Select a dry clean mould & place it on a clean tile. 3. Shred the fat with fine food grater. weigh the required amount , avoiding lumps that would slow to melt. 4. Finely powder the medicaments & pass each through a sieve no 180.Weigh the required quantities. 5. Heat a small tile until it is comfortably warm. 6. Mix the powders on a tile 7. Place the base on the water bath until about 2/3 rd of the content has melted & then remove from the heat. The rest will melt with stirring. 8. Overheating will occur if the base is left over the heat until completely melted. 9. Pour about half of the melted base on mixed medicaments and levigate into smooth dispersion with spatula 10. Transfer the dispersion to dish , stir to form homogeneous mixture. 11. Continue stirring until the mixture begins to thicken Then fill each cavity of the mould to overflowing to prevent depression in the top. stir the mass continuously to prevent sedimentation of insoluble solids. 12. Allow to cool. remove excess from the mould with a sharp knife.	**4M**
6	**e.**	**Describe the various methods for the preparation of syrups.** Method of preparation 1) By simple solution method e.g. simple syrup or ginger syrup Add sucrose to purified water and heat to dissolve sucrose with occasional stirring cool and than add water to make	**4M (any 2 methods)**

		required weight. 2) By process of extraction e.g tolu syrup Add boiling purified water to tolu balsam, cover the vessel lightly and boil the content for half an hour stirring frequently add purified water to adjust the specific weight ,cool and filter the solution add sucrose and dissolve by add of heat. (3)Syrups made by **chemical reaction** e,g comp syrup of ferrous phosphate In this preparation the reaction takes place between iron wire and phosphoric acid result in formation of ferrous phosphate reaction also takes place between calcium carbonate potassium bicarbonate and phosphoric acid resulting in formation of corresponding phosphate salts after the reaction is complete add sucrose and flavoring agent than adjust the volume with purified water.	
6	**f.**	**Write a note on jellies.** **Jellies**:- Jellies are transparent or translucent non-greasy, semisolid preparation for external application to the skin or mucous membrane. **Classification of Jellies :** **(i)Medicated Jellies**:- these are chiefly used on mucous membrane & skin for their spermicidal, local anaesthetic & antiseptic properties. These jellies contain sufficient water. After evaporation of water, jellies provide a local cooling effect & residual film gives protection. **(ii)Lubricating jellies**:- These are used a lubricating agent for catheters, rubber gloves, thermometers. These jellies should be sterile. (iii)**Miscellaneous jellies**:- These jellies meant for a)Patch testing: These are used as vehicle for allergens during sensitivity testing. b) Electro-cardiography jelly applied on electrode to reduce electrical resistance between patients skin and the electrode. **Formulation of Jellies** Gelling agent: a. Tragacanth b. Sodium alginate c. Pectin	**4M**

		d. Starch e. Gelatin f. Cellulose derivatives 2. Preservatives: Methyl p-hydroxybensoate (0.1 – 0.2 % w/v), Propyl p- hydroxybensoate (0.5 %), Chlorocresol (0.1 – 0.2 %), Benzoic acid (0.2 %), Benzalkonium chloride (0.005%) **Disadvantages:** 1. Addition of preservative required. 2. Hygroscopic. 3. Prone to growth of microorganism. 4. Overnight soaking of jelly is required while manufacturing. 5. Fluctuation in temperature may change the consistency. **Container & storage:** Jellies are stored in well filled well closed container to prevent evaporation of water. Jellies are stored in cool place to prevent drying out.	

WINTER– 19 EXAMINATION

Subject Title: PHARMACEUTICS-ll Subject Code: 0811

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.

<table>
<tr><th>Q. No.</th><th>Sub Q. N.</th><th>Answer</th><th>Marking Scheme</th></tr>
<tr><td>1</td><td></td><td>Answer any Eight of the followings:</td><td></td></tr>
<tr><td>1</td><td>a)</td><td>Define emulsion. Write its significance.
Definition: Emulsion is a biphasic liquid preparation containing two immiscible liquids which are made miscible by adding emulsifying agent.
Significance: (0.5 X 2 = 1M)
❖ Mask the Unpleasant taste.
❖ Improved Bio-availability (Griseofulvin).
❖ Sustained Release Medication (depot).
❖ Nutritional supplement.
❖ Diagnostic purpose (x-rays examination).
❖ External use preparation (cream lotion foam aerosol).</td><td>(2M = 01 +01)</td></tr>
<tr><td>1</td><td>b)</td><td>Differentiate between liniments and lotions.
<table>
<tr><th>Liniments</th><th>Lotion</th></tr>
<tr><td>1. They are used for counter irritant, rubefacient, soothing or stimulating purpose.</td><td>1. They are used for topical effect such as local cooling, soothing protective & emollient effect.</td></tr>
<tr><td>2.Applied with friction</td><td>2. Applied without friction.</td></tr>
<tr><td>3.Vehicle is mostly oily or alcoholic</td><td>3. Vehicle is mostly aqueous.</td></tr>
<tr><td>4. These are used for application to the unbroken skin.</td><td>4. Lotions can be applied on broken skin.</td></tr>
<tr><td>5.Applied directly</td><td>5. Applied with cotton gauze</td></tr>
<tr><td>6. alcohol is added to improve penetration power</td><td>6. Alcohol is added for cooling action.</td></tr>
<tr><td>7.These are semi-liquid preparations</td><td>7.These are liquid preparation</td></tr>
<tr><td>8.Turpentine liniment</td><td>8 .Sulphur lotion.</td></tr>
</table></td><td>(2M = 0.5 X 4)</td></tr>
</table>

1	c)	**Translate the following Latin terms in English.** **Jantaculum -**Breakfast **Capiendus-** To be taken **Haustous:** A droughts **Hora Somni:** at bed time or before sleep.	**(2M = 0.5 X 4)**
1	d)	**Why most of emulsion appears white or opaque.** Emulsions usually appear cloudy or white because light is scattered off the phase interphases between the components in the mixture. If all of the light is scattered equally, the emulsion will appear white.	**2M**
1	e)	**Give any four properties of suppositories base.** ● It must retain the shape and size. ● It should melt at body temperature. ● It should shrink sufficiently to remove from mould. ● It should permit incorporation of drug. ● It should be physically stable on storage. ● It should not be soften or harden on storage. ● It should be compatible with variety of drugs. ● It should not interfere in release or absorption of drug. ● It should be non-irritant.	**(2M = 0.5 X 4)**
1	f)	**How will you dispense a powder containing eutectic mixture?** When two or more substances are mixed together they liquefy due to the formation of new compound which has a lower melting point than room temperature such substances are called as eutectic mixtures. The can be dispensed in separate packets or equal quantity of inert solid is mixed. Rx Menthol 5 parts Camphor 5 parts Ammonium chloride 30 parts Magnesium carbonate 60 parts	**2M**

1	g)	**Give stokes equation for creaming in emulsion.** $V = \frac{2r^2 (d_1 - d_2)}{9\mu} g$ Where, V= Rate of creaming. r = Radius of globules. d_1-d_2 = Density of dispersion medium/dispersing medium. μ = Viscosity. g = Gravitational constant	**2M**
1	h)	**White Vaseline is not used in ophthalmic ointment.** • White Vaseline is semi-solid hydrocarbon obtained by bleaching (de-colourization) of yellow soft paraffin. • White Vaseline not used in the preparation of ophthalmic ointment because it may contain the traces of bleaching agent which may produce the irritation.	**2M**
1	i)	**What is rouge? Name the types of rouges.** **What is rouge: (1M)** • Rouges are the cosmetic preparations which are applied to the cheeks for enhancing the face beauty. • It also imparts and stimulates the rosy freshness of the young and healthy skin. **Types: (0.5 X2 =1M)** • Solid. • Liquid. • Cream form.	**(2M= 1+1)**
1	j)	**What is LAL test?** **LAL test** is used for the detection and quantification of bacterial endotoxins: Limulus amebocyte lysate (LAL) is an aqueous extract of blood cells (amoebocytes) from the horseshoe crab, Limulus polyphemus. LAL reacts with bacterial endotoxin or lipopolysaccharide (LPS), which is a membrane component of Gram negative bacteria.	**2M**

		The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polymhemus). The result of the reaction is turbidity or precipitation or gelation of the mixture.	
1	**k)**	**What precautions needed to be taken in storage of eye drop?** Following precautions taken during storage of eye drops: i. If the dropper is separate, always hold it with its tip down. ii. Never touch the surface of dropper iii. Never rinse the dropper iv. Never used eye drops that have changed color v. When the dropper is at the top of the bottle, avoid contaminating the cap when removed. vi. Use within one month after opening the container. vii. If colour of preparation changes discard it. viii. Store in cool place protected from light. ix. Do not freeze it.	**(2M= 0.5 X 4)**
1	**l)**	**The adult dose of phenobarbitone is 15 mg. What is the dose for a child weighing 40 pound?** **Data given:** Child weight=40 pound Adult dose = 15 mg Clarks formula, Child dose = weight in pound /150 X adult dose Child dose = 40/150 X 15 Child dose = 4 mg	**2M**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Define and explain the various parts of prescription.** **Prescription:** Prescription is a written order given by registered medical practitioner, any other licensed person, veterinarians or dentist to pharmacist to dispense proper medication to patient. **Parts of prescription:** 1. **Date**: It is important to avoid misuse of prescription if it is presented by the patient,	**(3M = 1 + 2)**

		a number of times for dispensing. 2. **Name, age, sex & address of the patient:** The Name, age, sex & address of the patient is important for proper handling of prescription & also identification of patient .Age & sex is important especially for children to check prescribed dose of medication. 3. **Superscription:** Rx stands for Latin word recipe meaning 'you take'. It is the symbol in the name of god of healing called Jupiter to pray for quick recovery of patient. 4. **Inscription:** This is main part of prescription contains Base, Adjuvant and vehicle or name & quantities of the prescribed ingredients. 5. **Subscription:** Direction to the pharmacist for preparing dosage form as instructed with quantity. Ex. 'Mix', 'Send tablets', or 'capsules' etc. 6. **Signatura :** It consist of the direction to be given to the patient regarding administration of the drug. 7. **Renewal instructions :** The prescriber indicate on every prescription order whether it may be renewed & if so, how many times. It is important particularly in the prescription containing the narcotic & other habit forming drugs to prevent misuse. 8. **Signature, address & registration number of the prescriber:** The prescription bears signature, address & registration number of the prescriber. It is important particularly in the prescription containing the narcotic & other habit forming drugs to prevent misuse.	
2	**b)**	**Define elixir and discuss various formulation aspects of elixir.** **Definition:** Elixir: Elixirs are clear, sweetened, aromatic, hydroalcoholic liquids preparation intended for oral use. **Formulation:** 1. Vehicles: • Vehicle should be free from volatile and non-volatile impurities. • They are added for production of clear solution, for improving solubility and stability.	**(3M= 1 + 2)**

		• E.g. Water, Alcohol, syrup, glycerin, sorbitol and propylene glycol 2. Adjuncts: Used to improve Safety, efficacy and palatability. • Chemical Stabilizer: protecting the drug for oxidation and reduction. • Citric acid added in Neomycin Elixir to prevent the darkening of it. • Disodium EDTA as sequestering agent for metal ions which catalyzes decomposition of antibiotics. • Preservative: These are added to prevent growth of microorganisms. • 20% alochol, syrup and methyl paraben and propyl paraben • Colouring Agent: these makes the preparation attractive. • Coal tar dyes, amaranth solution, titanium dioxide etc. • Flavouring agent: these are added to improve the taste of the formulation. • Black current syrup, raspberry syrup, lemon syrup and orange syrup etc.	
2	**c)**	**Write a short note on poultice.** **Definition: (1M)** Poultices are soft, viscous wet masses of solid substances applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as a counter-irritant. **Ingredients: (1M)** Rx Heavy kaolin finely sifted and dried at 100^0C ----- 527 g Boric acid ---------- 45 g. Thymol ---------- 0.5 g. Peppermint oil ---------- 0.5 ml Methyl salicylate ---------- 2 ml. Glycerin ---------- 425 g. Send 20 gm Direction: to be used as directed. **Method of Preparation: (1M)** • Sieve kaolin & Boric acid through a sieve no. 180.	**(3M= 1+1+1)**

		• Mix the Heavy kaolin & Boric acid with glycerin to form a smooth paste in a mortar. • Transferred to a heat resistant glace jar protected suitable and heat at 120^0C for one hour in hot air oven with occasional stirring. • Dissolve thymol in methyl salicylate and Peppermint oil. • Add this solution to cooled mixture and mix thoroughly. • Transfer it to suitable container closes it tightly and labels it.	
2	**d)**	**Name the various ophthalmic products. Give there essential characteristics.** **Ophthalmic products: (0.5 X 3=1.5M)** ☐ Eye drop ☐ Eye lotion ☐ Eye ointment ☐ Eye suspension ☐ Contact lens solution **Essential characteristics: (0.5 X 3=1.5M)** ☐ It should be free from foreign particle. ☐ It should be Isotonic with lachrymal secretion. ☐ Viscosity must be high. ☐ It should have pH matching with lachrymal secretion. ☐ It should be sterile. ☐ Surface activity: wetting	**(3M= 1.5 + 1.5)**
2	**e)**	**Classify suppositories bases. Explain oleaginous bases.** **Classification: (0.5 X 3 =1.5M)** A. Oleaginous bases: 1. Cocoa butter. 2. Emulsified cocoa butter. 3. Hydrogenated oils. B. Hydrophilic bases/ aqueous bases: 1. Glycero-gelatin base. 2. Soap-glycerin base.	**(3M=1. 5+1.5)**

3. Polyethylene glycol.

C. Emulsifying/Synthetic bases:

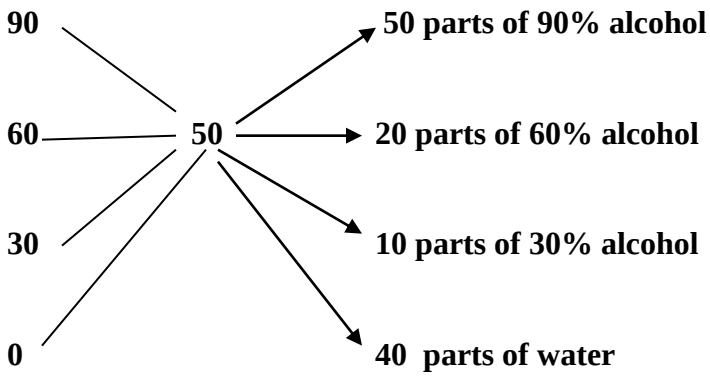
1. Witepsol
2. Massa estarinum
3. Massuppol.

Oleaginous bases/Fatty bases: (0.5 X3=1.5M)

Cocoa butter:

- **Source:**
  - Cocoa butter is fat obtained from the roasted seed of Theobroma cocoa.
- **Properties:**
  - At room temperature it is a yellowish, white solid having a faint, agreeable chocolate like odour.
  - Chemically, it is a triglyceride (combination of glycerin and one or different fatty acids) primarily of oleopalmitostearin and oleodistearine.
  - It melts at 30 - 35^0C,
- **Advantages**:
  - Melting just below the body temperature.
  - Maintaining its solidity at usual room temperatures.
  - Readily liquefy on heating and solidify on cooling.
- **Disadvantages:**
  - Exhibits marked polymorphism.
  - Rancidity.
  - Stick to mould.
  - Leakage from body cavity.
  - Costly.
  - Immiscibility with body fluid.
  - Chloral hydrate or lactic acid liquefies it.

		Emulsified theobroma oil: • It is used as base when large quantities of aqueous solution are to be incorporated. • The use of glyceryl monostearate5%, 10% lenette wax, 2-3% cetyl alcohol, 4% bees wax and 12% spermaceti is recommended to prepare emulsified theobroma oil suppositories. **Hydrogenated oils:** • These are obtained by hydrogenation of various vegetable oils. • These include hydrogenated vegetable oils, such as coconut, palm kernel, cottonseed, peanut, fractionated palm kernel oil etc. • **Advantages:** • Hydrogenation increases resistance to oxidation. • Increases chemical inertness, • Lubrication not required. • **Disadvantages:** • Become brittle on rapid cooling. • Sedimentation of added substance take place.	
2	**f)**	**Define displacement value. Explain with the help of an example how displacement value helps in formulation of suppositories.** **Definition:** It is the amount of drug required to displace one part of base. **Displacement value helps in formulation of suppositories for determine the quantity of base required.** **Example: (any example by students can be granted full marks)** Rx, Zinc oxide .....500mg Theobroma oil ... QS Prepare 6suppositories of 2gm each. Displacement value of zinc oxide = 5. **Calculation:** Calculate for 2 extra suppositories	**3M=1+ 2)**

		Weight of **Theobroma oil** for one suppository= 2 gm Weight of **Theobroma oil** for 08 suppositories = 2x 08=16g Weight of **Zinc oxide** for one suppository=500 mg = 0.5gm Weight of **Zinc oxide** for 08 suppositories= 0.5 g X 8 = 4gm Displacement value of **Zinc oxide** = 5.0 The quantity of **Theobroma oil** required = Total amount of base -Total amount of drug/Displacement Value = 16 – 4/5 = 16 – 0.8 = 15.2gm **Formula for 08 suppositories is as under** **Rx,** **Zinc oxide ..... 4gm** **Theobroma oil ... 15.2gm**	
3		**Attempt any FOUR of the followings**	
3	**a)**	**Find out amount each of 90%, 60% and 30% alcohol and water required to produce 500ml of 50% alcohol.**  **120 parts of water** Therefore, when 50 parts of 90% alcohol,20 parts of 60% alcohol,10 parts of 30% alcohol and 40 parts of water are mixed together, the resulting solution will produce 50 % alcohol.	**3M**

		i) Volume of 90% alcohol required = 120 parts : 500 ml :: 50 parts : V $V = \frac{500 \times 50}{120} = \frac{2500}{12} = 208.33$ ml ii) Volume of 60% alcohol required =120 parts : 500 ml :: 20parts : V $V = \frac{500 \times 20}{120} = \frac{1000}{12} = 83.33$ ml iii) Volume of 30% alcohol required =120 parts : 500 ml :: 10parts : V $V = \frac{500 \times 10}{120} = \frac{500}{12} = 41.67$ ml iv) Volume of water required = 500- (208.33+83.33+41.67) = 166.67 ml	
3	**b)**	**What are principle behind sterility test? Explain the official method of sterility test.** The test for sterility is done by detecting the presence of viable forms of bacteria, fungi & yeast in parental preparations. **Principle:** The test is based on the principle that if bacteria or fungi are placed in a medium which provides nutritive material & water & kept a favourable temperature the organism will grow & their presence can be indicated by turbidity in the clear medium. Sterility Testing Methods: **I) Membrane filtration method:-** The membrane filtration method is performed in following cases : • An oil or oily preparation. • An ointment that can be put into solution.	**(3M=1 mark principle and 2 marks for 2 methods)**

		• A soluble powder or a liquid that possess bacteriostatic & fugistatic properties. • Liquid products where the volume in container is 100 ml or more. ➢ It involves the filtration of sample under test through a membrane filter having porosity of 0.45 u & diameter 47 mm ➢ After filtration, membrane is removed aseptically & divided into 2 parts. ➢ The first part is transferred into 100ml of culture media meant for fungi & incubated at 20^{o} to 25^{o}C for not less than 7 days. ➢ The other half part is transferred into 100ml of fluid thioglycollate medium & incubated at 30^{0} to 35^{o}C for not less than 7 days. ➢ Observe the growth in media. **II) Direct Inoculation Method:** • In this method the specified quantity of sample under test is drawn aseptically from the container & transferred into a vessel of culture medium. (Fluid Thioglycolate and Soybean Casein Digest medium.) • Mix the liquid with the medium & incubate for not less than 14 days. • Observe the growth of microorganisms in the medium.	
3	**c)**	**Discuss the various additives in formulation of suspensions.** Following are various additives in formulation of suspensions 1. Thickening agent. 2. Flocculating agents 3. Wetting agents. 4. Preservatives 5. Organoleptic additives **1. Thickening agent.** The thickening agent used to stabilize the Suspension are classified into 3 major group **1) polysaccharides : Two types** **a) Natural polysaccharides:** **i) Gum acacia:** It is a good protective colloid & suspending agent. It is more effective when it is used as compound tragacanth powder which is used in concentration of 2 g per 100 ml of mixture when the vehicle is other than water & chloroform water.	**(3M= any 3 additives ,)**

ii) Tragacanth : It is used as compound tragacanth powder or tragacanth mucilage.

Tragacanth mucilage is used when the vehicle is water or chloroform water in the concentration of ¼ th of the total volume of the mixture.

iii) Starch: It is sometimes used with other suspending agents because of the high viscosity of its mucilage.

iv) Sodium alginate: It forms a viscous solution when dissolved in water.

b) Semisynthetic :

i) Methyl cellulose: It is generally used in the concentration of 0.5 to 2% both in external and internal preparation

ii) Sodium carboxymethylcellulose : It is used in 0.25 to 1% in preparations meant for oral, external and parenteral use.

iii) Microcrystalline cellulose: It is prepared from wood cellulose by acid hydrolysis.

2) Inorganic agents –

a) Clay: Bentonite & aluminum magnesium silicate is very commonly used as thickening agent.

b) Aluminum hydroxide: It is used as a suspending agent in suspension containing Barium sulphate, calamine, sulphonamide & sulphur.

3) Synthetic compounds :

a) Carbomer: (carboxy vinyl polymer): It is used as a thickening agent in the concentration of 0.1 to 0.4 percent for internal & external preparations.

b) Colloidal silicon dioxide : It is white powder & act as a suspending agent in the concentrations of 1.5 to 4 %

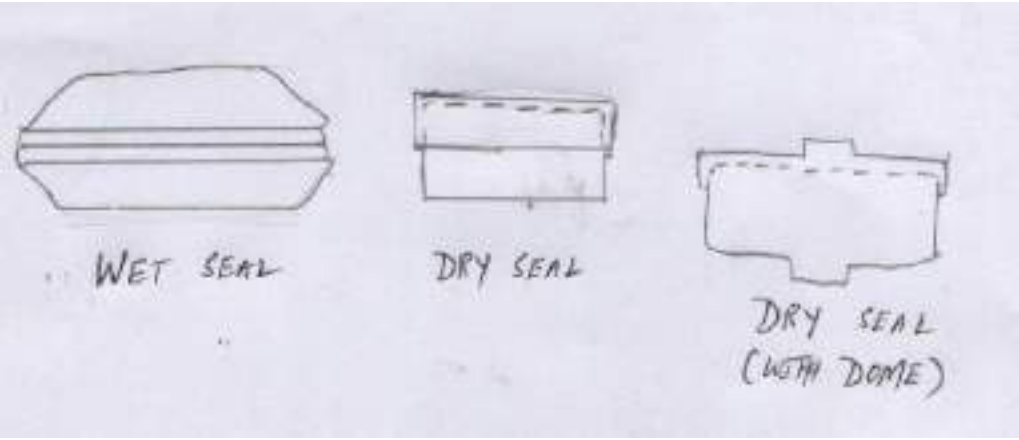
2. Flocculating agents

The flocculating agent act by reducing the surface tension and Thereby improving dispersion of solids and minimise flocculation.

eg. Sodium Lauryl Sulphate, tweens, spans and carbowaxes.

3. Wetting agents.

These are the substances which reduce the interfacial tension between solid particles and liquid medium, thus producing a suspension of required quality. For examples, alcohol in tragacanth mucilage, glycerine in sodium alginate or bentonite dispersion and polysorbate

		in oral and parenteral suspensions. **4. Preservatives** Used to preserve suspensions against bacterial growth. e.g. Benzoic acid, sodium benzoate, methyl paraben, propyl paraben **5. Organoleptic additives-** It includes colouring agents, sweetening agents and flavouring agents generally incorporated in oral suspensions.	
3	**d)**	**Write a note on cachets. (Students can write any three heads like definition, types, advantage or disadvantages etc.)** **Definition:-** Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used to enclose nauseous or disagreeable powders. **Types:** **Wet seal:** A wet seal cachet is made up of two similar convex halves having flat edges. The weighed quantity of powdered drug is placed in one half, the edges of the other half are moistened with water and placed exactly over the first half containing the drug. The flat edges of both the halves are pressed together in order to seal it perfectly. **Dry seal:** Dry seal cachets consists of two halves, the upper half and the lower half. The diameter of the upper half is slightly larger than the lower half. The powdered drug is filled in lower half and upper half is fitted over it. The filled cachets are then sealed in a machine by pressing the two halves, removed and packed in boxes.  	**3M**

		Advantages:- 1) They can made easily because no complicated machinery is required. 2) They disintegrate quickly in the stomach 3) The drug can be easily dispensed in cachets. 4) Large dose of drug can be swallowed by using cachets. **Disadvantages:-** 1) They must be softened before swallowing 2) They are easily damaged 3) They can't protect the enclosed drug from light & moisture 4) The shell of cachets are fragile, so the drug can't be compressed in cachets 5) Not suitable for filling the drug by large scale machinery. 6) They occupy more space than the corresponding sizes of capsules & tablets.	
3	**e)**	**Mention the different methods of removing unwanted hairs.** Following are different methods of removing unwanted hairs- **1) Epilation:** It is mechanical removal of hair by method like plucking, waxing, electrolysis. It is painful & may cause skin damage. Chances of skin secretion can be increased. Contains rosin, Beeswax along with vegetable oil, cooling agent, local anaesthetic & antibacterial agent. **2) Depilation:** It involves chemical breakdown of the hair without injury to skin. They are alkaline reducing agents which cause the hair fiber to swell & produce a cleavage of disulphide or cystein bridges between adjacent polypeptide chains & degrade the hair. **3) Electrolysis:** The method involves the inserting of needle into the hair follicle and hair root is completely destroyed by means of weak D.C. current. The hair is removed permanently. The method is very expensive and time consuming. But once the treatment is given successfully the hair does not grow again.	**(3M=1 mark for each method)**
3	**f)**	**Describe the method for the preparation of mixtures containing indiffusible solids.** **Method for the preparation of mixtures containing indiffusible solids-** **1st Method:- When Tragacanth Powder is used** 1) Finally powder diffusible, indiffusible solid and soluble solids mixed them with tragacanth powder	**(3M= each method 1.5 marks)**

		2) Measure 3/4th of the vehicle triturate it with apportion of it till there is formation of cream. Then add remaining of the vehicle. 3) Examine the contents for foreign particles present filter through muslin cloth. 4) Add any liquid ingredients if present. 5) Transfer the mixture to a measuring cylinder and make up the volume. 6) Transfer to suitable container and label **2nd Method:- Tragacanth mucilage is used when vehicle is water or chloroform water.** 1) Finally powder indiffusible solid and add soluble solids and diffusible solids mixed them 2) Triturate the material with tragacanth mucilage (1/4th of the volume) to form smooth cream. 3) Then gradually dilute with ½ of the vehicle. 4) Examine the contents for foreign particles present filter through muslin cloth. 5) Add any liquid ingredients if present. 6) Transfer the mixture to a measuring cylinder and make up the volume. 7) Transfer to suitable container and label	
4		**Attempt any FOUR of the following.**	
4	**a)**	**Define therapeutic incompatibility. What are the various types and causes of therapeutic incompatibility?** **Therapeutic Incompatibility**:- When the intensity or nature of action drug is different from that intended by prescriber, then such effects are termed as therapeutic incompatibility. **Various types and causes of therapeutic incompatibility-** **1. Error in dosage:-** • It is error in writing or interpreting the prescription order. • The most serious type of dosage error in the dispensing is overdose of a medication. • So it is the duty of a pharmacist to check the prescription before dispensing it. E.g.	**(3M= 1mark def., 2 marks types causes)**

Rx

Atropine sulphate -------0.006gm

Phenobarbitone----------0.015gm

Asprin ----------0.300gm

Prepare 10 capsule

In this prescription, the quantity of atropine sulphate in each capsule is more than its minimum recommended dose of 2mg. So the prescription is referred back to the prescriber to correct the overdose of atropine sulphate.

2. Wrong drug or dosage form:-

- There are certain drugs which have quite similar name & there is always a danger of dispensing of wrong drug.
- For e.g. Prednisone & Prednisolone, Digoxin & Digitoxin
- Sometimes many drugs are available in different dosage forms & hence dosage form should be clearly mentioned on prescription.

3. Contra-indicated drugs:

- There are certain drugs which may be contra-indicated in a particular disease or particular patient who is allergic to it. For e.g. Corticosteroids are contraindicated in patients having an active peptic ulcer.
- Penicillin & sulpha drugs are contra-indicated to the patients who are allergic to it.

4. Synergistic & antagonistic drugs:-

Many drugs exhibit synergism & antagonism when administered in combination.

- Synergism:- When two drugs are prescribed together, they increase the activity of each other. For e.g. a combination of aspirin & paracetamol increases the analgesic activity.
- Antagonism:-When two drugs having the opposing pharmacological effects are prescribed together antagonism occurs. For e.g. Acetyl acetic acid & probenecid are used in the treatment of gout, the combination of these lead to neutralization.

5. Drug interaction:-

- The effect of one drug is altered by prior or simultaneous administration of another drug or any food items & it is corrected by proper adjustment of dosage, or

		appropriate directions. For e.g. Rx Tetracycline HCL---------- 250mg Send 10 capsules. Direction: Take 1 capsule every 6 hours with milk. In this tetracycline is inactivated by calcium which is present in milk. So tetracycline capsule should not be taken with milk. So prescription may by refer back to the physician.	
4	**b)**	**Write a note on dentifrices.** **Definition**- Dentifrices are the preparations meant to be applied to the teeth with a help of tooth brush for the purpose of cleaning the accessible surface of the teeth. **Qualities of good Dentifrices-** 1) It should be economical. 2) It should be non toxic. 3) It should be properly sweetened and flavoured. 4) It should give fresh and clean sensation. 5) It should be efficient in removing food substances, plaque and other foreign particles. 6) It should clean the teeth. **Formulation-** **1. Abrasive agents:** • The abrasive agents such as calcium sulphate, magnesium carbonate, sodium carbonate and sodium chloride are used in fine powder. • A strong abrasive substance should however not to be used as it may damage the tooth structure. **2. Detergents:** • They contain a suitable detergent or soap. • Soap removes the debris from surface of tooth by the mechanism of emulsification	**(3M=1 mark def., 1 mark qualities, 1 mark formulation)**

3. Humectants:

- Humectants are added to prevent the drying of preparation.
- Ex. Glycerin, propylene glycol, etc.

4. Sweeteners:

- Sweeteners are added to change the taste of the formulation and to avoid the bitter taste of the ingredients.
- Ex. Saccharine sodium, sucrose, etc.

5. Colours: Colour is added to improve appearance of preparation to make it attractive.

Ex. Coal tar dyes,

6. Flavours:

- Flavours are added to improve the taste of the formulation.
- Ex. Peppermint oil, cinnamon oil, etc.

4 c) Differentiate between flocculated and non flocculated suspensions. **(3M any 6 points for 3 marks)**

Flocculated suspension	**Non flocculated suspension**
1)Particle form loose aggregates & form network like structure.	1) Particle exist as separate entities
2) The rate of sedimentation is high	2)The rate of sedimentation is slow
3) Sediment is rapidly formed.	3) Sediment is slowly formed
4)Sediment is easy to redisperse	4)Sediment difficult to redisperse
5)Sediment is loosely packed & does not Form a hard cake.	5)Sediment is very closely packed & a hard cake Formed.
6)Supernatant liquid is clear.	6)Supernatant liquid is not clear
7)The floccules stick to the sides of bottle	7)The floccules do not stick to the sides of bottle.
8)Suspension is not pleasing in appearance.	8)Suspension is pleasing in appearance.

4	d)	**Write the various methods and give the formulae for the calculations of doses.** **1) Proportionate to age-** **1. Young's formula:** $\text{Dose for a child} = \frac{\text{Age in years}}{\text{Age in years} + 12} \times \text{Adult dose}$ **2. Dilling's formula:** $\text{Dose for a child} = \frac{\text{Age in years}}{20} \times \text{Adult dose}$ **3. Fried's formula:** $\text{Dose for a child} = \frac{\text{Age in months}}{150} \times \text{Adult dose}$ **2) Proportionate to body weight-** $\text{Dose for a child} = \frac{\text{Weight of the child lb}}{150} \times \text{Adult dose}$ **3) Proportionate to body surface area-** $\text{Dose for a child} = \frac{\text{Surface area of child}}{\text{Surface area of Adult}} \times \text{Adult dose}$ The average body area for an adult is = $1.73m^2$ Hence, $\text{Dose for a child} = \frac{\text{Surface area of child}}{1.73m^2} \times \text{Adult dose}$	**(3M=1 mark for each method)**

4	**e)**	**Describe the tests to differentiate types of emulsions.** **1) Dilution Test -** I. Emulsion diluted with water - i)Emulsion remains stable then it is o/w emulsion ii)Emulsion break it is w/o emulsion II. Emulsion diluted with oil- i)Emulsion remains stable then it is w/o emulsion ii)Emulsion break it is o/w emulsion **2) Dye Test-** I. Emulsion diluted with scarlet red dye – i)Dispersed globules appear red & background is colourless then it is o/w type ii) Dispersed globules appear colourless & back ground is red then it is w/o type. II. Emulsion diluted with amaranth dye – i)Dispersed globules appear red & background is colourless then it is w/o type ii) Dispersed globules appear colourless & back ground is red then it is o/w type. **3) Conductivity Test-** This type of emulsion show bulb glowing on passing electric current. I. If bulb glow the emulsion is o/w type II. If bulb does not glow the emulsion is w/o type **4) Fluorescence Test**: I. If an emulsion on exposure to ultra-violet radiations globules shows continuous fluorescence under UV light, observed under microscope, then it is o/w type II. If it shows only spotty fluorescence, then it is o/w type. **5) Cobalt Chloride Test**: When a cobalt chloride test paper dipped in to an emulsion, if it turns from blue to pink, indicating that the emulsion is o/w type.	**3 M= any 3 tests.**
4	**f)**	**What are pastes? Give its classification.** **Definition:** Paste are semisolid preparation intended for external application to the skin as protective, antiseptic, or soothing dressing. **Types of bases for pastes-** 1) **Paste with gelatin base** -A hot 2% gelatin solution is used which becomes jelly on	**(3M=1 mark def., 2 marks classific**

		cooling, to this 10-15% glycerin is added which act as preservative and emollient and in this solution solid substances are incorporated example Unnas paste 2) **Paste with starch base** (gelatinized or ungelatinised) In case of gelatinized paste 10% starch solution is prepared and gelatinized by heating and then glycerin is added in this solution solid substances are added, in case of ungelatinised paste large portion of starch powder is mixed with other solid ingredients and water to form the paste. 3) **Paste with tragacanth base** also called as Bassorin pastes In this the tragacanth powder is mixed with alcohol and triturated briskly followed by addition of glycerin and water. 4) **Paste with cellulose derivatives**- cellulose are dissolve in cold water and allowed to stand overnight it forms jelly and in this solid substances are incorporated. 5) **Paste with pectin base**- Pectin is triturated with medicament and glycerine followed by addition of salon solution to form paste. 6) **Paste with colloidal base aluminum hydroxide and bentonite** are used as colloidal base. The colloidal base is triturated with solid substances followed by addition of glycerin and water.	**ation)**
Q.5		**Answer any FOUR of the following:**	
Q.5	**a.**	**Define antiperspirants and deodorants. How do they function?** **Antiperspirant:** It prevents the flow of perspiration to overcome bad smell which is due to bacterial decomposition. Antiperspirants contain a substance having **astringent** action on reacting with skin proteins it causes coagulation which is accompanied by swelling at the opening of sweat glands. This blocks opening of sweat gland preventing flow of sweat. Eg. Aluminium chlorohydrate, any marketed preparation students may write. **Deodorant:** Deodorant inhibits the formation of bad odour in perspiration by suppressing the growth of bacteria or masks the unpleasant odour. Eg. Salicyclic acid, boric acid, zinc stearate, talc and starch powder, any marketed	**(3M = 1+1+1)**

		preparation. **How do they function:** They inhibit the flow if perspiration where and deodorants inhibit formation of bad odor in perspiration by suppressing the growth of bacteria or mask the unpleasant odor.	
Q.5	**b.**	**Define ointments. Give its classification with examples.** Ointments are semisolid preparations meant for external application to the skin or mucous membrane. They usually contain a medicament dissolved, suspended or emulsification of ointment Classification of ointment: **1)Therapeutic properties based on penetration** 1. Epidemic ointments 2. Endodermic ointments 3. Diadermic ointments **a) Epidermic ointments:** These ointments are meant for action on epidermis & produce local effect. They are not absorbed. Used for protective, antiseptic, local anti-infective effect. **b) Endodermic ointments**: These are meant for deeper layers of cutaneous tissues. They are partially absorbed & act as emollients, stimulants & local irritants **c) Diadermic ointments** : Meant for deep penetration & release the medicament that pass through the skin & produces systemic effects. **2) Therapeutic uses** 1. Antibiotic ointments 2. Antifungal ointments 3. Anti-inflammatory ointments 4. Antipruritic ointments 5. Astringent ointments 6. Anti-eczematous ointments 7. Keratolytic ointments 8. Counter irritant ointments 9. For Dandruff treatments 10. For Psoriasis 11. Parasiticide ointments 12. Protectant ointments	**3M = 1+2)**

Therapeutic uses

1. Antibiotic ointments :

Used to kill micro organism.

Eg. Bacitracin , neomycin , Chlorotetracycline

2. Antifungal ointments:

inhibit or kill fungi

eg.Benzoic acid, salicylic acid , & nystatin

3. Anti-inflammatory ointments:

Used to relieve anti inflammatory ,allergic , & pruritic conditions of skin.

Eg. Betamethasone valerate, hydrocortisone.

4. Antipruritic ointments

Used to relieve itching

Eg. Benzocain & coal tar.

5. Astringent ointments

Causes contraction of skin & decreases discharge.

Eg. Calamine , zinc oxide, acetic acid & tannic acid.

6. Anti-eczematous ointments

Used to prevent oozing & excrection from vesicles on the skin

Eg Hydro cortisone, coal tar &

7. Keratolytic ointments

Used to remove & soften horny layer of skin

Eg. Resorcinol ,salicylic acid , & sulphur.

8. Counter irritant ointments

Applied locally to irritate the skin , thus reducing or relieving another irritation or deep sited pain.

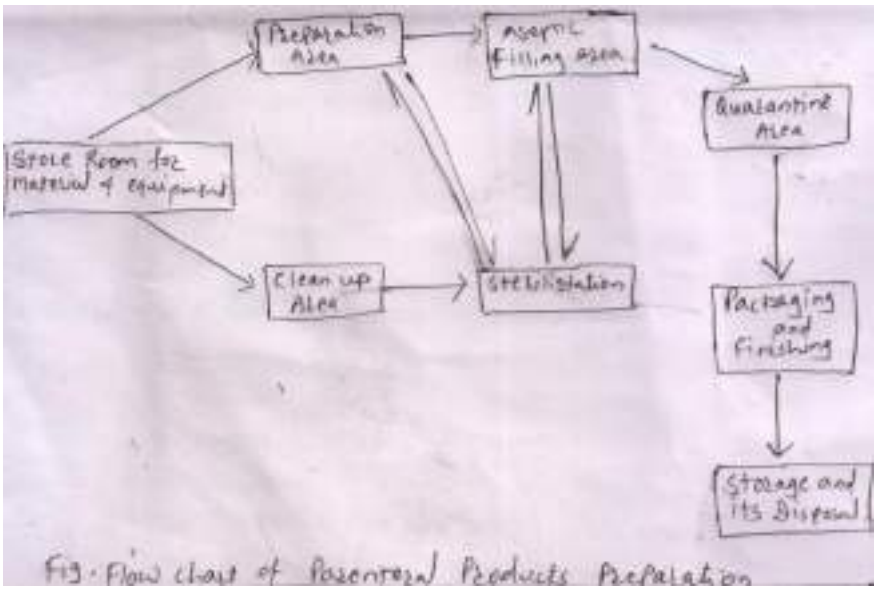
9. For Dandruff treatments

To get relief from dandruff . eg.salicylic acid, cetrimide.

10. For Psoriasis

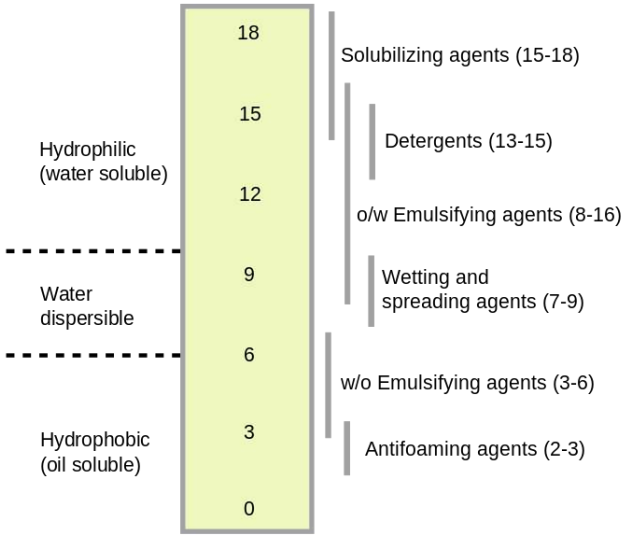
Coal tar ,corticosteroids, dithranol ,& salicylic acid .

11. Parasiticide ointments

		Destroy or inhibit living infestation, such as lice & ticks. Eg.benzyl benzoate, hexachloride , sulphur. 12. Protectant ointments Protect skin from moisture , air, sun rays. Eg. Calamine ,zinc oxide , silicones , titanium dioxide.	
Q.5	**c.**	**Describe the layout of sterile area**  Fig. Flow chart of Parenteral Products Preparation **Clean up area:-**In such area cleaning and steaming of packing materials and utensils is done therefore the walls and ceiling are constructed in such a way, that they withstand the effects of steam and chemicals. Generally, epoxy or vinyl paint is coated to solve the purpose. This area must be kept clean by washing it regularly. Precaution must be taken to prevent the growth of microorganism and collection of dust. **Compounding area:-**It is nothing but a "preparation" area, where the formula is compounded, and not necessarily aseptic. There should be strict control it that these should not catch dust. The cabinets and counters should be of stainless steel. Ceiling wall and floor should be sealed and can be coated with Epoxy paint. Adequate sink and counter space should be provided. **Aseptic Area: -** It is an entirely sealed area from outside atmosphere to keep aseptic environment free from physical and biological contamination. Therefore, at the time of designing and constructing the aseptic area civil work can compose to HVAC (High	**3M= 1M for layout,(0.5x4=2 M for explana tion**

		ventilating and air conditioning) system including the electrical wire fittings and switches. The walls facing outside should have double walled glass partition. Epoxy paints should be used.to prevent wall, ceiling ,and floor from the accumulation of dust and microorganisms The air in the aseptic area should be free from fibers ,,dust and microorganism. This can be achieved by the use of high efficiency particulate air filers (HEPA) which can remove particles upto 0.3 um. HEPA filters are fitted in laminar air flow system in which air free from dust and microorganism flows with uniform velocity.The air is supplied under positive pressure which prevents particulate contamination from sweeping from adjoining areas .Ultraviolet lamps are fitted to maintain sterility. The personnel enter in this area through air lock door. Movement should be minimum and restricted during filling procedure **Quarantine area:-** Approved batches from QC department can be kept here before labelling and packing.It must contain space that separates 'Approved batches' and 'In process batches'.This area is only restricted to a responsible person. **Labelling and packing area:-**Adequate space is required for installation of printing devices and packaging machines In this area, label printing and labelling can be take place. **Storage and its disposal:-** The finished product are stored under specified storage condition and dispensed off.	
Q.5	**d.**	**Report the incompatibility in the following prescription with method to correct it.** **Rx** **Codeine phosphate -0.5 gm** **Prepare 10 powders** **Label-one to be taken at bed time.** **Solution:** Its Therapeutic incompatibility of error in dose. Therapeutic dose of Codeine phosphate is 5mg, prescriber has written 0.5gm which is 500 mg. **method of correction:** Refer back prescription to prescriber for correction of dose	**3M= 2+1)**

Q.5	**e.**	**What are additives employed in the formulation of effervescent granules?Give their functions.** **Additives employed in the formulation of effervescent granules** 1)Sodium bicarbonate : 2) Citric acid. 3)Tartaric acid : 4)Sodium sacchrine: **functions.** 1)Sodium bicarbonate : It reacts with acid when preparation is added to water. The evolved carbon dioxide produce the effervescence 2) Citric acid a)To release water of crystallization & to create conditions for release of more water . b)Partial neutralization of bicarbonate. 3)Tartaric acid : Only for neutralisation 4)Sodium sacchrine: sometime added as sweetning agent.	**3M=1+2)**
Q.5	**f.**	**What is HLB value? Give its importance in formulation of Emulsion.** The HLB scale means (Hydrophilic – Lipophilic Balance) System and has an arbitrary scale of 1-18 HLB numbers are experimentally determined for different emulsifiers in laboratory.	**3M = 1+2)**



Role of HLB in formulation of Emulsion:

HLB scale is useful for calculating balanced mixture of emulsifying agent. It is very difficult to **select proper emulsifying agent** from different emulsifying agent to prepare stable emulsion, therefore sometimes it is necessary to use two or more than two emulsifying agent. No single emulsifying agent possesses all the properties required for preparing stable emulsion.

Q.6		**Answer any FOUR of the following:**	
Q.6	**a.**	**Describe the various types of ingredients used in formulation of shampoo.** **Various additives used in formulation of shampoos** **1)Conditioning Agent:-** used to lubricate the hair & improve the texture of hair & it reduces the fluffiness & make the hair soft & shiny. e.g. Lotion & its derivatives, Glycerin, PG **2)Thickening Agents:-** Use to increase the viscosity of shampoo & provide desired consistency.e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate **3)Solubilizig Agent :-** Used to solubilize poorly soluble subs.e.g. ethyl alcohol, glycerol, PG. **4)Opacifying Agents:-** used to make shampoo opaque. e.g. glycerol, glyceryl stearate, stearyl alcohol. **5) Preservatives:-** used to preserve the shampoo against bacteria or mould. e.g. Methyl	**4M = 1X 4)**

		Paraben, Propyl Paraben**.**	
6	**b.**	**Explain cracking of Emulsions.** The following factors results in the cracking of emulsion. • Decomposition of the emulsifying agent • Addition of a solvent which dissolves both the phases • High temperature and change in pH. • Addition of opposite types of emulgents • Growth of micro – organism • Extensive creaming. **Decomposition of emulsifying agent:** • When acid is added to alkali soap emulsion it causes decomposition of emulsifying agent & thus leading to cracking of emulsion. **Addition of common solvent:** • Addition of common solvent in which both disperse & continuous phase are soluble forms one phase system & destroys the emulsion. • Eg. Turpentine, soft soap & water are soluble in alcohol. **Change in Temperature:** • Increase in temperature leads to reduction in viscosity; encourage creaming thus leads to cracking. Low temperature causes freezing of water content. **Addition of emulsifying agent of opposite type:** • **Soaps of monovalent** metal produces **o/w** emulsion,& Soaps of **divalent metal** produces **w/o** emulsion. But addition of monovalent soap to divalent soap emulsion & vice versa may leads to cracking. **Growth of microorganism:** • Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking. **Extensive creaming:** Extensive creaming leads to cracking.	**4M=1X 4)**

6	c.	**Comment;(any one)** **(i) Total parenteral nutrition** (ii) **Bacterial Endotoxin test for parenteral.** **Definition:** **Total <u>parenteral</u> nutrition** (TPN), is the practice of feeding a person intravenously, bypassing the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. **Need:** o When the gastrointestinal tract is nonfunctional because of an interruption in its continuity or because it's absorptive capacity is impaired. o To treat people suffering the extended consequences of an accident or surgery or digestive disorder. o Needed for children born with non-existent or severely deformed guts. **Requirement:** o Normal calories required for an adult is approximately 2500 kcal /day which can be supported by injecting dextrose 25%. o TPN requires water (30 to 40 mL/kg/day), **energy (30 to 60 kcal/kg/day, depending on energy expenditure)**, amino acids (1 to 2.0 g/kg/day, depending on the degree of catabolism), essential fatty acids, vitamins, and minerals **OR** **Bacterial Endotoxin test for parenteral:** **Bacterial endotoxin test is used for pyrogen testing (LAL test)** • An extract from the blood cells of the horse shoe crab contains enzyme and protein system that coagulates in the presence of low level of lipopolysaccharides. • This discovery led to the development of the limulus ameboytes lysate LAL test for the presence of bacterial endotoxin The advantage of this test is that it is more sensitive test then the rabbit test use for detection of pyrogen. The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polymhemus). The result of the reaction is	**4M**

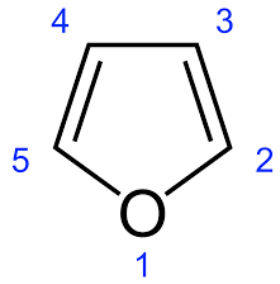
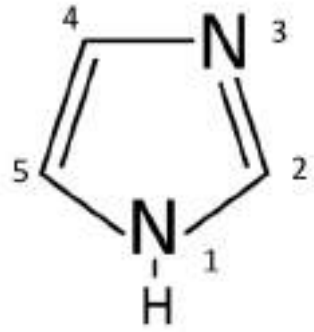
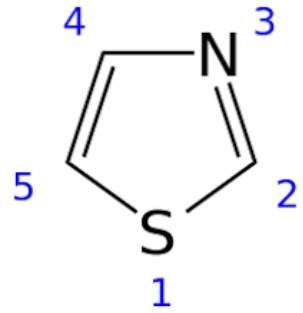
		turbidity or precipitation or gelation of the mixture. This is used as a quantitative measure to estimate the endotoxin content. The rate of reaction depends upon conc. of endotoxins, pH, temperature and presence of clotting enzyme system and clottable proteins from lysate	
6	**d.**	**Describe general method for a preparation of suppositories.** **General method for a preparation of suppositories: (Fusion Method)** 1. Calculate the qualities required taking displacement value into the account. An excess must be made(two extra suppository)because of unavoidable wastage during preparation . 2. Select a dry clean mould & place it on a clean tile. 3. Shred the fat with fine food grater. weigh the required amount , avoiding lumps that would slow to melt. 4. Finely powder the medicaments & pass each through a sieve no 180.Weigh the required quantities. 5. Heat a small tile until it is comfortably warm. 6. Mix the powders on a tile 7. Place the base on the water bath until about 2/3 rd of the content has melted & then remove from the heat. The rest will melt with stirring. 8. Overheating will occur if the base is left over the heat until completely melted. 9. Pour about half of the melted base on mixed medicaments and levigate into smooth dispersion with spatula 10. Transfer the dispersion to dish , stir to form homogeneous mixture. 11. Continue stirring until the mixture begins to thicken Then fill each cavity of the mould to overflowing to prevent depression in the top. stir the mass continuously to prevent sedimentation of insoluble solids. 12. Allow to cool. remove excess from the mould with a sharp knife.	**4M**
6	**e.**	**Describe the various methods for the preparation of syrups.** Method of preparation 1) By simple solution method e.g. simple syrup or ginger syrup Add sucrose to purified water and heat to dissolve sucrose with occasional stirring cool and than add water to make	**4M (any 2 methods)**

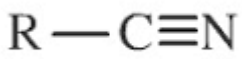
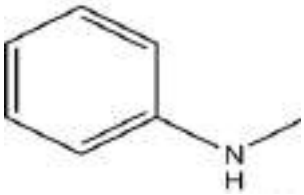
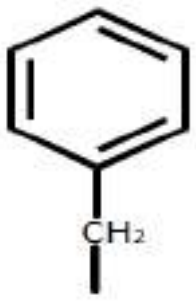
		required weight. 2) By process of extraction e.g tolu syrup Add boiling purified water to tolu balsam, cover the vessel lightly and boil the content for half an hour stirring frequently add purified water to adjust the specific weight ,cool and filter the solution add sucrose and dissolve by add of heat. (3)Syrups made by **chemical reaction** e,g comp syrup of ferrous phosphate In this preparation the reaction takes place between iron wire and phosphoric acid result in formation of ferrous phosphate reaction also takes place between calcium carbonate potassium bicarbonate and phosphoric acid resulting in formation of corresponding phosphate salts after the reaction is complete add sucrose and flavoring agent than adjust the volume with purified water.	
6	**f.**	**Write a note on jellies.** **Jellies**:- Jellies are transparent or translucent non-greasy, semisolid preparation for external application to the skin or mucous membrane. **Classification of Jellies :** **(i)Medicated Jellies**:- these are chiefly used on mucous membrane & skin for their spermicidal, local anaesthetic & antiseptic properties. These jellies contain sufficient water. After evaporation of water, jellies provide a local cooling effect & residual film gives protection. **(ii)Lubricating jellies**:- These are used a lubricating agent for catheters, rubber gloves, thermometers. These jellies should be sterile. (iii)**Miscellaneous jellies**:- These jellies meant for a)Patch testing: These are used as vehicle for allergens during sensitivity testing. b) Electro-cardiography jelly applied on electrode to reduce electrical resistance between patients skin and the electrode. **Formulation of Jellies** Gelling agent: a. Tragacanth b. Sodium alginate c. Pectin	**4M**

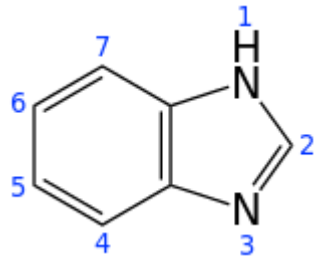
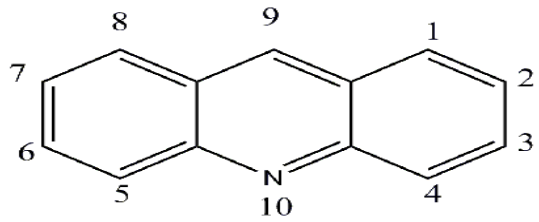
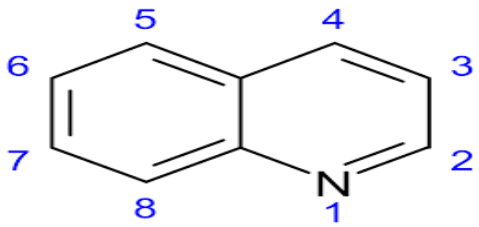
		d. Starch e. Gelatin f. Cellulose derivatives 2. Preservatives: Methyl p-hydroxybensoate (0.1 – 0.2 % w/v), Propyl p- hydroxybensoate (0.5 %), Chlorocresol (0.1 – 0.2 %), Benzoic acid (0.2 %), Benzalkonium chloride (0.005%) **Disadvantages:** 1. Addition of preservative required. 2. Hygroscopic. 3. Prone to growth of microorganism. 4. Overnight soaking of jelly is required while manufacturing. 5. Fluctuation in temperature may change the consistency. **Container & storage:** Jellies are stored in well filled well closed container to prevent evaporation of water. Jellies are stored in cool place to prevent drying out.	

Important Instructions to examiners:

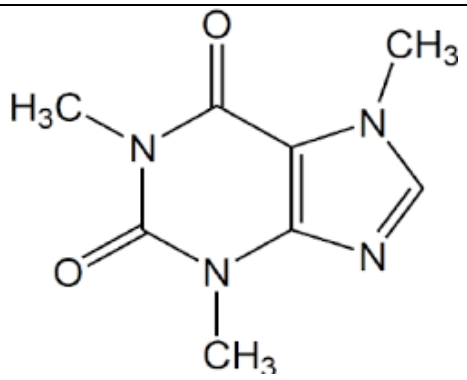
1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling 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.

1		**Attempt any <u>EIGHT</u> of the following:**	**16M (8X2 M)**
1	**a)**	**Give structure and numbering method for (any two):** **i) Furan**  **ii) Imidazole**  **iii) Thiazole** 	**1 M each**

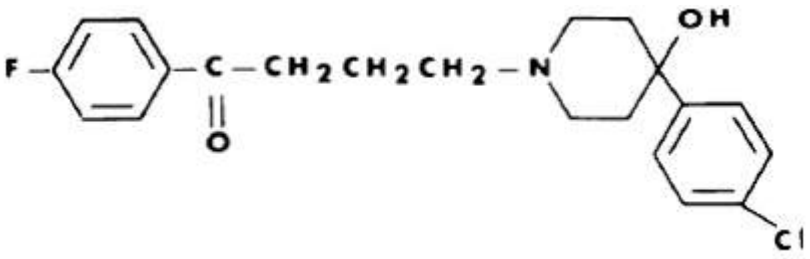
1	b)	**Define following terms (any two):** i) **Diuretics**: Drugs which promote excretion of water & electrolytes from body through kidneys in the form of urine are called diuretics. ii) **Antineoplastics:** Antineoplastic agents, also known as cytotoxic agents and are used in the treatment of malignant diseases when surgery or radiotherapy is not possible or has proved ineffective, in other words, the agents used in the treatment of neoplasm/cancer are called antineoplastic agents. **ii) Anti-coagulants:** Anticoagulants are the substances that prevent coagulation of blood or prolong the coagulation time. They are used to prevent thrombosis.	**1 M each**
1	c)	**Give the structure of following organic group (any two):** i) **Cyano**  **ii) Aniline**  **iii) Benzyl** 	**1 M each**

1	d)	**Give the structure and numbering method for following (any two):** **i) Benzimidazole**  **ii) Acridine**  **iii) Quinoline** 	**1 M each**
1	e)	**Give the uses of (any two):** **i) Paracetamol:** 1. Antipyretic. 2. Analgesics for relief of pain such as headache, toothache, neuralgia. **ii) Proflavin:** 1. It is slow acting antiseptic. 2. It is effective against many gram positive and gram negative bacteria. 3. It is used in treatment of infected wounds, dressing of wounds and burns. 4. Also used for local infection of external ear, mouth, throat and skin **ii) 5-fluorouracil:**It is cytotoxic agent. It is used :	**1 M each**

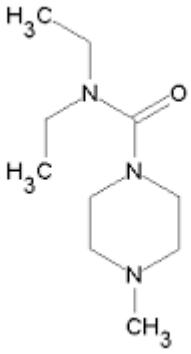
		1. Alone or in conjuction with radiotherapy, in palliative treatment of neoplasm of gastro-intestinal tract, breast and pancreas and respiratory tract. 2. To treat solar keratoses and other malignant conditions of skin.	
1	**f)**	**Give the stability – storage condition of (any two):** i) **Heparin**: The aqueous solution is stable for at least 7 years at pH 7 to 8.It is stored in sealed, sterile container so as to exclude microorganism and moisture. ii) **Insulin**: As insulin is affected by heat & light, all insulin preparations must be stored at low temperatures between 2-8°C. It should not be allowed to freeze. iii) **Thrombin**: It is affected by air, heat and light. Storage condition it is stored in the atmosphere of nitrogen, in glass containers which are sealed so as to exclude microorganisms and moisture. The containers are kept at a temperature between 2° and 8° C and are protected from light. It may contain suitable bactericide.	**1 M each**
1	**g)**	**Give the brand names of (any two):** i) **Phenformin** : Sucronase, Bislim, Diaformin ii) **Tetracyclin**: Achromycin, Enterocyclin, Cadicyclin iii) **Aspirin**: Aspro, Anacin, Coldarin, Powerin, Mejorol, codopyrin	**1 M each**
1	**h)**	**Give the names of two drugs from the following categories (any two):** i) **Antiseptic and Disinfectants**: Phenol, Chlorocresol. Chloroxylenol, Hexachlorophene, Alcohol, Formaldehyde, Chloramine T, Povidone iodine, , Thiomersal, Brilliant green, Proflavine, Crystal Violet (gentian violet), Benzalkonium chloride, Cetrimide, ichthamol, Nitrofurazone ii) **Antihypertensives**: α-methyldopa, clonidine, Pentolinium, Reserpine, Guanethidine, Propranalol, Atenolol, Prazosin, Tolazoline, Hydralazine, Minoxidil, Verapamil, Captopril, enalapril, losartan, Nifedipin iii) **Antihistaminic**: Diphenhydramine, mepyramine, pheniramine, chlorpheniramine, triprolidine, promethazine, meclzine, cyproheptadine	**1 M each (for 2 correct names)**
1	**i)**	**Draw the structure of following (any two):** i) **Caffeine**:	**1 M each**

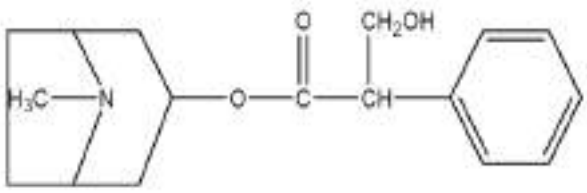


ii) **Haloperidol**:



iii)**DEC**:



1	**j)**	**Give structure and uses of (any one):** **i) Atropine:**  **Uses**: 1. By acting on CNS a) To treat parkinsonism	**1 M for stru.** **1 M for uses**

b) In small doses it is CNS stimulant

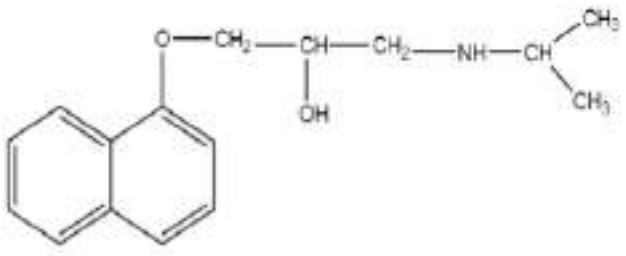
3. Due to antimuscarinic activity

a) As a mydriatic in ophthalmology

b) As an antispasmodic to treat renal and biliary colic and bronchial asthama

4. For anaesthetic premedication
5. To treat sialorrhoea(excessive secretion of saliva)
6. To treat acute rhinitis, hay fever
7. To treat organophosphorus compound poisoning
8. For gastric and duodenal ulcer
9. With morphine it is used to lower respiratory depression
10. In small doses to prevent excessive peristalsis and colic pain produced by irritant purgatives

ii) Propranolol:



Uses: It is used to treat: cardiac arrhythmia, auricular fibrilation, angina pectoris, arterial hypertention, hyperthyroidism in children and symptoms of anxiety

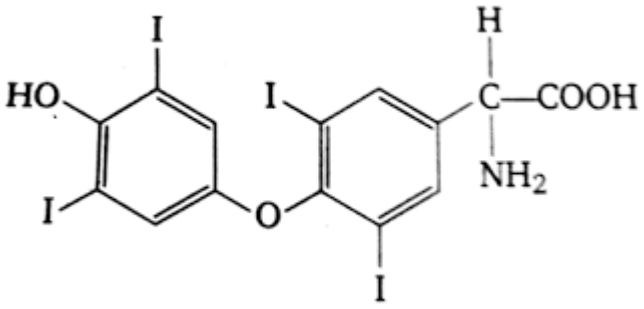
1	k)	**Define vitamins. Write the importance of vitamin A.**	**1 M for def** **1 M for importance**

- **Definition:** Vitamins may be defined as potent organic substances which are essential for normal growth and maintenance of life of human and animals, which are not able to synthesize in adequate quantity
- **Importance of vitamin A:**

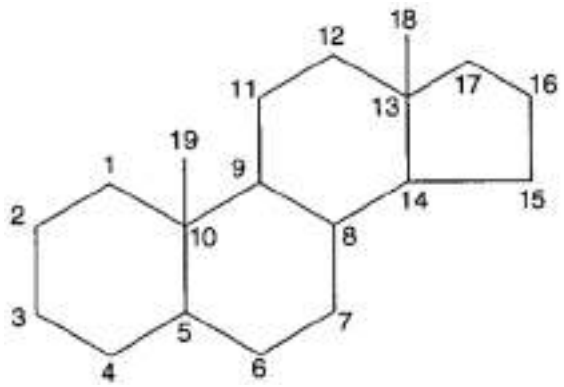
1. It is used for treating vitamin A deficiency.
2. Prevention and treatment of Night blindness, Xerophthalmia and keratomalacia.
3. Vitamin A is important for growth, development and maintenance of immune system.
4. Some people use vitamin A for improving vision and treating eye disorders including age-

		related macular degeneration (AMD), glaucoma and cataracts. 5. Vitamin A is also used for skin conditions including acne, eczema, psoriasis, cold sores, wounds, burns, sunburn.	
1	**l)**	**Write uses of (any two):** **i) Evan's blue:** • Evans Blue is a di-azo compound used to determine blood volume in humans and animals. • The dye combines firmly with plasma albumin when injected into the blood stream and leaves the circulation very slowly. **ii) Congo red:** • It is employed as a diagnostic aid in amyloidosis (In medicin a variety of conditions in which amyloid proteins are abnormally deposited in tissues) • It is used in laboratory as indicator **iii) Indigocarmine:** • It is administered intravenously to test renal function (by estimating the rate of excretion of urine) & to locate the ureteral orifices during ureteral catheterisation and cystoscopy. • In the lab it is used as indicator.	**1 M each**
2		**Attempt any <u>FOUR</u> of the following:**	**12M (4x3 M)**
2	**a)**	**What is co-trimoxazole? Explain mechanism of action and give two brand names of Co-trimoxazole.** • Cotrimoxazole is the combination of two drugs i.e. Sulphamethoxazole and Trimethoprim in a proportion of 5:1. • Mechanism of action: Sulphonamides block the biosynthesis of folic acid from p-amino benzoic acid. Trimethoprim inhibits the enzyme folate reductase and blocks the conversion of	**1M** **1 M**

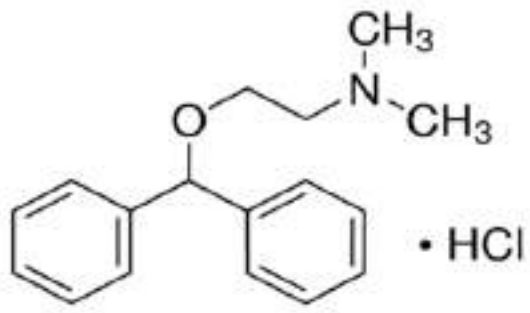
		folic acid to tetrahydofolic acid (THF). THF is the form required for coenzyme synthesis. Combination of Sulphamethoxazole and Trimethoprim by synergism produces bactericidal effect. • Brand names: Septran, bactrim, ciplin, uritrim, septabid, sepmax	**1 M**
2	**b)**	**Define "neoplasm" and classify antineoplastic agents.** **Neoplasm:** Neoplasm is the medical term for cancer or tumour which means a relatively autonomous growth of tissues. **Classification:** 1. Alkylating Agents. a) Nitrogen mustard drugs: Mustine, Chormabucil, cyclophosphamide b) Aziridines: Thiotepa c) Alkyl sulphonate: Busulphan d) Nitrosourea group compound: Lomustine 2) Antimetabolites: Methotrexate, Mercaptopurine, Azathioprine, Fluorouracil 3) Antibiotics: Actinomycin, Daunorubicin, Doxorubicin 4) Plant Products: Sulphates of vinblastin and vincristine. 5) Hormones and related drugs: Glucocorticoids, Tamoxifen 6) Miscellaneous agents: Hydroxyurea, cisplat	**1 M** **2 M**
2	**c)**	**Explain diabetes mellitus. Classify hypoglycaemic agents with examples.** Diabetes Mellitus: - Diabetes Mellitus is a condition characterized by hyperglycemia (excessive sugar in blood, than the threshold value) & glycosuria (presence of sugar in urine).The disease is caused by deficiency of insulin, a protein hormone secreted by beta cells of islets of Langerhans, responsible for proper carbohydrate metabolism.	**1M** **2 M**

		Classification 1. Parenteral hypoglycemics agents (Insulin) a) Short acting- Neutral Insulin b) Intermediate acting- Isophane (NPH) Insulin, Lente Insulin c) Longer acting- Ultralente Insulin 2. Oral hypoglycemic agents a) Sulphonylureas- Tolbutamide, Chlorpropamide, , libenclamide b) Biguanides- Phenformin, Metformin c) Thiazolidinediones (TZDs)- Rosiglitazone, Pioglitazone d) Alpha glucosidase inhibitors- Acarbose, Miglitol, Voglibose	
2	**d)**	**Give structure properties and uses of 'Thyroxin'.** **Srtucture**  **Properties:** • It is light yellow to buff coloured powder which is odourless and tasteless • It is slightly soluble in water and in alcohol and soluble in solutions of alkali hydroxide and carbonates. **Uses: -** 1. To treat Hypothyroidism. 2. To suppress Goitre. 3. To treat cretinism 4. To treat thyrotoxicosis.	**1 M each**
2	**e)**	**Name the drug used in (any three):** i) **Myasthenia gravis** : Neostigmine, Physostigmine, Pyridostigmine ii) **Leprosy:** Dapsone, solapsone, thiacetazone, clofazimine, thiambutosin, sulphadoxine,	**1 M each (for 2**

		rifampicin, kannamycin iii) **Gout:** Diclofenac, Ibuprofen, Naproxen, Celecoxib, Allopurinol, Colchicine iv) **Tuberculosis:** Isoniazide, ethambutol, pyrazinamide, rifampicin, PAS, streptomycin, cycloserin v) **Parkinsonism:** Atropine, Levodopa-carbidopa, Benserazide, Amantadine,, Bromocriptine, Trihexyphenidyl(Benzhexol), Biperiden, selegiline,	**correct drugs)**
2	**f)**	**Define Cholinergic drugs. Write the uses of Pilocarpine and Physostigmine.** **Definition:** The agents that mimic the action of acetylcholine or produce the effect of parasympathetic nerve stimulation are called as cholinergic agents or parasympathomimetic agents. **Uses:** • Pilocarpine 1. Used in solutions of 1 to 5% as miotic to constrict pupil. 2. Decreases intraocular pressure in glaucoma 3. Used to counteract effects of short acting mydriatic on the eye 4. For diagnosis of Adie's pupil 5. For accommodation of near vision of eye. 6. To counteract anticholinergic side effects(dryness of mouth, constipation and impaired vision) • Physostigmine: 1. Used as miotic 2. Decreases intraocular pressure in glaucoma. 3. Used for reversal of post-operative over sedation 4. Used for the treatment of poisoning due to anticholinergic and Tricyclic antidepressants 5. To treat some psychiatric and neurological disorders(e.g. Alzheimer's disease)	**1 M** **1 M** **1M**
3		**Attempt any <u>FOUR</u> of the following:**	**12M (4x3 M)**
3	**a)**	**Define sedative and hypnotics. Classify them.** **Definition**-Hypnotics are drugs which induce sleep by depression of central nervous system function, while sedatives are the agents which reduce excitement & motor activity, & produce a	**1 M**

		calming effect without inducing sleep. Thus, small doses of hypnotics may act as a sedative, while large doses act as hypnotic agent. **Classification:** 1. Barbiturates – These drugs contains barbituric acid nucleus in the structure and depending upon duration of action sub classified as follows : a) Long acting barbiturates – (6 hrs or more) e.g. Barbitone, phenobarbitone b) Intermediate acting barbiturates – (3 to 6 hrs) e.g. Butobarbitone c) Short acting barbiturates- (less than 3 hrs) e.g. Cyclobarbitone d) Ultrashort acting (intravenous) barbiturates – (1/2 to 1 hr) E.g. Methohexitone sodium, thiopentone sodium 2. Non-barbiturates. They are as follows below:- a) Benzo 1,4, diazepine derivative e.g. Diazepam, Nitrazepam b) Piperidin-2,6 dione deravitive e.g. Glutethimide, Methyprylone c) Quinazolinones e.g. Methaqulone d) Alcohol and their derivatives e.g. Triclofos sodium e) Aldehyde and its derivatives e.g. Paraldehyde f) Acyclic nitrogen containing compound e.g. Meprobamate g) Miscellaneous e.g. Diphenhydramine hydrochloride, promethazine	**2 M**
3	**b)**	**Draw the structure of steroidal nucleus with numbering. Write uses of testosterone.**  **Uses of testosterone:-** • Testosterone as well as other androgenic compounds finds use in the male for replacement in	**1 M each**

		hypogonadism, eunuchoidism & the male climacteric. • They also find use in the treatment of gynaecomastia. • They also find use in the treatment of disseminated breast cancer in postmenopausal women. • Testosterone in the form of esters are used in the form of an oily injection & administered intramuscularly subcutaneously.	
3	**c)**	**Define "Cardiovascular agent". Classify them based on their therapeutic uses with examples.** **Definition** • Cardiovascular agents include various types of drugs having an action on the heart or on other parts of the vascular system and they have the ability to alter cardiovascular function. **OR** • Cardiovascular Agents represents a group of drugs which have direct action on the heart or other parts of the vascular system so that they modify the total output to the heart or the distribution of blood to certain parts of the circulatory system. **Classification of cardiovascular agents:-** Different kinds of drugs fall under this category like: 1) Cardiotonics (Positive cardiac inotropic agents):- e.g. Cardiac glycosides obtained from Digitalis, Stropanthus, squill such as Digoxin, Digitoxin, Lanatoside C etc. 2) Antiarrhythmic drugs:- a) Membrane-stabilizing agents (Na channel blockers):- e.g. Quinidine, Procainamide, Disopyramide, Phenytoin, lignocaine hydrochloride etc. b) Drug causing β-adrenergic blockade e.g. propranalol and others. c) Drug that prolong the duration of cardiac action potential e.g.Amiodarone d) Calcium channel blockers: e.g. verapamil 3) Antianginal agents:- a) Organic nitrates e.g. Amyl nitrate, Isosorbid nitrate b) Calcium-channel blockers e.g. Verapamil c) β-adrenergic blockers e.g. Propranolol 4) Anti-hypertensive:- a) Centrally acting agents: e.g. α-methyldopa, clonidine b) Ganglion blockers : e.g. Pentolinium, Mecamylamine	**1M** **2 M**

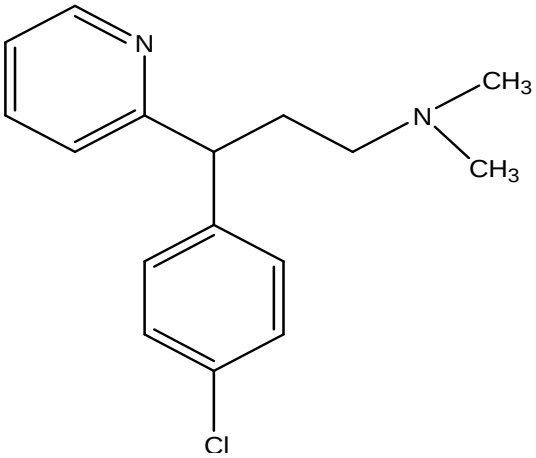
		c) Adrenergic neuron blockers e.g. Reserpine, Guanethidine d) β-adrenergic blockers e.g. Propranalol, Atenolol e) α-adrenergic blockers e.g. Prazosin, Tolazoline f) Direct-acting vasodilators e.g. Hydralazine, Minoxidil g) Calcium channel blockers eg. Verapamil h) Angiotensin converting enzyme inhibitors (ACE inhibitors) e.g. Captopril 5) Antihyperlipidemic agents: (lipid lowering agents) e.g Clofibrate, Nicotinic acid 6) AntithromboticS. eg. Urokinase 7) Anticoagulants eg. Heparin 8) Antiplatelet drugs eg. Aspirin 9) Diuretics (used as adjuvant to antihypertensive therapy) eg. Thiazides, Furosemide	
3	**d)**	**What is Histamine? Give structure and uses of any antihistaminic agent.** • Histamine is a biogenic amine involved in local immune responses as well as regulating physiological function in the gut and acting as a neurotransmitter. • Histamine triggers the inflammatory response. As part of an immune response to foreign pathogens, histamine is produced by basophils and by mast cells found in nearby connective tissues. • Histamine increases the permeability of the capillaries to white blood cells and other proteins, in order to allow them to engage foreign invaders in the affected tissues. • It is found in virtually all animal body cells. **Diphenhydramine hydrochloride:-**  **Uses of diphenhydramine:-** • Diphenhydramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the	**1 M each**

common cold.

- These symptoms include rash, itching, watery eyes, itchy eyes/nose/throat, cough, runny nose, and sneezing.
- It is also used to prevent and treat nausea, vomiting and dizziness caused by motion sickness.
- Diphenhydramine can also be used to help you relax and fall asleep.

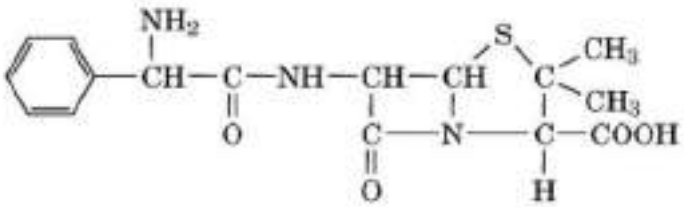
OR

Chlorpheniramine:-



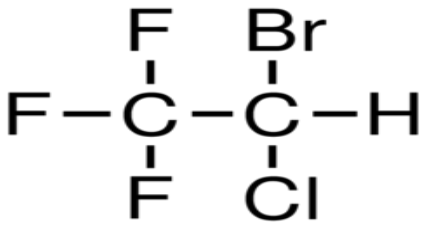
Uses of Chlorpheniramine:-

- Chlorpheniramine is an antihistamine that reduces the effects of natural chemical histamine in the body.
- Histamine can produce symptoms of sneezing, itching, watery eyes, and runny nose.
- Chlorpheniramine is used to treat runny nose, sneezing, itching, and watery eyes caused by allergies, the common cold, or the flu.

3	e)	**Give the structure and uses of (any two):** **(i) Ampicillin- Structure** 	**1 M** **str.** **0.5 M** **uses**

Uses- Generally indicated for a number of bacterial infections including shigellosis (dysentery), gonorrhoea, meningitis, Escherichia coli, Streptococcal and Staphylococcal infections.

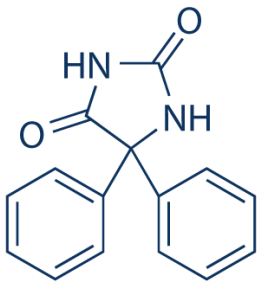
(ii) Halothane- Structure



Uses-

- It is the most potent anaesthetic & is administered by inhalation.
- Induction of anaesthesia by halothane is smooth & rapid, & does not cause irritation to the mucous membrane.

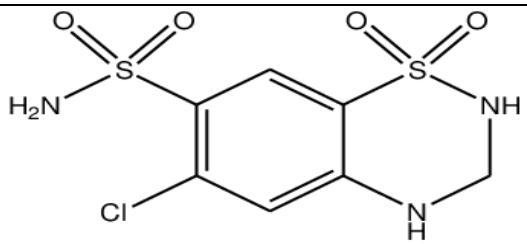
(iii) Phenytoin- Structure



Uses-

- It is used in symptomatic therapy of epilepsy.
- It is the drug of choice in preventing major convulsive seizures.
- It is also used in cardiac arrhythmias.

(iv) Hydrochlorthiazide- Structure



Uses-

- Hydrochlorothiazide is a thiazide diuretic that helps prevent your body from absorbing too much salt, which can cause fluid retention.
- Hydrochlorothiazide is used to treat high blood pressure (hypertension).
- Hydrochlorothiazide is also used to treat fluid retention (edema) in people with congestive heart failure, cirrhosis of the liver, or kidney disorders, or edema caused by taking steroids or estrogen.

3 f) Define and classify diuretics with examples.

Definition-Drugs which promote excretion of water & electrolytes from body through kidneys in the form of urine are called diuretics. **1 M**

Classification of diuretics **2 M**

1. Water & Osmotic agents-
   a) Electrolytes:-Sodium & Potassium salts
   b) Non electrolytes:- Mannitol, Urea
2. Organic mercurials:- Mersalyl acid,Mercaptomerin
3. Acidifying agents:-Ammonium chloride, Arginine hydrochloride
4. Alpha-beta unsaturated ketones:- Ethacrynic acid (High ceiling diuretic, loop diuretic)
5. Purines & related compound: Caffeine
6. Sulphonamides:-
   a) Carbonic anhydrase inhibitors-e.g. Acetazolamide
   b) Benzothidiazines (Thiazides): - Chlorthiazide, Hydrochlorothiazide
   c) Sulphamoyl benzoic acid derivatives e.g. Furosemide (High ceiling diuretic, loop diuretic)

		7. Endocrine antagonists: (aldosterone antagonists) e.g. Spironolactone 8. Miscellaneous agents: - Triamterene, Amiloride (Potassium sparing diuretic)	
4		**Attempt any <u>FOUR</u> of the following:**	**12M (4X3 M)**
4	**a)**	**Define and classify Antimalarial agents.** **Definition-**Antimalarial drugs are intended to treat and prevent malaria by killing the parasite in the liver or the bloodstream. **Classification-** • Quinine salts E.g. Quinine sulphate, Quinine phosphate, Quinine dihydrochloride. • 8-Aminoquinolines E.g. Pamaquine, Primaquine. • 4-Aminoquinolines E.g. Chloroquine , Amodiaquine. • 9-Aminoacridines E.g. Mepacrine. • Biguanides E.g. Proguanil. • Diaminopyrimidines. E.g. Pyrimethamine. • Artemisinin & its derivatives • Miscellaneous: - They are further classified as mentioned below a) Sulfones & sulfonamides Examples are sulphamethoxypyridazine, sulphadimethoxine, sulfadoxine, sulfalene, sulfadiazine, sulfisoxazole & dapsone b) Antibiotics c) Various vaccines d) Insecticides	**1 M** **2 M**
4	**b)**	**Define the term Cardiotonic. Write about their hydrolysis products.** **Definition-** Cardiotonics are the agents which have a stimulating action on cardiac muscles. They increase the force of contraction of heart (positive inotropic action) without increasing the oxygen consumption. They are used in the treatment of congestive cardiac failure (CCF). • These glycosides on hydrolysis, yield corresponding aglycones and sugars. The cardiac activity of these glycosides resides in the aglycone moiety whereas the sugar residue provides favourable solubility and distribution characteristics. Digitoxin, Digoxin are some of the	**1 M** **2 M**

examples of cardiac glycosides.

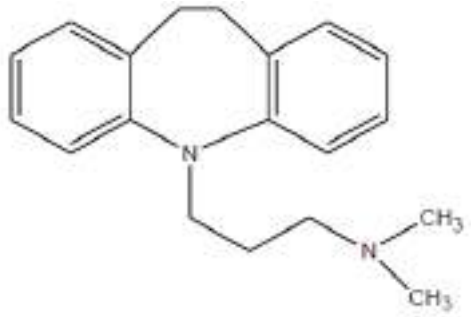
- The hydrolysis products of these are as follows:

Cardiac glycoside	Sugar moiety	Aglycone moiety
Digitoxin	3 molecules of Digitoxose	Digitoxigenin
Digoxin	3 molecules of Digitoxose	Digoxigenin
Lanatoside C	(i) two molecules of Digitoxose (ii) one molecules of acetyl digitoxose (iii) one molecule of D-glucose	Digoxigenin

4 c) Define Thymoleptics/Antidepressant. Give structure and uses of imipramine. **1 M each**

Definition- Antidepressants are drugs which counteract or overcome mental depression. These drugs are therapeutically useful in a variety of cases pertaining to mentally ill patients.

Structure-



Uses-

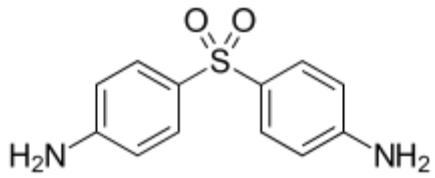
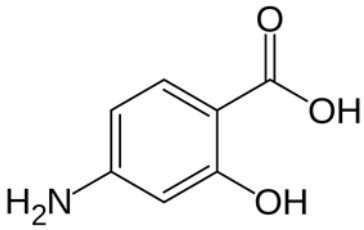
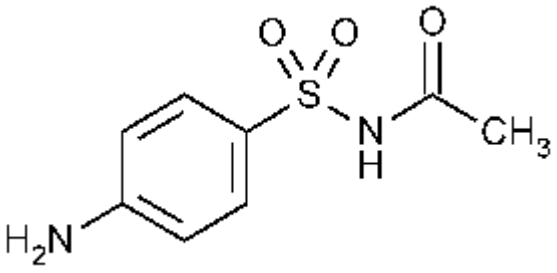
1**.** Imipramine is a tricyclic antidepressant.

2. Imipramine affects chemicals in the brain that may be unbalanced in people with depression.

3. Imipramine is used to treat symptoms of depression.

4. Imipramine is sometimes used to treat bed-wetting in children ages 6 and older.

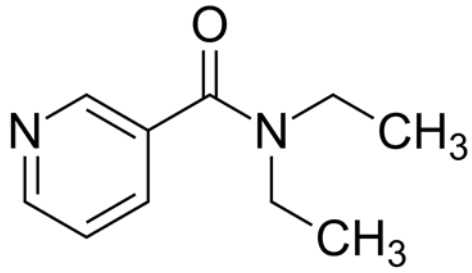
4 d) Give the structure, chemical name and uses of Dapsone. **1 M**

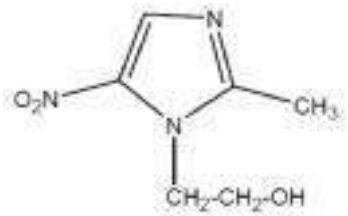
		Structure-  **Chemical name- bis (4-aminophenyl) sulphone or 4,4'-diamino, diphenyl sulphone** **Uses-** • Dapsone (diamino-diphenyl sulfone) is a pharmacological medication most commonly used in combination with rifampicin and clofazimine as multidrug therapy (MDT) for the treatment of *Mycobacterium leprae* infections (leprosy). • Dapsone is used in combination with pyrimethamine in the treatment of malaria.	**each**
4	**e)**	**Draw the structure from the chemical name and name the drugs:** **(i) 4 amino 2 hydroxy benzoic acid-** para amino salicylic acid(PAS)  **(ii) Ni-acetyl Sulfanilamide-** Sulfacetamide 	**1.5 M** **each**
4	**f)**	**Define CNS stimulants. Discuss their uses and draw structure of Coramine.** **Definition-** Are drugs that increase activity in certain areas or the whole of the brain. Also known as "analeptics".	**1 M** **each**

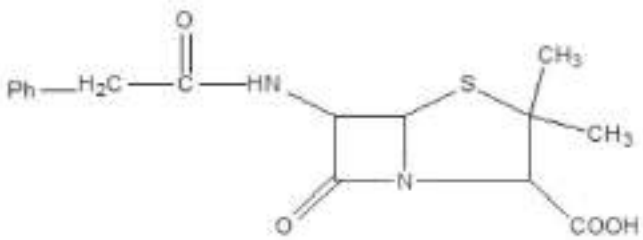
Uses-Can have a number of therapeutic uses:-

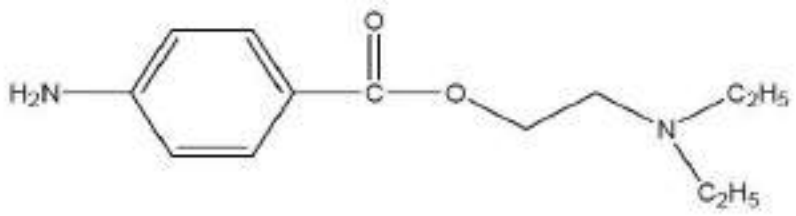
- These drugs are used to improve wakefulness in patients that have narcolepsy.
- Useful as respiratory stimulants & this action is brought about through chemo receptors & the vasomotor centre.
- Some of them also have "anorexient" effects.

Structure of Coramine

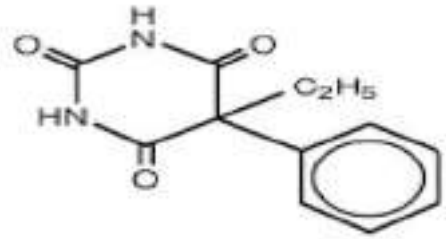


5		**Attempt any <u>FOUR</u> of the following**	**12M (4X3 M)**
5	**a)**	**What is amoebiasis? Write structure and uses of metronidazole.** **Amoebiasis:** Amoebiasis is a parasitic infection of the intestines caused by the protozoan *Entamoeba histolytica.* The symptoms of amoebiasis include abdominal pain, passage of soft stools with mucus & occasional blood, fatigue, excessive gas, rectal pain, unintentional weight loss etc. **Structure of Metronidazole:**  **Uses:** 1. It has antiprotozoal and antibacterial action 2. It is used in the treatment of severe intestinal amoebiasis 3. It is active against anaerobic bacteria like streptococci and H-Pylori 4. It is a primary drug in the treatment of hepatic amoebiasis. 5. Treatment of *Trichomonous vaginalis*, infection due to *entamoeba histolytica*, *giardia lamblia* etc.	**1 M Each**

5	b)	**Define & classify general Anaesthetics based on their route of administration.** **Definition**: General anaesthetics are the central nervous system depressant drugs which bring about loss of all modalities of sensations along with a reversible loss of consciousness. **Classification:** 1) Inhalation anaesthetics: which include the liquids of volatile nature and gaseous substances used by inhalation to produce anaesthesia. These may be sub-classified as follows: i. Volatile liquids: a) Halogenated hydrocarbons: e.g. Chloroform, Halothane, Trichloroethylene, Ethylchloride b) Ethers : e.g. Diethyl ether, Vinyl ether ii. Gases: e.g. Cyclopropane, Nitrous oxide 2) Intraveneous anaesthetics:- i. Barbiturates: Ultra short acting barbiturates such as Methohexitone, Thiopentone sodium ii. Non-barbituates: a) Eugenol derivatives. e.g. Propanidid b) Phencyclidine derivatives. e.g Ketamine c) Steroids. e.g. Althesin d) Miscellaneous. E.g. Etomidate, Propofol.	**1 M** **2 M**
5	c)	**Define antibiotics. Give structure preparation and uses of Benzyl Penicillin.** **Definition**: Antibiotics are chemical substances produced by certain species of microorganisms during their growth on suitable culture media and having the property of inhibiting the growth of or destroying other microorganisms in high dilutions or low concentration. **Structure:**  **Preparation:**	**1 M** **1 M**

		1. Benzyl penicillin injection 2. Benzyl penicillin sodium injection **Uses:** It is used in the treatment of following diseases: 1) Respiratory tract infection 2) Urinary tract infection 3) Gonorrhea 4) Meningitis 5) Enteric infection 6) Septicemia.	**0.5 M** **0.5 M**
5	**d)**	**Define local anaesthetics? Write structure and chemical name of procaine hydrochloride.** **Definition:** Local anesthetics are drugs which produce insensitivity in a limited area around the site of application or injection of the drug by preventing generation and conduction of impulses along nerve fibres and nerve ending and the effects are reversible. **Structure of procaine**  **Chemical name –** 4-amino-(2-diethyl amino ethyl) benzoate or 2-(Diethyl amino) ethyl-4-amino benzoate.	**1 M Each**
5	**e)**	**What are anti-hypelipidemic agents? Give properties and brand names of clofibrate.** **Anti-hypelipidemic agents:** Hyperlipidemia is the most prevalent indicator for susceptibility to atherosclerotic heart disease & it also describes elevated plasma levels of lipids that are usually in the form of lipoproteins. Drugs which are used to reduce the elevated levels of the lipids in the blood are called anti-hypelipidemic agents. **Properties:** 1. It is a stable, clear, and colorless to pale yellow liquid with a characteristic faintly acrid odor.	**1 M Each**

		2. It is very slightly soluble in water; miscible with alcohol, chloroform & ether. **Brand names:** Clobibram, Clofinit, Claripe, Abitrate, Atromid, Amotril, Lipamid,	
5	**f)**	**Name the respective vitamins of which nutritional deficiency leads to;** **i. Beri-beri:** Vitamin B1/ Thiamine **ii. Rickets:** Vitamin D **iii. Scurvy:** Vitamin-C	**1 M Each**
6		**Attempt any <u>FOUR</u> of the following**	**16M (4X4 M)**
6	**a)**	**What is epilepsy? Classify anti consultants with examples?** **Epilepsy:** It is defined as paroxysmal (sudden), self-sustaining and self-limiting cerebral dysrhythmia. It is characterized by an abnormal and excessive neuronal discharge and by disturbance of consciousness. It is proposed that seizures were caused by sudden, occasional, rapid, excessive, local electrical (nervous) discharges which originate in grey matter &spread to other parts of CNS. Epilepsy may or may not be associated with body movements or hyperactivity of ANS. Convulsive states have been observed in systems where concentration of GABA (Gamma Amino Butyric Acid) in brain is below certain level or the effect of GABA is blocked. **Classification:** 1) Barbiturates: e.g.:Phenobarbitone, Mephobarbitone. 2) Hydantoin Derivatives: e.g.: Phenytoin ,Methoin , Ethotoin 3) Succinimides : e.g.: Ethosuccimide, Phensuccimide 4) Oxazolidine 2, 4 diones e.g. Trimethadione ,Paramethadione. 5) Glutarimides e.g. Amino glutethimide 6) Acyl ureides/acylureas e.g. Phenacemide. 7) Benzodiazepine derivatives e.g. Diazepam, Clonazepam, Nitrazepam 8) Dibenzazepines e.g. carbamazepine 9) Hexahydrapyrimide 4,6 dione e.g. Primidone 10) Carboxylic acids e.g. Sodium Valproate	**1 M** **3 M**

		11) Sulphonamides e.g. Acetazolamide	
6	**b)**	**Classify antibiotics with examples.** **Classification:** I. β-Lactam antibiotics: e.g. Benzyl Penicillin, Phenoxymethyl penicillin, Cephaloridine, cephalothin II. Non-β-Lactam antibiotics: 1. Tetracyclines: e.g chlortetracycline, oxytetracycline. 2. Aminoglycoside antibiotics : e.g: Streptomycin, neomycin, gentamicin 3. Macrolide antibiotics : e.g : Erythromicin 4. Ansamycins : e.g: Rifamycin 5. Polyene macrolide antibiotics: e.g: Nystatin, Hamycin 6. Anthracycline antibiotics : e.g :actinomycin, daunorubicin 7. Peptide antibiotics: e.g: Bacitracin. 8. Steroidal antibiotics : e.g : Fusidic acid 9. Nucleoside anitibiotics: e.g : Puromycin 10. Non- classifiable antibiotics : e.g : Chloramphenicol	
6	**c)**	**Give structure, properties, uses and brand names of Phenobarbitone.** **Phenobarbitone:**  **Properties:** 1. It is white, crystalline, odorless solid. 2. It has bitter taste. 3. It is soluble in water and alcohol, slightly soluble in chloroform and solution of alkali hydroxide and carbonates. 4. It may exhibit polymorphism.	**1 M Each**

		Uses: 1. It is used as antiepileptic agent to control tonic-clonic seizures. 2. It is also have been used as a hypnotic and sedative. **Brand names:** Luminal, Gardenal, Pheno, Phenoson, Barbit, Berdinal	
6	**d)**	**Give uses & preparation (any two)** **i. Chloramphenicol** **Uses:** 1. It was used in the treatment of typhoid. 2. It may be used as a second-line agent in the treatment of tetracycline-resistant cholera. 3. It is also useful in the treatment of brain abscesses. 4. It is also applied locally for treatment of ear, eye and skin infection. 5. It is used in treatment of Rickettsia, Chlamydia and mycoplasma. **Preparation:** 1. Chloramphenicol capsules 2. Chloramphenicol injection 3. Chloramphenicol eye drops 4. Chloramphenicol Palmitate suspension. **ii. Salbutamol** **Uses:** 1. It has bronchodilator action 2. Treatment of asthma. 3. Prevention of bronchospasm. **Preparation:** 1. Salbutamol injection 2. Salbutamol tablet 3. Salbutamol syrup	**(2M each for Uses & Preparation)**

		4. Salbutamol aerosol inhalation **iii. Hyoscine** **Uses:** 1. Used in motion sickness. 2. Used as mydriatic. 3. It is used for relief of withdrawal symptom of morphine dependence. 4. Used in treatment of acute mania & delirium with morphine. **Preparation:** 1. Hyoscine tablet 2. Hyoscine injection 3. Hyoscine eyedrops 4. Hyoscine hydrobromide tablet **iv. Promethazine** **Uses:** 1. It has antihistaminic properties. 2. Used as an antiemetic drug. 3. It also has tranquilizing action. 4. It potentiates the action of other analgesic and sedative drugs. 5. Used in allergic conditions. **Preparation:** 1. Promethazine hydrochloride tablet 2. Promethazine hydrochloride injection 3. Promethazine hydrochloride elixir 4. Promethazine hydrochloride injection	
6	**e)**	**Give uses & stability-storage condition of (any two)** **i. Paraldehyde:** **Uses:** 1. Hypnotic & sedative	**(2M each for Uses &**

2. Used as basal anaesthesia.
3. Anticonvulsants agent

Stability-Storage:

It should be stored in tightly closed airtight container in complete darkness in cool place because it undergoes atmospheric oxidation & produces peroxides.

ii. Cyclopropane:

Uses:

Potent gaseous anesthetics

Stability-Storage:

It is stored in metal cylinder designed to hold compressed gases and kept in a cool room free from inflammable material.

The whole cylinder is painted orange. The shoulder should be stenciled with name or symbol "C_3H_6". The name or symbol should be clearly stamped on the cylinder valve.

iii. Diethyl ether:

Uses:

1. General anesthetic
2. Solvent

Stability-Storage:

It is oxidized by atmospheric oxygen and is affected by light. Hence it is stored in tightly closed, light resistant containers in a cool place. If cork is used as a closer than it should be protected with metal foil. An antioxidant like hydroquinone or propyl gallate in suitable proportion should be added.

iv. Rifampicin

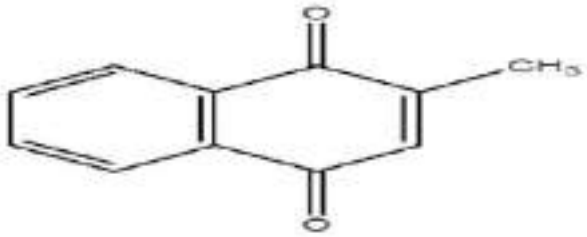
Uses:

1. It is used for treatment of pulmonary tuberculosis.
2. By combination with Dapsone and Clofazimine it is used in the treatment of leprosy.

Stability-Storage:

It should be stored in air tight light resistant containers at a temperature not exceeding 15^oC.

Storage)

6	f)	**Give structure, properties, uses and preparations of Menadione.** **Structure:**  **Properties:** 1. It occurs as a bright yellow crystalline powder. 2. It is practically insoluble in water, sparingly soluble in alcohol & soluble in chloroform. **Uses:** 1. Coagulants 2. In treatment of haemorrhage. 3. To treat vitamin K deficiency. 4. To treat hypoprothrombinemia. 5. Used as radio sensitizer in cancer. **Preparation:** 1. Menadione 2. Menadione injection 3. Menadione tablet	**1M Each**

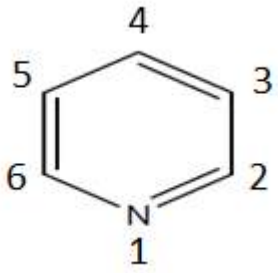
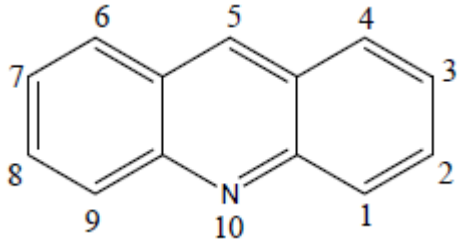
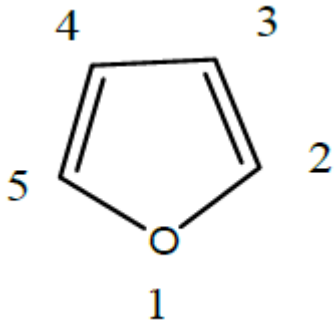
MODEL ANSWER

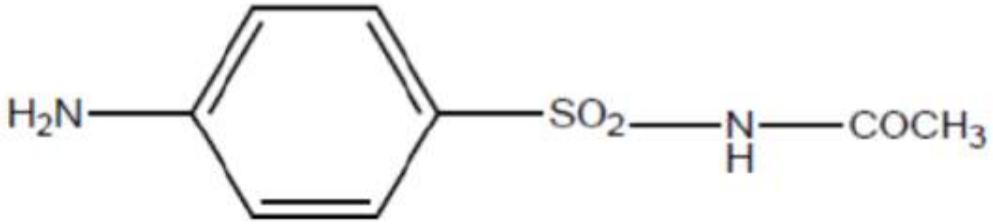
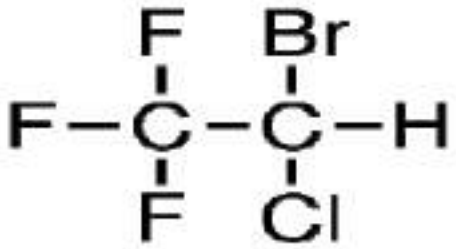
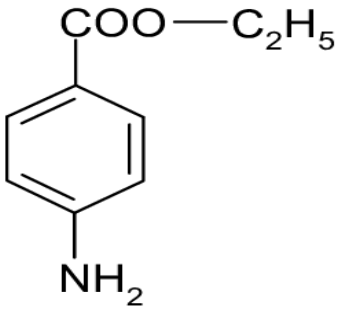
WINTER – 19 EXAMINATION

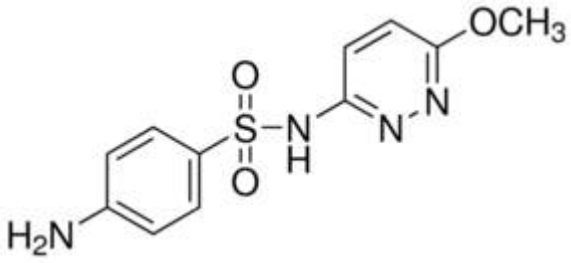
Subject Title: PHARMACEUTICAL CHEMISTRY-ll **Subject Code:** 0812

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.

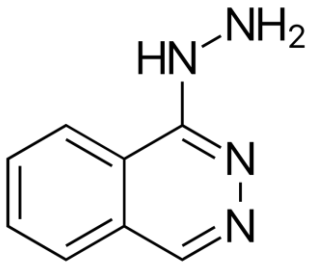
1		**Attempt any <u>EIGHT</u> of the following:**	**16 M (8X2M)**
1	**a)**	**Give structure and method of numbering for (any two)** **(i) Pyridine**  **(ii) Acridine**  **(iii)Furan** 	**1 M each**

1	b)	**Draw structure from given chemical name. (any two)** **(i) N-acetyl sulfanilamide**  **(ii) 2-Bromo, 2- Chloro-1, 1 , 1-trifluoroethane**  **(iii) Ethyl – P- amino benzoate** 	**1 M each**
1	c)	**Write name and structure of the drug containing following heterocycle. (any two)** **(i) Pyridazine** **Name of drug:** Sulfamethoxy pyridazine, Hydralazine **Structure** Sulfamethoxy pyridazine	**1 M each**



OR

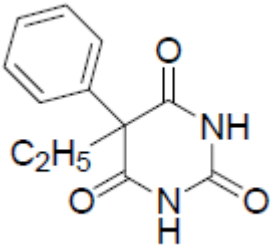
Structure: Hydralazine



(ii) Barbituric acid

Name of drug: Phenobarbitone

Structure:

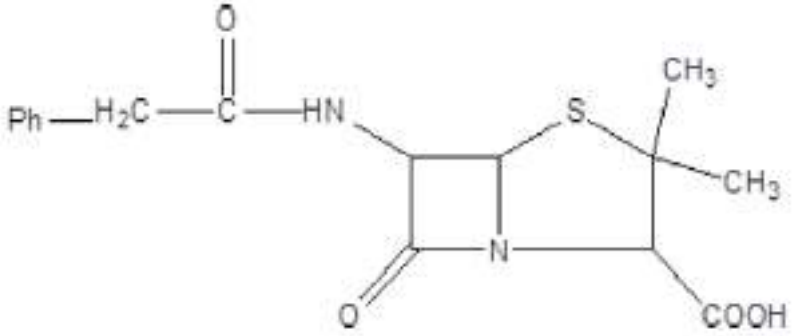


(iii) Penam

Name of drug: Penicilline-G, Penicilline-V, Ampicillin,

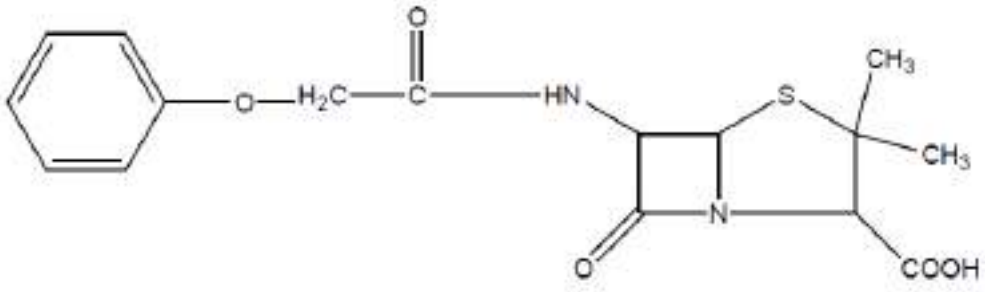
Structure:

Penicilline-G



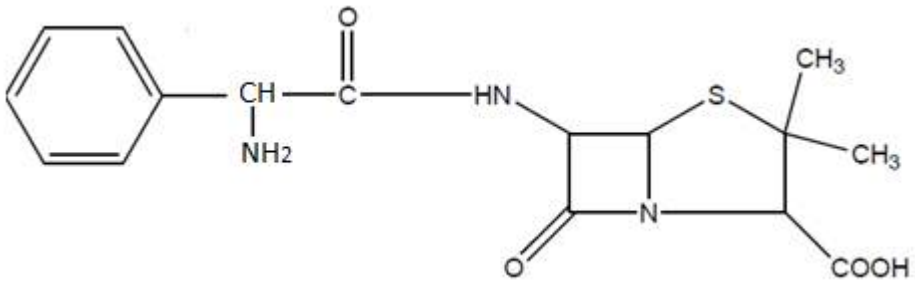
OR

Penicilline-V

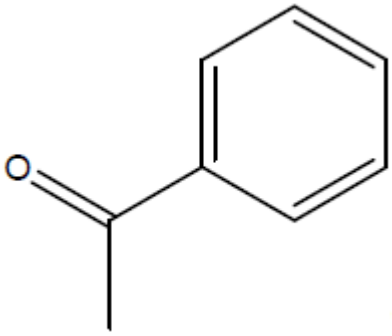
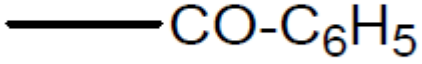
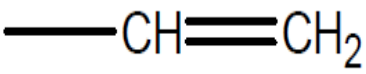


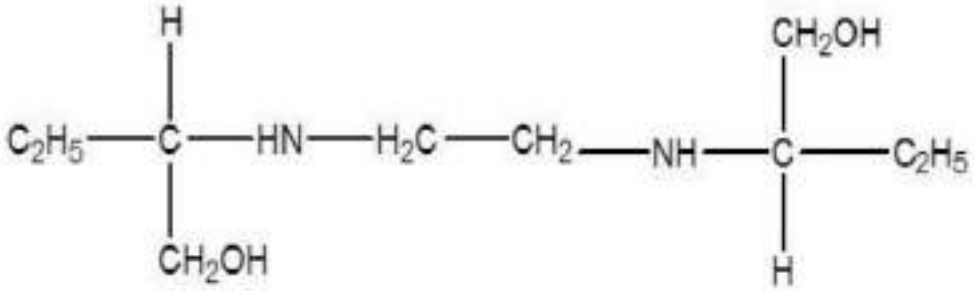
OR

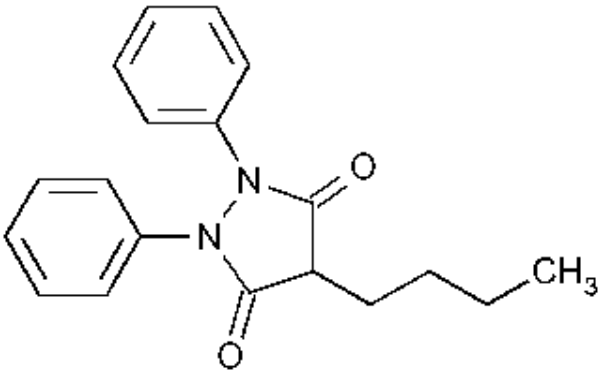
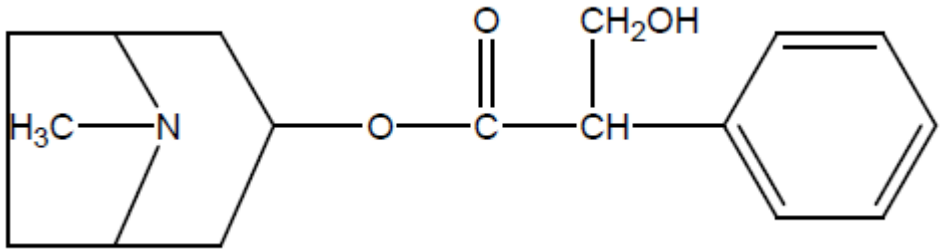
Amipicillin

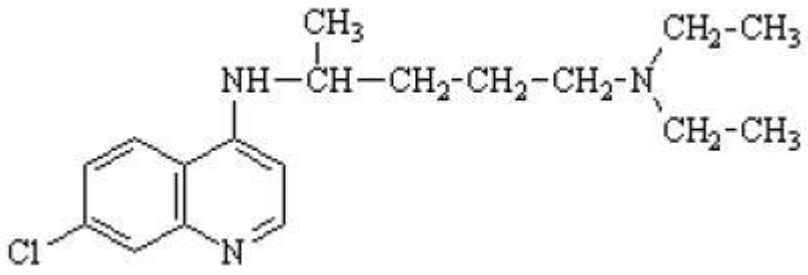


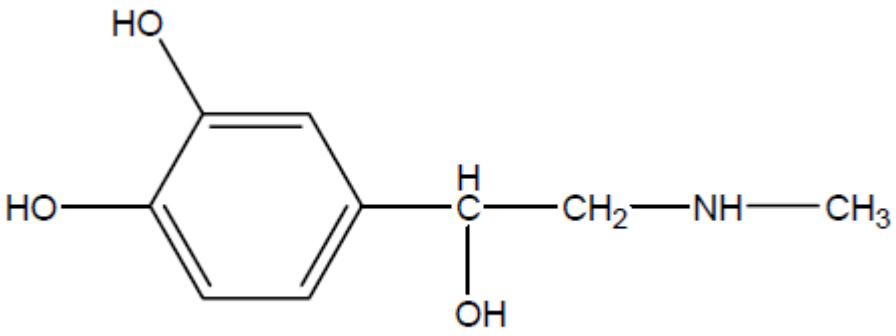
1	d)	**Define the following terms with example (any two)** (i) **Cardiotonic: The** drugs or compounds which increase force of contraction without increasing its oxygen consumption are known as cardiotonic e.g. Digitalis, stropanthus like Digoxin, Digitoxin, Gitoxin. (ii) **Vasodilator**: These are the drugs which produces dilation of blood vessels by relaxing smooth muscle cells. e.g. Hydralazine, Minoxidil, Nifedipine, Verapamil, Nitroglycerine, Losartan, Prazosin, Doxazosin (iii) **Antidepressants** Antidepressants are drugs which counteract or overcome mental depression. These drugs are therapeutically useful in a variety of cases pertaining to mentally ill patients. Mental depression is a phenomenon which may arise in normal individuals or in mentally ill persons. E.g. Imipramine, Amitriptyline, Nortriptyline, Phenelzinesulphate, Isocarboxid, Tranylcypromine, Mitrazapine, Trazodone	**1 M each**
1	e)	**Give two brand names of following drugs (any two)** (i) **Paracetamol**: Tylenol, Calpol, panadol, crocin, metacin, valadol, paldesic, Dolo (ii) **Metronidazole**: Aristogyl, Flagyl, Metrogyl, Aldezol, Unimezol (iii) **Salbutamol**: Ashtalin, Respira, Salbetol, Ambrodil, Sobrex,, Salbuton, Asthasol	**1 M each**
1	f)	**In what dosage form the following drugs are given (any two)** (i) **Insulin** : 1) Insulin Injection, 2) Insulin Injection Biphasic 3) Neutral Insulin Injection 4) Globin zinc Insulin Injection 5) Isophane Insulin Injection 6) Protamin zinc Insulin Injection 7) Insulin zinc Suspension (ii) **Mebendazole** 1) Mebendazole Tablet 2) Mebensazole Syrup (iii) **Procaine** : Procaine Injection	**1 M each**

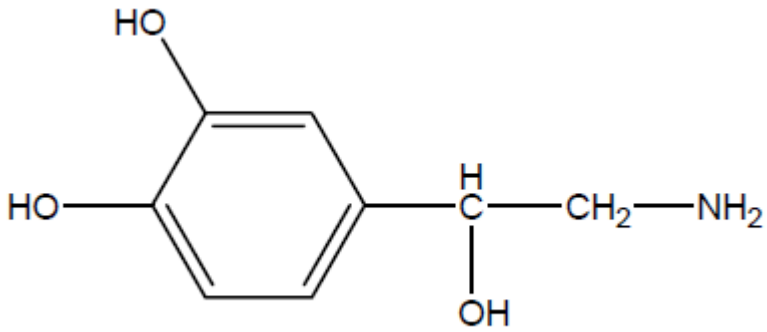
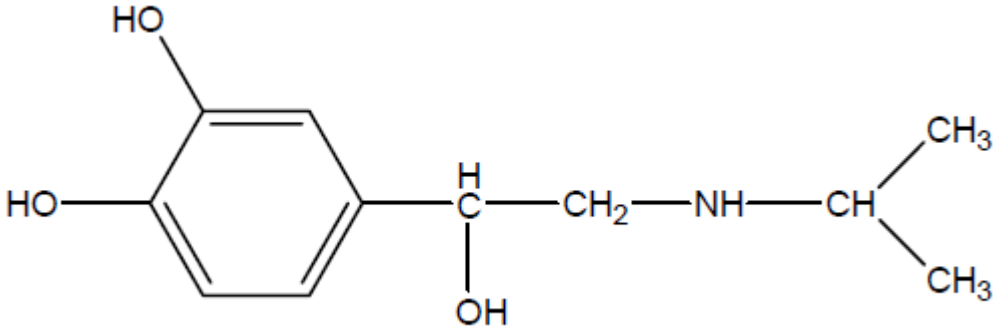
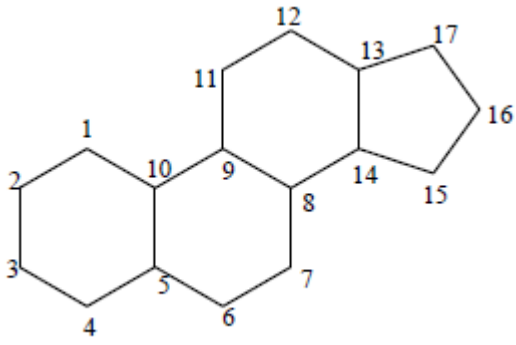
1	g)	**Write structure of the following groups (any two)** **(i) Benzoyl**  **OR**  **(ii) Vinyl**  **(iii) Amino** 	**1 M each**
1	h)	**Give uses of Evans blue and Indigo-carmine.** **Evans blue:-** 1) Evans Blue Dye is a di-azo compound and has been the principal method of determining blood volume in humans and animals. 2) The dye combines firmly with plasma albumin when injected into the blood stream and leaves the circulation very slowly. **Indigo-carmine.** 1) It is administered intravenously to test renal function (by estimating the rate of excretion in urine) & to locate the uretheral orifices. 2) In the lab it is used as coloring agents.	**1 M each**
1	i)	**Classify antitubercular drugs with examples.** **Classification** i) p-amino salicylic acid derivative – e.g. PAS ii) Pyridine derivatives – e.g. Isoniazid, Ethionamide	**2 M**

		iii) Pyrazine derivatives- e.g. Pyrazinamide iv) Ethylene diamine derivatives – e.g. Ethambutol v) Antibiotics – e.g. Cycloserine, Streptomycin, Rifampicin **OR** i) First line drugs: e.g.Isoniazid, Rifampin, Ethambutol, Pyrazinamide, Streptomycin, Thioacetazone etc. ii) Second line drugs e.g.Ethionamide, Kanamycin, capreomycin, Cycloserin, Para amino salicylic acid etc. iii) Third line drugs e.g.Clarithromycin, Thioacetazone **OR** **1. Synthetic anti-tubercular drugs:** Para Amino Salicylic acid (PAS), Isoniazide, Ethambutol, Pyrazinamide, Ethionamide **2. Antibiotics:** Streptomycin, Cycloserine, Rifampin, Clarithromycin	
1	**j)**	**Write structure of the following drugs. (any two)** **(i) Ethambutol** 	**1 M each**

		(ii) Phenbutazone  **(iii) Atropine** 	
1	**k)**	**Name the drug present in following brands. (any two)** (i) **Mebex**: Mebendazole (ii) **Valium**: Diazepam (iii) **Corex**: Chlorpheniramine maleate and Codeine phosphate	**1 M each**
1	**l)**	**Write uses of the following (any two)** **(i) Thiambutosine** 1. It is use as antileprotic drug 2. It is also used as a second line drug in dapsone resistant cases. **(ii) Thyroxin** 1. Treatment of metabolic insufficiency. 2. Treatment of Hypothyroidism.	**1 M each**

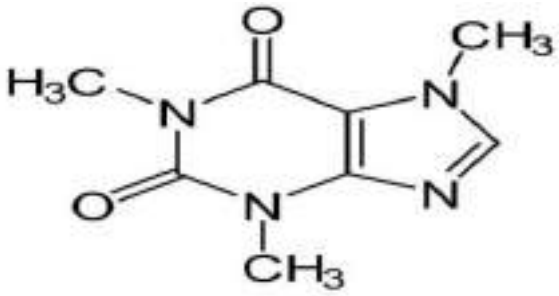
		3. Treatment of thyroid carcinoma. 4. Treatment of obesity. 5. It increases metabolism of carbohydrates, protein. 6. Rarely used in the treatment of male infertility and some gynaecological disorders. 7. It decreases serum cholesterol level. **(iii)Thrombin** 1. Blood Coagulant. 2. Topically to control minor oozing due to superficial cuts. 3. Orally to prevent GIT bleeding.	
2		**Attempt any <u>FOUR</u> of the following:**	**12M (4X3M)**
2	**a)**	**Classify Antimalarial drugs. Give structure of chloroquine** **Classification:** a) Alkaloids – e.g. Quinine b) 4-amino quinolines – e.g. Chloroquine, Amodiaquine c) 8-amino quinolines – e.g. Primaquine d) 9- aminoAcridine : e.g. Mepacrine e) Biguanides – e.g. Proguanil f) Pyrimidines – e.g. Pyrimethamine, Trimethoprim g) Miscellaneous – e.g Protonsil, Dapsone, Artesunate, Artemether etc. **Structure of Chloroquine :** 	**2 M Classification,** **1M-Structure-**
2	**b)**	**Name one drug used for :** (i) **Candidiasis**: - Nystatin, Amphotericin-B, Fluconazole, Ketoconazole, Itraconazole, Clotrimazole.	**1 M each**

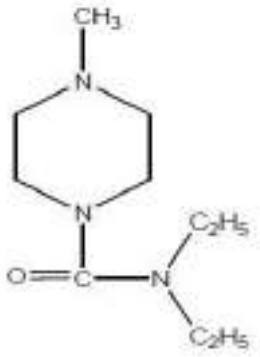
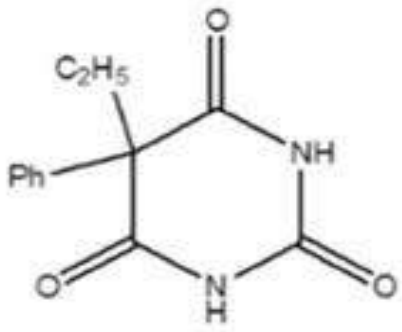
		(ii) **Amoebiasis**: Emetine, Clioquinol, Diiodohydroxyquinoline, Metronidazole, Tinidazole, Ornidazole, Carbarsone, Diloxanide furoate, Paramomycin, Erythromycin. (iii) **Leprosy** : Dapsone,Rifampicin, Clofazimine, Thiambutosine, Solapsone, Thiacetazone.	
2	**c)**	**Classify Adrenergic drugs. Draw structure of any one Catecholamine.** The adrenergic drugs can be classified based on their chemical structure. 1) Catecholamines e.g : Adrenaline, Nor-adrenaline, Isoprenaline 2) Non-Catecholamines e.g. Phenylephrine, Salbutamol, Terbutaline, Ephedrine, Pseudoephedrine. 3) Imidazoline derivatives eg. Naphazoline, Tetrahydrozolium OR 1. Vasoconstrictors (↑ B. P.): Noradrenaline (Norepinephrine), Dopamine, Ephedrine etc. 2. Cardiac stimulants: Dopamine, Adrenaline, Isoprenaline 3. CNS stimulants: Amphetamine 4. Smooth muscle relaxants: Adrenaline, Isoprenaline, salbutamol etc. 5. Drugs used in allergic reactions: Ephedrine 6. Local vasoconstrictor/ nasal decongestants: Phenylephrine, pseudoephedrine 7. Anorectics: Amphetamine, Phentermine. **Catecholamine: (Any one Structure will carry ONE mark)** **Adrenaline**  **OR**	**2 M Classification, 1M-Structure-**

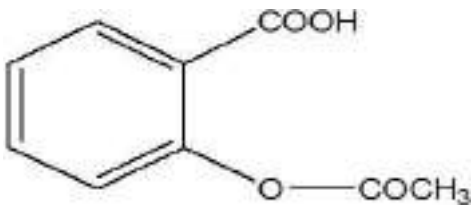
		Nor adrenaline  **OR** **Isoprenaline** 	
2	**d)**	**Draw the basic steroidal nucleus with numbering. Give properties and uses of testosterone.** **Basic steroidal nucleus:** 	**1 M each**

		Properties: 1. It occurs as an odorless, white crystalline powder. 2. It is very slightly soluble in water, freely soluble in alcohol. 3. It is dextrorotatory. **Uses of testosterone :** 1. It has both androgenic and anabolic activity. Its primary use is as androgen replacement therapy in men at maturity age in case of testosterone deficiency. 2. It is useful in certain anemias, osteoporosis and to stimulate growth in undergrown boys. 3. It is used to increase athletic performance and maintain muscle tone. 4. Used in palliative treatment of disseminated breast cancer in postmenopausal women. 5. Used in treatment of gynaecomastia.	
2	**e)**	**Define diuretics? Give any one method of classification for diuretics with example.** **Diuretics:** Drugs which promote excretion of water & electrolytes from body through kidneys in the form of urine are called diuretics. **Classification:-** 1) Water & Osmotic agents a) Electrolytes:-Sodium & Potassium salts b) Non electrolytes:- Mannitol, Urea 2) Organic mercurials:- Mersalyl acid 3) Acidifying agents:-Ammonium chloride, Arginine hydrochloride 4) Alpha-beta unsaturated ketones:- Ethacrynic acid 5) Purinase & related compound: Caffeine 6) Sulphonamides:- a) Carbonic anhydrase inhibitors-e.g. Acetazolamide b) Benzothidiazines: - Chlorthiazide, Hydrochlorthiazide c) Sulphamoyl benzoic acid derivatives e.g. Frusemide 7) Endocrine antagonists: (aldostrone antagonists) e.g. Spironolactone 8) Miscellaneous agents: - Trimaterene	**1M-Define, 2 M Classification,**

		OR **Diuretics can also be classified as** **1) Weak diuretics –** a) Osmotic diuretics:- Sodium & Potassium salts b) Xanthine deri.:- Aminophylline c) Carbonic anhydrase inhibitors-e.g. Acetazolamide **2) Moderatly efficacious diuretics: -** a) Osmotic diuretics: - Mannitol, Sucrose, Glycerol b) Benzothiadiazines deri.- Chlorthalidone, Chloroxozone **3) Very efficacious diuretics (High celling diuretics)** e.g. Frusemide & Ethacrynic acid **4) Potassium sparing diuretics:** a) Aldostrone antagonists: - Spironolactone b) Renal epithelial sodium channel inhibitors: - Trimaterene, Amiloride	
2	**f)**	**What are antihistaminics? Give classification of antihistaminics with examples.** An antihistaminic is an agent that inhibits the release or action of histamine and can be used to describe any histamine antagonist, but it is usually reserved for the classical antihistamines that act upon the H1 histamine receptor and H2 receptor blockers are used in the treatment of stomach ulcer, gastric ulcer, heart burn etc. **Classification of Antihistaminics:** 1. H1 blockers or H1 antagonist: a. Aminoalkylethers/Ethanolamines e.g. Diphenhydramine, Doxylamine b. Ethylenediamine e.g.Mepyramine, Tripelennamine, Pyrilamine c. Alkylamines/Propylamines e.g. Pheniramine, Chlorpheniramine, Triprolidine d. Phenothiazine derivatives e.g. Promethazine, Trimeprazine e. Piperazine derivatives. e.g Meclizine, Cyclizine, Chlorcyclizine f. Dibenzocycloheptenes: Cyproheptadine, Azatadine g. Second generation antihistaminics: e.g. Cetrizine, Levocetrizine, Fexofenadine, Terfenadine 2. H2 Blockers or H2 receptor antagonist e.g. Ranitidine, Cimetidine, Famotidine 3. An inhibitor of histamine release e. e.g. Sodium Cromoglycate	**1M-Meaning** **2 M Classification,**

3		**Attempt any <u>FOUR</u> of the following:**	**(12 M)** **(4x3M)**
3	**a)**	**Write structure, Give chemical name, properties, and uses of Caffeine?** **Structure of Caffeine:**  **<u>Chemical name</u>** :- 1,3,7 trimethyl xanthine **Properties**: 1. It occurs as white crystalline powder having bitter taste. 2. It sublimes on heating. 3. Sparingly soluble in water but very soluble in boiling water. 4. It is a very weak base. **Uses:** 1. Stimulation of central nervous system. 2. Used as diuretic. 3. Vasodilation of peripheral vessels. 4. Decreases drowsiness. 5. Relieve mental fatigue and headache of certain kind like neuralgia, rheumatism, migraine etc.	**1 M** **1 M** **0.5 M** **0.5 M**
3	**b)**	**Name any two halogenated hydroxyl Quinolines. Draw structure and Give chemical name of DEC?** **Halogenated hydroxyl Quinolines:** Iodoquinol **(**Di-iodohydroxyquinoline), clioquinol(chloroiodoquinol), Cloxyquin (chlorohydroxyquinoline)	**1 M each**

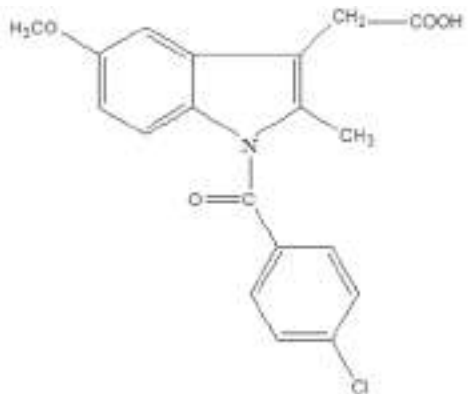
		Structure:  **Chemical Name:** N,N-diethyl, 4-methyl, piperizine-1-carboxamide	
3	**c)**	**Name the two barbiturates used as "General anaesthetics". Draw structure and Give chemical name of Phenobarbitone.** **Barbiturates used as General anaesthetics:** Methohexitone, Thiopentone sodium **Structure:**  **Chemical name:** 5-ethyl, 5-phenyl barbituric acid.	**1 M each**

3	d)	**Give structure, chemical name and storage condition of Aspirin?** **Structure:**  **Chemical name:** Acetyl salicylic acid **Storage conditions:** It should be stored in air tight containers, in a cool, dry place.	**1 M each**
3	e)	**What are narcotic analgesics? Give classification of narcotics analgesic with examples.** **Narcotic analgesics** Narcotic analgesics are derivatives of opium, semi synthetic or synthetic agents having potent analgesic & narcotic activity and effective for the treatment of severe pain. **Classification of Narcotic analgesics:** Narcotic analgesic are classified as:- 1. Morphine and related compounds (Natural alkaloids of opium) e.g. Morphine, Codeine. 2. Semi-synthetic derivatives of morphine- Heroin, Brown Sugar 3. Synthetic Agents- Methadone, Pethidine, Dextropropoxyphen hydrochloride. **OR** **Classification of Narcotic analgesics:** 1. Naturally occurring: a) Morphine and it's analogues: e.g.: Morphine, Codeine 2. Synthetic: a) Morphinan analogues: e.g.: Levorphenol b) Benzomorphan analogues: e.g.: Pentazocin c) 4-Phenylpiperidine analogues: e.g.: Pethidine	**1 M** **2 M**

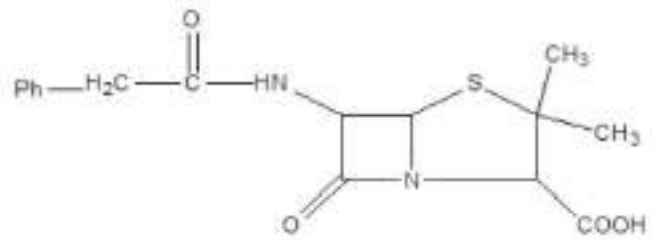
		d) Phenylpropylamine analogues: e.g.: Methadone, Dextropropoxyphene.	
3	f)	**What are vitamins? Give classification of vitamins with examples.** **Vitamins:** Vitamins may be defined as potent organic substances which are essential for normal growth and maintenance of life of animals, which they are not able to synthesize in adequate quantity and their deficiency may cause various diseases. **Classification:** 1. Fat soluble vitamins: E.g.: Vitamin A (Retinol), Vitamin D (Calciferol), Vitamin E (Tocopherol), Vitamin K (Phytomenadione) 2. Water-soluble vitamins: E.g.: Vitamin B1 (Thiamine), Vitamin B2 (Riboflavin / Lactoflavin), Vitamin B6 (Pyridoxine), Vitamin B12 (Cyanocobalamin), Folic acid, Nicotinic acid, Vitamin C (Ascorbic acid) 3. Fat- water insoluble vitamin: E.g.: Vitamin H (Biotin) **OR** 1. Fat soluble vitamins: a) Are obtained from β-ionone ring: e.g.: Vitamin-A b) Are obtained from steroids/sterol: e.g.: Vitamin-D c) Contain chromane ring: e.g.: Vitamin-E d) Contain naphthaquinone ring: e.g.: Vitamin-K 2. Water-soluble vitamins: E.g.: Vitamin B1 (Thiamine), Vitamin B2 (Riboflavin / Lactoflavin), Vitamin B6 (Pyridoxine), Vitamin B12 (Cyanocobalamin), Folic acid, Nicotinic acid, Vitamin C (Ascorbic acid)	**1M** **2 M**

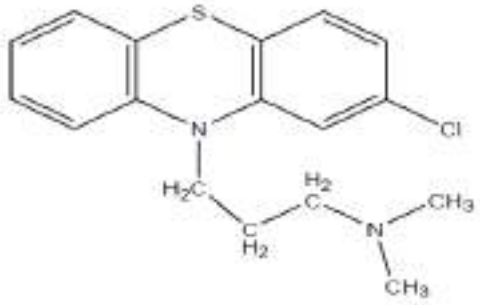
4		**Attempt any <u>FOUR</u> of the following:**	**(12 M) (4x3M)**
4	**a)**	**Classify of Antibiotics with examples** I. β-Lactam antibiotics: e.g. Benzyl Penicillin, Phenoxymethyl penicillin, Cephaloridine, cephalothin II. Non-β-Lactam antibiotics: 1. Tetracyclines: e.g chlortetracycline, oxytetracycline. 2. Aminoglycoside antibiotics : e.g: Streptomycin, neomycin, gentamicin 3. Macrolide antibiotics : e.g : Erythromicin 4. Ansamycins : e.g: Rifamycin 5. Polyene macrolide antibiotics: e.g: Nystatin, Hamycin 6. Anthracycline antibiotics : e.g :actinomycin, daunorubicin 7. Peptide antibiotics: e.g: Bacitracin. 8. Steroidal antibiotics : e.g : Fusidic acid 9. Nucleoside anitibiotics: e.g : Puromycin 10. Non- classifiable antibiotics : e.g : Chloramphenicol	**3 M**
4	**b)**	**Explain the terms "Lipid Lowering Agent". Give properties and uses of Clofibrate.** **Lipid lowering agents:** Hyperlipidemia is the most prevalent indicator for susceptibility to atherosclerotic heart disease & it also describes elevated plasma levels of lipids that are usually in the form of lipoproteins. Drugs which are used to reduce the elevated levels of the lipids in the blood are called Lipid lowering agents. **Properties:** 1. It is a clear, almost colorless liquid. 2. It has a characteristic odor. 3. It is having acrid taste first and then becomes sweet. 4. It is very slightly miscible in water and miscible in alcohol. 5. It is heat stable.	**1 M each**

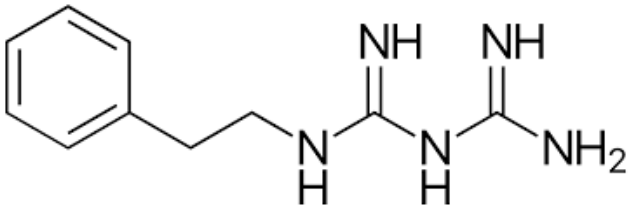
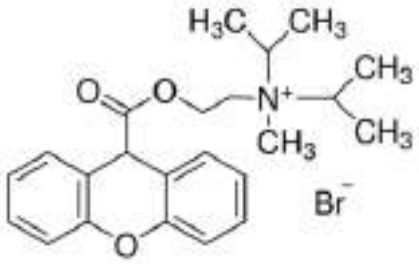
		Uses: 1. It is used in the treatment of type III hyperlipoproteinaemia. 2. It is used in the treatment of severe hypertriglyceridemia. 3. It is also used in long term treatment and prophylaxis of coronary heart disease.	
4	**c)**	**Define anti-neoplastic drugs. Write uses of cyclophosphamide and methotrexate.** **Definition:** Anti-neoplastic agents, also known as Cytotoxic agents are used in the treatment of malignant diseases, when surgery or radiotherapy is not possible or has proved ineffective. **Uses of Cyclophosphamide:** 1. Used in treatment of solid tumours such as carcinoma of the breast, cervix, lung and ovary. 2. Used in combination of other agents in the treatment of lymphomas, myeloma. 3. Used as immunosuppressant in tissue and organ transplantation. 4. Used in the management of autoimmune disorders such as nephritic syndrome and rheumatoid arthritis. **Uses of Methotrexate:** 1. Used in the management of acute lymphoblastic leukemia. 2. Used as immunosuppressant. 3. Given by mouth or by injection as methotrexate sodium.	**1 M each**
4	**d)**	**Define 'Parasympathomimetics'. Give properties and uses of Pilocarpine.** **Parasympathomimetics:** The drug which exert or mimic the pharmacological action / effects of acetylcholine or drugs which bring about stimulation of parasympathetic nervous system are called parasympathomimetics. **Properties of Pilocarpine:** 1. Pilocarpine is colourless crystals or a white crystalline powder. 2. It is odourless. 3. It is sensitive to light. **Uses of Pilocarpine:**It is used : i) As miotic. ii) To reduce intraocular pressure in glaucoma.	**1 M each**

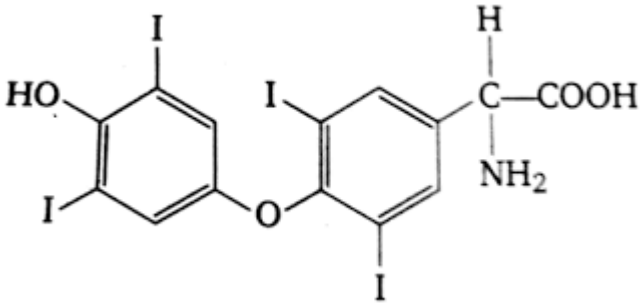
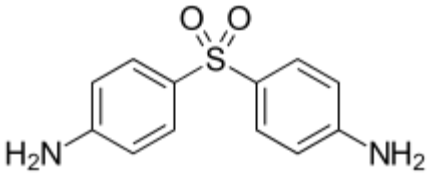
		iii) For diagnosis of Adie's (tonic) pupil. iv) To counteract anticholinergic side effects (eg. Dryness of mouth, constipation etc).	
4	e)	**Define Diabetes Mellitus? Discuss storage, precautions and labelling of Insulin Preparation.** **Diabetes Mellitus:** Diabetes mellitus is a metabolic disorder characterized by hyperglycaemia usually associated with polyphagia, polydypsia; polyuria, glycosuria, weight loss, dehydration etc. caused due to deficiency or diminished effectiveness of insulin (insulin resistance). **Storage condition:** All insulin preparations must be stored at low temperatures between 2-8°C in a dark place. **Precautions:** Insulin is affected by heat, light and moisture so protect from it. In case of multi-dose container should be shaken gently before withdrawal of dose. **Labelling:**The label should bear- a) number of unit per ml b) the animal source of insulin c) expiry date d) do not freeze	**1M** **1 M** **0.5 M** **0.5 M**
4	f)	**Give structure, chemical name, properties and uses of Indomethacin.** **Structure:**  **Chemical Name:** 1-(p-chlorobenzoyl)5-methoxy 2-methyl indol-3yl-acetic acid **Properties of Indomethacin:** 1. It occurs as a pale yellow to brownish yellow crystalline powder.	**1M** **1 M** **0.5 M**

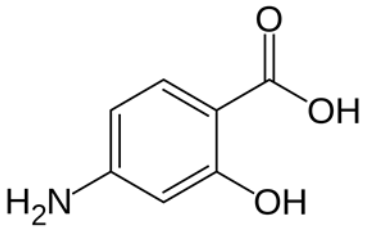
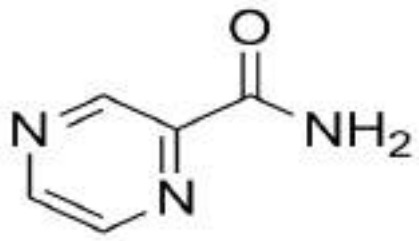
		2. It is odorless and almost tasteless. 3. It is very slightly soluble in water and sparingly soluble in alcohol. 4. It is stable in neutral or slightly acidic media. 5. It is decomposed by strong alkali and sunlight. **Uses of Indomethacin:** It is used as Analgesic, Anti-inflammatory and Antipyretics for the treatment of – 1. Rheumatoid arthritis 2. Acute gout 3. Spondylitis 4. Dysmenorrhea 5. Acute musculo-skeletal disorder 6. Pain in malignant disease	**0.5 M**
5		**Attempt any <u>FOUR</u> of the following**	**12M (4X3M)**
5	**a)**	**What are Cardiovascular drugs? Classify them with examples.** **Definition** • Cardiovascular agents include various types of drugs having an action on the heart or on other parts of the vascular system and they have the ability to alter cardiovascular function. **<u>OR</u>** • Cardiovascular Agents represents a group of drugs which have direct action on the heart or other parts of the vascular system so that they modify the total output to the heart or the distribution of blood to certain parts of the circulatory system. **Classification of cardiovascular agents:-** Different kinds of drugs fall under this category like: 1) Cardiotonics (Positive cardiac inotropic agents):- they increase the force of contraction of the myocardium e.g. Cardiac glycosides obtained from Digitalis, Stropanthus, squill such as Digoxin, Digitoxin, Lanatoside C etc. 2) Antiarrhythmic drugs:- used to regulate arrhythmic (irregular) contraction of cardiac muscles of the heart. eg. Quinidine, Procainamide, Phenytoin, lignocaine hydrochloride, propranalol etc.	**1 M** **2M**

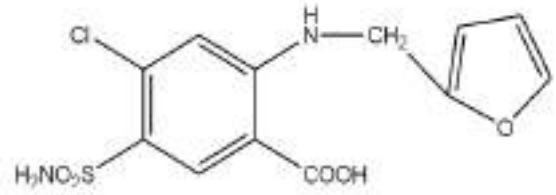
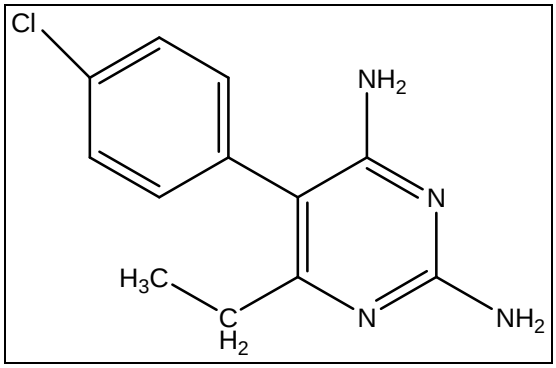
		3) Antianginal agents:-which are used in the treatment of angina pectoris, enabling the heart to meet its metabolic demands for oxygen. e.g. Amyl nitrate, Isosorbid nitrate, Verapamil, Propranolol 4) Anti-hypertensive:-which regulate the blood pressure by decreasing the elevated blood pressure. e.g. α-methyldopa, clonidine, Pentolinium, Mecamylamine, Reserpine, Guanethidine, Propranalol, Atenolol, Prazosin, Tolazoline, Hydralazine, Minoxidil, Verapamil, Captopril etc. 5) Antihyperlipidemic agents: (lipid lowering agents) e.g Clofibrate, Nicotinic acid 6) Other drugs which indirectly affect cardiovascular system: a) Anticoagulants eg. Warfarin, Dicoumarol b) Diuretics eg. Furosemide, Hydrochlorthiazide c) Antiplatelet drugs eg. Aspirin	
5	**b)**	**Write structure, give chemical name, properties and uses of Penicillin G.** **Structure :**  	**1M**
		Chemical name: 6-(2-phenyl acetamido) penicillanic acid. OR 6-(2-phenyl ethanoylamino) 2,2-dimethyl penam-3-carboxylic acid.	**0.5M**
		Properties: • White, finely crystalline powder with faint characteristic odour • Hygroscopic, Dextrorotatory • Very soluble in water • Degraded rapidly in strong acidic and basic media • Inactivated by enzyme *penicillinase* and gastric juice • Structural modifications are possible	**0.5M**
		Uses: It is used in the treatment of following diseases:	**1M**

		1) Respiratory tract infection 2) Urinary tract infection 3) Gonorrhea 4) Syphilis 5) Meningitis 6) Enteric infection 7) Septicemia. 8) Abscesses Prophylactically used before dental and surgical procedures to prevent from developing endocarditis and re-occurrence of rheumatic fever.	
5	**c)**	**What are tranquilizers? Write structure, give chemical name and popular trade name of Chlorpromazine.** **Tranquilizers: -** Tranquillizers are CNS depressants which bring about a calming effect and induce a mild sedative effect. These are the agents or drugs which reduce anxiety, induce mental repose, and suppress agitation without significantly diminishing mental alacrity, they may cause some drowsiness but tolerance soon develops to this effect. **Structure:**  **Chemical name:** 2-chloro-10-(3-dimethylaminopropyl)phenothiazine **Trade names: (any one)** Largactil, Chlorozine, Copamide, Chlorectil plus, Chlorzen plus, Clozine	**1M** **1M** **0.5M** **0.5M**

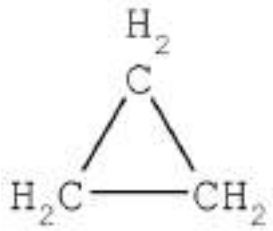
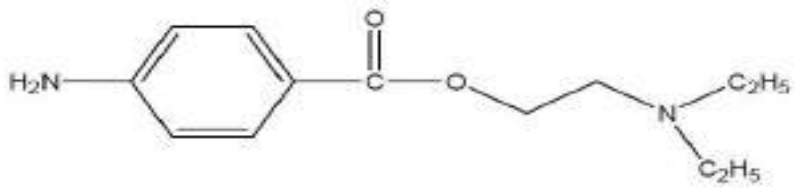
5	d)	**Name one biguanide derivative used as hypoglycemic agent. Write its structure and uses.** Following biguanide derivatives are used as hypoglycemic agent. Phenformin, Metformin **Structure of Phenformin:**  **Uses of phenformin:** • To treat non-insulin dependent diabetes mellitus • To reduce blood sugar level in cortisone induced hyperglycemia • To reduce blood cholesterol in maturity onset diabetes.	**1M each**
5	e)	**Write structure of Propantheline bromide, give its chemical name, properties and uses.** **Structure:** 	**1M**
		Chemical name: N,N-di-isopropyl-N-methyl-N-[2-(xanthene-9-yl carbonyloxy)ethyl]ammonium bromide	**0.5M**
		Properties: • It occurs as white or yellowish white powder, odorless and has very bitter taste • Slightly hygroscopic and soluble in water	**0.5M** **1M**
		Uses: • To treat gastric and duodenal ulcers. • To treat intestinal hypermotility.	

		• To reduce gastric secretion. • To produce reactive hypoglycemia (by stimulating insulin release). • To reduce biliary and uterine spasm. • To control excessive sweating and salivation. • To prevent nocturnal enuresis in children.	
5	**f)**	**Name two antithyroid drugs. Draw structure of thyroxine.** Following drugs are used as antithyroid drugs: Propylthiouracil, carbimazol, methimazole, methylthiourocil. **Structure of thyroxine:** 	**1M each**
6		**Attempt any <u>FOUR</u> of the following**	**16M (4X4M)**
6	**a)**	**Write the name of the microorganism which is responsible for human Leprosy. Write structure, give chemical name, properties and uses of DDS.** Leprosy is caused by slow growing bacteria, **Mycobacterium Leprae** **Structure of DDS (Dapsone)**  **Chemical name:** Bis (4-aminophenyl) sulphone **or** 4,4'-diamino, diphenyl sulphone **Properties:** • It is white or slightly white crystalline powder.	**0.5M** **1M** **1M** **0.5M**

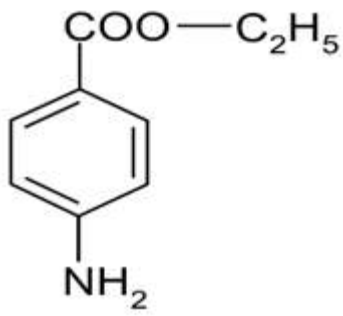
		• It is odorless. • It is bitter in taste, practically insoluble in water, soluble in alcohol, freely soluble in acetone and dilute mineral acids. **Uses-** • Dapsone (diamino-diphenyl sulfone) is a pharmacological medication most commonly used in combination with rifampicin and clofazimine as multidrug therapy (MDT) for the treatment of *Mycobacterium leprae* infections (leprosy). • Dapsone is used in combination with pyrimethamine in the treatment of malaria. • It is also used in the treatment of dermatitis herpetiformis and relapsing polychondritis • In combination with trimethoprim or pyrimethamine it is used to treat pneumonia.	**1M**
6	**b)**	**Write structure and give chemical name of PAS and Pyrazinamide.** **Structure of PAS:**  **Chemical name:** p-amino salicylic acid **Structure of Pyrazinamide:**  **Chemical name:** Pyrazine-2-carboxamide	**1M each**

6	c)	**Write structure, give chemical name, properties and uses of Furosemide.** **Structure:**  **Chemical name:** 4-chloro-N-furfuryl-5-sulphamoyl anthranilic acid OR 4-chloro-2-furfuralamino-5-sulphamoyl benzoic acid **Properties:** • It is white crystalline powder, odorless, tasteless, • Very slightly soluble in water but soluble in solution of alkali hydroxides **Uses:** • It is used as diuretic • To treat oedema associated with congestive heart failure, liver cirrhosis and renal diseases • For management of hypertension	**1M each**
6	d)	**Draw structure of Pyrimethamine. Give its properties, storage conditions and pharmaceutical uses.** **Structure:** 	**1M each**

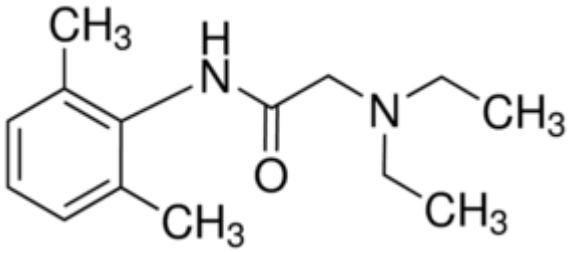
		Properties: • It is white crystalline powder. • Odourless, tasteless. • Practically insoluble in water and soluble in warm dilute mineral acids. **Storage conditions:** It is affected by light and hence it is stored in tightly closed light resistant container **Pharmaceutical uses:** • It is used for prophylaxis and treatment of malaria. • In combination with sulphadiazine it is used to treat toxoplasmosis.	
6	**e)**	**What are general anaesthetics? Classify them with examples. Draw structure of cyclopropane.** **Definition**: General anaesthetics are the central nervous system depressant drugs which bring about loss of all modalities of sensations along with a reversible loss of consciousness. **Classification:** 1) Inhalation anaesthetics: which include the liquids of volatile nature and gaseous substances used by inhalation to produce anaesthesia. These may be sub-classified as follows: i. Volatile liquids: a) Halogenated hydrocarbons: e.g. Chloroform, Halothane, Trichloroethylene, Ethylchloride b) Ethers : e.g. Diethyl ether, Vinyl ether ii. Gases: e.g. Cyclopropane, Nitrous oxide 2) Intraveneous anaesthetics:- i. Barbiturates: Ultra short acting barbiturates such as Methohexitone, Thiopentone sodium ii. Non-barbituates: a) Eugenol derivatives. e.g. Propanidid b) Phencyclidine derivatives. e.g Ketamine c) Steroids. e.g. Althesin	**1M** **2M**

		Miscellaneous such as Etomidate, Propofol. **Structure of cyclopropane:** 	**1M**
6	**f)**	**What are 'Local Anaesthetics'? Write structure, give chemical name of local Anaesthetic drug having following chemical feature.** **i) Ester** **ii) Amide**	
		Definition: Local anaesthetics are drugs which produce insensitivity in a limited area around the site of application or injection of the drug by preventing generation and conduction of impulses along nerve fibres and nerve ending and the effects are reversible.	**1M**
		Structure of drug having **i) Ester : (Procaine)** 	**1.5M each**
		Chemical name : 4-amino-(2-diethyl amino ethyl) benzoate or 2-(Diethyl amino) ethyl-4-amino benzoate.	

Benzocaine -Ethyl – P- amino benzoate



ii) Amide : (Lignocaine)



Chemical Name: 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide OR
N-diethylaminoacetyl-2,6-xylidine

MAHARASHTRA STATE BOARD OF TECHNICAL EDUCATION
(Autonomous)
(ISO/IEC - 27001 - 2013 Certified)
MODEL ANSWER
SUMMER 2019 EXAMINATION
Subject Title: Pharmacology & Toxicology Subject Code: 0813

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.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Define any EIGHT of the following terms with two examples of each.**	**16M**
1	**a)**	**Chemotherapy:** It is defined as the use of chemical compounds in the treatment of infectious disease so as to destroy the microorganisms without damaging the host tissues. Ex. Peniciliins, Cephalosporins, Tetracyclines, Streptomycin, Amoxycillin, etc.	**1M def. Any two correct examples 1M.**
	b)	**Antiemetic:-** These are the agents used in treatment of vomiting. Eg: Phenothiazine, Hyoscine, Meclizine, Promethazine, Domperidone, Ondansetron ,Chlorpromazine etc.	**1M def. Any two correct examples 1M.**
	c)	**Haemostatic:-** These are the pharmacological agents which when administered stop or arrest bleeding from capillary vessels. E.g. Gelatin sponge, Oxidized cellulose, Fibrinogen, Thrombin, Thromboplastin, Vitamin,K ,Ethamsylate	**1M def. Any two correct examples 1M.**
	d)	**Antiarrhythmic agents:-** These are the agents used to correct cardiac arrhythmia i.e. disturbance in cardiac rhythm. Eg: Quinidine, Procainamide, Propranolol, Lignocaine, Phenytoin, etc.	**1M def. Any two correct examples 1M.**
	e)	**Vermicidal:-** These are the agents which kill parasitic worms. Ex. Piperazine, Mebendazole, Pyrantel pamoate, Tetramisole Albendazole etc.	**1M def. Any two correct examples 1M.**
	f)	**Autocoids:-**	**1M def.**

		Autocoids are local hormones with high biological activity and naturally found in body as active or inactive forms. Ex. Histamine, Serotonin, 5 hydroxytryptamine, Bradykinin, Angiotensin, Prostaglandins etc.	**Any two correct examples 1M.**
	g)	**Miotics:-** These are the agents which produce miosis i.e. constriction of pupil. Eg. Parasympathomimetics like Physostigmine, Pilocarpine,Carbachol etc.	**1M def. Any two correct examples 1M.**
	h)	**Fibrinolytics:-** The drugs which activate blood plasminogen to cause lysis / breakdown of thrombus are called fibrinolytics. Ex. Urokinase, Streptokinase etc.	**1M def. Any two correct examples 1M.**
	i)	**Analeptics:-** These drugs stimulate central nervous system and stimulate the respiratory centre improving respiration. Examples: Caffeine, Amphetamine, Nikethamide, Doxapram, Bemigride etc.	**1M def. Any two correct examples 1M.**
	j)	**Expectorants:-** These are the drugs which increase the secretion of the respiratory tract, thereby reducing the viscosity of the mucus and help in its removal from the respiratory tract. Eg: Ammonium chloride, Potassium iodide, Ammonium bicarbonate, Ipecac etc.	**1M def. Any two correct examples 1M.**
	k)	**Diuretics:-** These are the pharmacological agents which when administered, increase rate of formation of urine as well as excretion of urine. Examples: Mannitol, Theophylline, Acetazolamide, Furosemide, Spironolactone, Chlorothiazide etc.	**1M def. Any two correct examples 1M.**

	l)	**Disinfectants:-** These are the pharmacological agents having bactericidal properties that can be directly applied on inanimate objects for making them free from microorganisms. Examples: Phenols, Formaldehyde, Cresol, Chlorocresol, etc.	**1M def. Any two correct examples 1M.**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Define Pharmacodynamics. Explain different mechanisms of drug action.** **Pharmacodynamics**: It includes the study of mechanism of action and pharmacological effects of drug on biological system. It is what drug does to the body. **Different mechanisms of drug action**:- 1) Physical action: physical property of drugs like adsorptive property or osmotic or radio-opacity, Radioactivity. Ex. Bulk laxative ispaghula 2) Chemical Action: Drugs act by chemical reaction Ex. Antacids directly neutralizes gastric acid. 3) Enzyme inhibition or ion channel blocking: All biological reactions are carried out by enzymes; if particular enzyme is inhibited there is loss of particular function. Ex. ACE inhibitors: Enalapril, Captopril. 4) Receptors: Various drugs act by either stimulating or inhibiting receptors in the body. Ex. Salbutamol stimulates beta adrenergic receptor and produce bronchodilation and help in bronchial asthma. 5) By altering metabolic processes: drugs like antimicrobial alter metabolic pathway in microorganisms. Ex. Sulphonamide interfere with bacterial folic acid synthesis. **OR** 1) Stimulation: Certain drugs produce their action by increasing the activity of specialized cells.eg Caffeine stimulates brain cells, cardiac stimulants like Digoxin stimulate cardiac cells	**1M def. Mecha. 2M.**

		2) Depression: Certain drugs produce their action by decreasing the activity of specialized cells. E.g. CNS depressants like Diazepam, Phenobarbitone etc. 3) Replacement: Drugs can be used as replacement when production of endogenous substance is reduced. E.g. Use of Insulin in Diabetes mellitus, also Hormone replacement treatment 4) Inhibition of Microorganisms: e.g. antibiotics, antifungals etc. 5) Irritation: certain drugs produce changes in cellular structure and affect growth of cells. G I irritants like Senna glycosides 6) Physical Action: Drugs like kaolin act in mechanical way because of its adsorption property. 7) Chemical Reaction: Drugs show their effect due to chemical reaction. E.g. Antacids neutralize gastric acidity.	
2	**b)**	**Explain plasma protein binding of drugs and give its significance.** This is the phenomenon seen when the drug gets distributed in the blood plasma. Some drugs have affinity to get bound to plasma proteins depending upon their physicochemical Properties. So drugs may exist as Free drug (i.e. Unbound) & bound Drugs. Some drugs are highly protein bound: e.g. Sulpha drugs, Aspirin, warfarin, diazepam etc. **Significance:** 1) Increase in duration of action of drugs: To maintain dynamic equilibrium between free and bound drug, there would be release of drug from protein bound fraction. Hence highly protein bound drug would have longer duration of action and its dose & dosing frequency should be decided accordingly. 2) Possibility of drug interactions: drug interactions can occur when 2 or more drugs having high protein binding affinity for the same plasma protein are given simultaneously. This may result in displacement of one drug by the other & may result in toxicity.	**Explain 1.5M Significance 1.5M**
2	**c)**	**Define antagonism. Differentiate between competitive and non-competitive antagonism.**	**1M Def. 2M for**

		Define: The opposite action of two drugs on the same physiological system is called as Antagonism.	**any four correct points**

Competitive antagonism (Reversible)	**Non-competitive antagonism (Non-reversible)**
1) Competitive antagonists bind to same receptor as agonist.	1) Non-competitive antagonist binds to another site over the receptor other than agonist.
2) Competitive antagonist chemically resembles with agonist.	2) Non-competitive antagonist does not resemble with agonist.
3) Same maximal response can be attained by increasing dose of agonist.	3) Maximal response cannot be attained by increasing dose of agonist.
4) It reduces affinity	4) Non-competitive antagonist reduces efficacy.
5) Response depends upon concentration of both agonist and antagonist.	5) Response depends only on concentration of antagonist.
6) Examples:Atropine,Propranolol etc.	7) Examples Verapamil , Isoprenaline , Phenoxybenzamine etc

2	**d)**	**Classify oral hypoglycemic with examples. Give Mechanism of action of metformin.** **Classification:-** 1) Sulfonylureas a) First generation:- Ex. Tolbutamide, Chlorpropamide b) Second generation:-Ex. Glibenclamide, Glipizide, Gliclazide 2) Biaguanides: Metformin, Phenformin 3) Thiazolidinediones: Pioglitazone 4) Meglitinides: Repaglinides	**2M Classification 1M for MOA.**

		5) Alpha Glucosidase inhibitors: Acarbose 6) Newer agents: Sitagliptin, Extenaide, Canagliflozin etc. **OR** A. Enhance insulin secretion 1. Sulfonylureas i) First generation:- Ex. Tolbutamide ii) Second generation:-Ex. Glibenclamide, glipizide, gliclazide. 2. Meglitinides Ex. Repaglinide, Nateglinide 3. Glucagon like peptide-1 receptor agonists Ex. Exenatide, Liraglutide 4. Dipeptidyl peptidase-4 inhibtors Ex. Sitagliptin, vildagliptin, Sexagliptin B. Overcome insulin resistance I) Biguanide: Ex. Metformin II) Thaizolidinediones: Ex. Pioglitazone C) Miscellaneous antidiabetic drugs a) alpha glucosidase inhibitors: Ex. Acarbose, miglitol b) Sodium glucose cotransport-2:- Dapagliflozin **Mechanism of action**:- **Metformin** decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.	
2	**e)**	**Define drug metabolism. Explain first pass effect.** It is the alteration of drugs within living organism so as to modify its activity or nature. It is the chemical transformation of drug from one form to another within the body to	**1M def.** **2M Expl.**

		make it easier for excretion. **First pass effect:-** A **first-pass effect** is defined as the rapid uptake and metabolism of an agent into inactive compounds by the liver, immediately after enteric absorption and before it reaches the systemic circulation.	
2	**f)**	**Give advantages and disadvantages of intramuscular route of drug administration.** **Advantages:-** 1) Mild irritants, suspensions, colloids and injections with insoluble oily bases can be administered in this route. 2) This route also ensures uniform and slow absorption of drugs which includes drugs with low solubility as well as repository penicillin preparations. **Disadvantages:-** 1) If proper care is not taken there is possibility of injury to the nerves. 2) Injected drug may produce local pain and abscess formation. 3) Total volume of drug injected is restricted up to 10 ml. 4) Certain intramuscular injections need more time for absorption as compared to oral administration.	**1.5M. For any two correct points each**
3		**Attempt any FOUR of the followings**	**12M**
3	**a)**	**Name the drug producing following effect:** **i)** **Osteoporosis:** Corticosteroids like Beclomethazone, cortisone; Antacids like Cimetidine,ranitidine; Anticovulsants like Carbamazepine,phenobarbiotne,phenytoin; Tricyclic Antidepressants ;Anticancer drugs like Methotrexate;Heparin **ii)** **G6PD deficiency**: Quinine, Pamaquine ,Primaquine, Quinidine, Aspirin,	**0.5 EACH**

		Sulphonamides, Antibiotics such as Quinolones, Nitrofurantoin **iii)** **Hypoglycemia:** Insulin, Sulphonylureas, Pioglitazone **iv)** **Hyperplasia of gums**:- Phenobarbital, Phenytoin **v)** **Extrapyramidal effect**: Haloperidol and Fluphenazine,Chlorpromazine; Metoclopramide **vi)** **Systemic alkalosis**: Sodium Bicarbonate, thiazide diuretics etc	
3	**b)**	**Mention the drug of choice in following condition:** i) **Rheumatoid arthritis**: NSAIDs, Prednisone, Hydroxychloroquine, Sulphasalazine, Methotrexate, ii) **Candidiasis:** Clotrimazole, Nystatin, fluconazole, Amphotericin B iii) **Atherosclerosis**: Atorvastatin, Lovastatin, Gemfibrozil, Fenofibrate , Nicotinic acid, Ezetimibe etc. iv) **Skeletal muscle spasm**: Chlorzoxazone, NSAIDs, Methocarbamol v) **Leprosy**: Dapsone,Rifampicin,Clofazimine vi) **Depression:** Amitriptyline, Imipramine, Phenelzine ,Fluoxetin	**0.5 EACH**
3	**c)**	**Mention the drug contraindicated in following condition:** i) **Gastric bleeding**: Aspirin, Clopidogrel, Heparin,Warfarin, Prednisone ii) **Hypokalemia:** Diuretics, Chlorthiazide, Digitalis, Theophylline iii) **Edema**: NSAIDs like ,Ibuprofen, Prednisone, Corticosteroids, iv) **Mysthenia Gravis:** Streptomycin, Kanamycin v) **Lactation**: Anticancer drugs, Cyclosporine, Radiopharmaceuticals vi) **Congestive cardiac failure**: Calcium channel blockers, Verapamil and Diltiazem, Quinidine	**0.5 EACH**
3	**d)**	**Give dose of following drugs:** i) **Omeprazole:** 20-40mg/day ii) **Albendazole:** 400 mg orally , Less than 60 kg: 15 mg/kg/day orally iii) **Diazepam**: 2 to 10 mg orally 2 to 4 times a day orally	**0.5 EACH**

		iv) **Diclofenac:** 50 mg orally 3 times a day v) **Metoprolol**: 25 mg or 50 mg orally twice a day vi) **Pioglitazone**: 15 mg or 30 mg orally once a day.	
3	**e)**	**Give adverse drug reaction of following drug:** i) **Rifampicin:** Orange-red coloured urine, Hepatotoxiciy, Nephritis ii) **Nitroglycerin**: Headache, Dizziness, light headedness, postural hypotension, flushing iii) **Ibuprofen**: Gastritis, allergic reaction, precipitation of bronchial asthma, nephrotoxicity iv) **Digitalis:** Hypokalemia, Cardiac arrhythmia ,Anorexia v) **Insulin:** Hypoglycemia, Allergic reaction vi) **Kanamycin**: Ototoxicity, Nephrotoxicity, teratogenicity	**0.5 EACH**
3	**f)**	**Give therapeutic use of following drugs:** i) **Acyclovir:** As antiviral agent in Chicken pox, Herpes ii) **Noscapine:** As antitussive agent ,used in cough iii) **Indapamide:** Diuretic, Antihypertensive iv) **Cetrizine:** As antihistaminic, antiallergic, v) **Loperamide:** As antidiarrheal agent vi) **Bisacodyl:** As laxative, in treatment of constipation.	**0.5 EACH**
4		**Attempt any FOUR of the followings**	**12M**
4	**a)**	**Classify antiasthmatic agents with examples.** **a)Bronchodilators :** i) Sympathomimetic: Salbutamol, Terbutaline, Adrenaline, Isoprenaline, Ephedrine ii) Xanthines: Theophylline, Aminophylline iii) Anticholinergics: Atropine **b)Anti-inflammatory agents:** i) Systemic: Hydrocortisone, Prednisolone	**3M**

		ii) Inhalational: Beclomethasone,Triamcinolone **c) Mast cell stabilizers**: Disodium chromoglycate, Ketotifen **d) Other agents**: Montelukast	
4	**b)**	**Give the pharmacological profile of adrenaline.** 1. On Heart: - Adrenaline with its action on B-receptors of heart increases heart rate, force of contraction and cardiac activity. 2. On Blood vessels and blood pressure: - The blood vessels of skin and mucous membrane are constricted. Adrenaline dilates blood vessels of skeletal muscles by acting on B-receptors. The net result is thus decrease in peripheral resistance. It show biphasic response in moderate dose 3. On Smooth muscles:-It causes relaxation of smooth muscles of bronchi, GIT, uterus etc. It is a powerful bronchodilator 4.Central Nervous system:- Therapeutic doses of adrenaline may give rise to tremors, restlessness, palpitation and apprehension 5. Metabolism:- It produces hyperglycemia by accelerating glycogenolysis in the liver. 6. Antiallergic action: - Adrenaline is a physiological antagonist of histamine and counters the bronchoconstriction and hypotension of anaphylactic shock. 7. If combined with local anesthetic prolongs its action locally.	**3M**
4	**c)**	**Define haematinics. Explain: Vitamin B12 injection is given in pernicious anaemia.** **Haematinics:** Are the drugs which when administered favour erythropoiesis i.e. synthesis of red blood cells and increase the oxygen carrying capacity of the blood. Eg: cynocobalamine, folic acid, iron etc. Pernicious anaemia is a type of vitamin B_{12} deficiency that results from impaired uptake of vitamin B_{12} due to the lack of a substance known as intrinsic factor produced by the	**1M defn.** **2M Expln.**

		stomach lining. So Vitamin B_{12} injection is given in pernicious anaemia because oral absorption is not possible due to lack of intrinsic factor	
4	**d)**	**Define epilepsy. Justify: During the treatment of epilepsy antiepileptic drugs should not be withdrawn abruptly.** Epilepsy is neurological disorder characterized by sudden periodic attacks of motor, sensory or psychological malfunction. The attacks called as seizures are initiated by the abnormal & irregular discharges of electricity from millions of neurons in the brain. Epilepsy is a periodic disturbance in the rhythm of the brain. The drugs used for the treatment of epilepsy require long term administration in order to prevent epileptic attacks. Since the antiepileptics mainly act by depressing the CNS, they may lead to recurrence of epileptic attack if withdrawn suddenly. So, during the treatment of epilepsy, drugs should be withdrawn gradually to avoid withdrawal syndrome.	**1M def.** **2M Expl.**
4	**e)**	**Classify Parasympathomimetics with examples.** **Parasympathomimetics-** These are the drugs which produce the actions similar to those seen by the stimulation of parasympathetic nervous system. **Classification:** □ Esters of choline- Methacoline, carbachol, Acetylcholine □ Cholinomimetic alkaloids- Piolcarpine, Muscarine □ Cholinestrase inhibitors- a) Reversible :-Neostigmine, physostigmine, pyridostigmine. b) Ireversible:- Organophosphorus compounds, (malathion, parathion)	**1.5M Types** **1.5M Examples**

4	**f)**	**Discuss the stages of general anaesthesia. Give two examples of parenterally administered general anaesthetics.** Stages of anaesthesia i. Stage of analgesia ii. Stage of delirium or excitement iii. Stage of surgical anaesthesia iv. Stage of respiratory paralysis STAGE 1- Stage of analgesia --- This stage is characterized by loss of pain sensation. Minor surgical operations and dental extractions are performed in stage STAGE 2-Stage of delirium --- This stage is characterized by excitement, thus no surgical procedures are performed in this stage STAGE 3- Stages of Surgical Anaesthesia: As more anaesthetic agents gets in deep breathing starts and the patient passes into the third stage of anaesthesia. The stage extends from the end of second stage until cessation of spontaneous respiration. The effects of this stage are recognized by following signs: 1. Regular respiration is regained after second stage. 2. Skeletal muscles are relaxed. 3. The gradual loss of reflexes such as eyelid and conjunctival reflexes and 4. The eye balls are roving. Major surgical operation is done in this stage. STAGE 4- Stage of respiratory paralysis--- Excessive administration of anaesthetic agent may lead to this stage. It is characterized by stoppage of breathing, fall of blood pressure	**2M for stages 1M for any two correct examples**

		and cardiac collapse. It leads to the death. **Examples Of general anaesthetic:** By Inhalation: Diethyl ether, Halothane, Trichloroethylene, Nitrous oxide. By intravenous : Thiopental sodium, Methohexital, Etomidate, Ketamine, Propofol	
5		**Attempt any <u>FOUR</u> of the following:**	**12M**
5	**a)**	**Classify antihypertensives with examples.** Classification (According to site of action): 1. Centrally acting Drugs: Clonidine, Methyl Dopa 2. Drugs acting on autonomic ganglia: Hexamethonium 3. Drugs acting on post ganglionic sympathetic nerve endings a) Adrenergic neuron blockers; Guanethidine b) Catecholamine depletors: Reserpine 4. Drugs acting on adrenergic receptors: a)Alpha adrenergic blockers: Phentolamine b) Beta adrenergic blockers: Propranolol 5. Vasodilators: Hydralazine 6. Drugs acting reflexly by stimulating baroreceptors: Veratrum 7. Oral Diuretics: Thiazides, Frusemide, spironolactone, amilorideetc 8. Calcium Channel Blockers: Nifedipine, Amlodipine, Felodipine 9. Drugs acting on rennin angiotensin system: a) ACE inhibitors: Enalapril, Ramipril b) Angiotensin Receptor Blockers: Losartan, Telmisartan 10.Miscellaneous: MAO inhibitors (Pargyline)	**3M**
5	**b)**	**What is cancer? Give examples of two anticancer drugs. Mention common side effects of anticancer drugs.** Cancer is uncontrolled growth of abnormal cells. It is characterized by excessive cell growth (in the form of tumor), ability to metastasize & a shift of cellular metabolism.	**1M def. 1M.any 2 correct examples**

		Examples of anticancer drugs: Chlorambucil, Cyclophosphamide,Busulphan Methotrexate, 6-mercaptopurine, 5-Flurouracil, Cytosine,Radioiodine, Radiophosphorous, Mitomycin, Actinomycin,Vincristine,Vinblastine etc. **Common side effects of anticancer drugs:** • Anemia ,Tiredness. • Nausea, vomiting. • Loss of appetite. • Constipation or diarrhoea. • Hair loss.(Alopecia) • Skin changes or reactions, Joint Pain • Electrolytes changes • Cardiac side effects	**1M any 4 side effects**
5	**c)**	**Classify antibiotics with example.** Classification of antimicrobial agents can be based on: Their site of action or Chemical structure or Activity against particular type of organisms. Based on site of action antibiotics can be classified as: 1. Inhibitors of cell wall synthesis eg Penicillins 2. Inhibitors of cell membrane function eg Polymixin 3. Inhibitors of protein synthesis eg Tetracyclins 4. Inhibitors of nucleic acid synthesis/ function; eg Rifampicin 5. Inhibitors of metabolism eg Sulpha drugs **Or** • Effective against gram +ve bacteria: Penicillin etc • Effective against gram -ve bacteria: Streptomycin etc • Effective against both gram +ve & gram -ve bacteria:	**3M.**

		Tetracycline, Chloramphenicol.etc Effective topically :Framycetin ,Polymixin B,neomycin etc **Any other correct classification can be considered.**	
5	**d)**	**Define analgesics. Justify: Morphine should not be given in abdominal pain.** **Analgesics:** These are the pharmacological agents which relieve or suppress the pain sensation. **Examples: N**arcotic analgesics like Morphine, Codeine etc., Non narcotics like Aspirin, Paracetamol, Indomethacin, Ibuprofen, Piroxicam, Diclofenac etc. **Justify: Morphine should not be given in abdominal pain.** Morphine is not given in severe abdominal pain before diagnosis is made because morphine is narcotic analgesic which relieves pain without modifying the underlying pathological process. It interferes with the diagnosis by masking pain and creates a false sense of security. It also induces vomiting. Its spasmogenic actions on the G.I.T. and biliary tract are additional drawbacks. Therefore morphine is not given in severe abdominal pain before diagnosis is made.	**1M Defn** **2M** **Jstifn**
5	**e)**	**Give pharmacological profile of aspirin.** i) Analgesia- aspirin relieve pain by acting centrally as well as peripherally by inhibiting the formation of prostaglandins. Epigastric distress, gastric bleeding and ulcers. ii) Antipyrexia- aspirin reduce body temperature by acting on hypothalamus (central effect) iii) Action on Gastrointestinal Tract: Aspirin causes GI irritation,.nausea, vomiting, dyspepsia, epigastric distress, gastric bleeding and ulcers. iv) Uricosuric effect- In large doses it inhibits reabsorption of urate by nephron. This results in uricosuria. v) Anti-inflammatory- aspirin acts as potent anti-inflammatory agent by	**3M for any six points**

		inhibiting prostaglandin synthesis. It decreases capillary permeability, reduces exudation of fluid & reduces development of inflammatory edema. vi) On blood- aspirin reduces platelet aggregation vii) On respiration- Aspirin stimulates respiration by direct action on medullary respiratory centre. It increases oxygen consumption by skeletal muscles thereby increasing plasma CO_2 concentration. viii) Hepatic and renal effects- may damage liver and kidneys in large doses. ix) Metabolic effects- aspirin causes conversion of large part of energy into heat. So it may cause hyperpyrexia in large doses. It may also cause hypoglycaemia.	
5	**f)**	**Give symptoms and management of acute barbiturate poisoning.** **Symptoms:-** Shallow respiration, fall in B.P., cardiovascular collapse, renal shut down, pulmonary complications, bullous eruptions. **Management:-** **Gastric lavage:** - leave a suspension of activated charcoal in the stomach to prevent absorption of the drug from intestine. **Artificial respiration:** Endo tracheal intubation: to treat hypoventilation **Supportive measures:** Intravenous fluids to prevent dehydration, to maintain blood volume and use of vasopressor if needed. **Alkaline diuresis:** - with sodium bicarbonate 1meq/kg iv. With or without mannitol (is helpful only in the case of long acting barbiturates which are eliminated primarily by renal excretion). Use of analeptic if needed	**1M Symptoms 2M Management**
6		**Give reasons for any <u>FOUR</u> of the following:**	**16M**
6	**a)**	**Sulphonamides are not much in use nowadays.** Sulphonamides show a number of side effects such as intolerance, fever, severe skin rashes, joint pain, toxic hepatitis, toxic nephritis, acute haemolytic anemia. It causes renal irritation, crystallurea, haematuria and obstruction of urine flow. Bacterial resistance is also a problem with sulpha drugs.	**4M**

		Since better drugs are available with fewer side effects for the treatment of diseases, Sulponamides are not much in use now a days.	
6	**b)**	**Atropine is given along with neostigmine in myasthenia gravis.** Myasthenia gravis is a skeletal muscle disorder causing muscle weakness and muscle fatigue. Nicotinic receptors are present in skeletal muscles and muscarinic receptors are present in heart blood vessels and eye balls. Neostigmine acts on both the receptors. In myasthenia gravis, only nicotinic action of neostigmine is required. Hence to mask the muscarinic actions of neostigmine, and thus to avoid the side effects, the muscarinic blocker atropine is given in combination	**4M**
6	**c)**	**Levodopa is given in combination with carbidopa.** Levodopa is the precursor of dopamine. And is used in treatment of parkinsonism. Levodopa can cross the blood brain barrier but dopamine cannot. In brain, L-dopa is metabolized to dopamine thereby replenishing the deficient neurotransmitter. The metabolism takes place in the presence of DOPA decarboxylase. Large amount of L-Dopa gets peripherally converted to dopamine and thus small amount reaches the brain. To overcome this problem, higher dose of Levodopa is required to increase the clinically effective level of dopamine in the brain which results in toxicity. Carbidopa does not cross the blood brain barrier but it inhibits peripherally dopa decarboxylase. Thus Carbidopa does not interfere with the conversion of L-dopa to dopamine in the CNS but prevents the conversion of Levodopa to dopamine peripherally.	**4M**
6	**d)**	**Penicillin are called lifesaving as well as life threatening drug.** Penicillin is an antibiotic used in different diseases like Syphillis ,Gonorrhea, Diphtheria, Gangrene, Tetatus, Meningitis etc. Thus it is a lifesaving drug. Penicillin in therapeutic dose if randomly administered by parenteral route to an individual without checking its allergy, then it may produce severe allergic reaction such as anaphylactic shock. Hence it is a life threatening drug.	**4M**
6	**e)**	**Quinidine is given to patient who is on digoxin therapy.** Quinidine is antiarrythmic drug while Digoxin is Cardiotonic drug.	**4M**

		Major adverse effect of digoxin is that it causes cardiac arrhythmias like extra systole & Bradycardia. Quinidine reduces heart rate and automaticity and corrects arrhythmia. Hence to avoid cardiotoxicity induced by digoxin, quinidine may be given. (Note: In some cases, Quinidine is found to increase the Digoxin serum concentration and may induce Digoxin toxicity and thus Digoxin- Quinidine interaction should be avoided or precautions should be taken.)	
6	**f)**	**Higher the therapeutic index, safer will be drug. Justify the statement.** Therapeutic index indicates the relative margin of safety of a drug. A dose of the drug which produces the stated effects in 50% of individuals within the population is called as 'median dose'. Depending on the stated effect it can be designated as 'median effective dose' (ED_{50}) and median lethal dose (LD_{50}). Therapeutic Index(TI) = $\frac{LD_{50}}{ED_{50}}$ The TI indicates how close the effective does is to the lethal dose for 50% of the test population. Thus, it gives an idea about the margin of safety. As the ED50 approaches the LD50, the danger of the drug toxicity increases significantly. Therefore, a drug with larger therapeutic index is safer than one with smaller therapeutic index. Hence, drug with lesser therapeutic index should be administered cautiously.	**4M**

Subject Title: Pharmacology and toxicology Subject Code: 0813

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.

Subject Title: Pharmacology and toxicology Subject Code: 0813

Q. No.	Sub Q. N.		Marking Scheme
1		**Answer any EIGHT of the following:**	**16M**
1	**a)**	**Explain the terms pharmacokinetics and plasma expanders.** **Pharmacokinetics:** It is the study of movement or passage of drug across the body. It is what body does to the drug. It includes study of Absorption, Distribution, Metabolism & Excretion (ADME) of drug. **Plasma expanders:** These are pharmacological agents with high molecular weight when administered parenterally remain in blood stream and increase circulatory fluid volume by exerting an osmotic pressure. **Examples:** Dextran, gelatin 6% solution, PVP, Physiological saline acts as plasma expanders.	**1M EACH**
1	**b)**	**Define following:** **i) Oral hypoglycaemic agents:** These are the pharmacological agents used in treatment of diabetes mellitus,are given by oral route & help in lowering elevated blood sugar level. **Examples**: Tolbutamide, Metformin,glimepiride,gliclazide,pioglitazone etc **ii) Antiseptic:** These are the agents which are used to prevent or inhibit the growth of microorganisms and can be applied to living tissues. **Examples:** Phenol, Potassium permanganate, Boric acid, Crystal violat,alocohol etc.	**1M EACH**
1	**c)**	**Mention the drug of choice in the following condition:** **i) Pernicious anaemia:** Vitamin B12, Folic acid **ii) Leukemia:** 6 mercaptopurine , Chlorambucil , Busulphan **iii) Syphilis:** Penicillin, tetracycline, doxycycline **iv) Glaucoma:** Pilocarpine, Timolol, Betaxalol, Physostigmine, Acetazolamide, Mannitol.	**0.5 M EACH**

1	**d)**	**Mention adverse effect of each of the following drug.** **i) Streptomycin:** Ototoxicity, skin rash, dermatitis, aplastic anaemia, nephrotoxicity,teratogenicity **ii) Diphenhydramine:** Blurred vision, dry mouth, sedation **iii) Phenformin:** Gastrointestinal upset, anorexia **iv) Morphine: Respiratory depression,**Euphoria, Mental clouding,addiction	**0.5 M EACH**
1	**e)**	**Mention therapeutic use of each of the following drug:** **i) Griseofulvin:** As antifungal (dermatophytic) (Used in fungal infections) **ii) Xylometazoline:** As nasal decongestants (used to treat nasal congestion) **iii) Streptokinase:** Thrombolytic agent (used to treat thromboembolism) **iv) Mebendazole:** As anthelmintic(in treatment of helminthiasis/worm infestation)	**0.5M EACH**
1	**f)**	**Mention dose of each of the following drug.** **i) Ranitidine:** 150-300mg 1-2 times daily for 4-8 weeks **ii) Ibuprofen:** 200 to 400 mg t.i.d. **iii) Verapamil:** 40 to 80 mg mg t.i.d. **iv) Amphetamine:** 5 mg to 60 mg daily in divided doses	**0.5M EACH**
1	**g)**	**Mention route of administration of the following drug.** **i) Nitroglycerine:** Sublingually/oral /parenteral /topical **ii) Insulin:** Parenteral (Subcutaneous) **iii) Paraldehyde:** Intramuscular, Rectal (enema), oral **iv) Sulphacetamide:** Opthalmic, Topical,	**0.5M EACH**
1	**h)**	**Mention the drug which produces following adverse effect:**	**0.5M EACH**

		i) Anaphylactic shock: Beta lactam antibiotics like Penicillin G injection,and **ii) Black water fever:** Quinine **iii) Methaemoglobinemia:** Aspirin, Paracetamol, Trimethoprim, Dapsone, Benzocaine, Aniline dyes **iv) Postural hypotension:** Propranolol,imipramine like TCAs,nitrates etc	
1	**i)**	**Explain triple response of histamine** When histamine is applied locally or injected intradermally on skin, histamine produces a typical response known as "triple response" which is characterized by three distinct signs: **i. Flush-** it is redness at the site of application because of hyperemia. **ii. Flare-** Patch formation in the vicinity of 1.5 cm of flush occurs due to vasodilation & this is called as flare. **iii. Wheal-** around 1.5cm of flare permeation of fluid occurs, raising the surface and its called as wheal (swelling formation)	**2M**
1	**j)**	**Mention the drug which is contraindicated in following condition:** **i) Oedema:** Estradiol, NSAIDs, All steroids etc. **ii) Insomnia:** Analeptics like Caffeine, Amphetamine etc. **iii) Constipation:** Morphine, Atropine etc. **iv) Photophobia:** Ibuprofen, Methotrexate, Tetracycline etc.	**0.5M EACH**
1	**k)**	**Explain mechanism of action of acetazolamide** Acetazolamide produces diuretic action by carbonic anhydrase inhibition in kidney. Due to carbonic anhydrase inhibition, H^+ ions are not produced. This reduces reabsorption of Na^+. Bicarbonate ions are also excreted in urine. It acts as self-limiting diuretic.	**2M**
1	**l)**	**Give reason- In treatment of myasthenia gravis atropine is used along with neostigmine.** • Myasthenia gravis is the disease characterised by skeletal muscle weakness. Skeletal muscles have nicotinic group of receptors • Neostigmine being a parasympathomimetic, acts on both muscarinic as well as nicotinic receptor.	**2M**

		• When neostigmine is used in treatment of myasthenia, it produces nicotinic action on skeletal muscle, which is desired therapeutic action but at the same time it produces several side effects on heart,smooth muscles,secretions by acting on muscarinic receptors • To mask these unwanted muscarinic actions of neostigmine, an anticholinergic, anti-muscarinic atropine is administered with neostigmine.	
2		**Attempt any FOUR of the following**	**12M**
2	**a)**	**Give symptoms and treatment of belladona poisoning.** **Symptoms:** Dryness of mouth, marked thirst, increase in body temp, weak pulse, Some central effects are restlessness, confusion, hallucination, Convulsions, coma, blurred vision **Treatment:** i) Gastric lavage: - to remove unabsorbed poison should be done if poisoning is through oral route. ii) The patient should be kept in dark quiet room iii) Cold sponging or ice bags are applied for reducing body temperature iv) Physostigmine 1-3mg S.C.or I.V.antagonizes both central and peripheral effects v) Catheterization in case of urine retention vi) IV fluids if necessary, artificial respiration.	**1M Symptom 2M Treat**
2	**b)**	**State the factors modifying drug absorption and explain any two of them** - Physical state of drug - Particle size - Diffusion rate of drug- - Absorbing surface area - Functional integrity of GIT - pH of drug and pH of GIT **Physical state of drug:** Liquid dosage forms absorb faster than solid dosage form. **Particle size:** Smaller the particle size greater is the absorption.	**1M factors 1M Each For any two Expl.**

		Diffusion rate of drug- Diffusion rate is directly proportional to lipid solubility of drug **Absorbing surface area:** Larger the surface area better is the absorption. Drugs better absorbed from small intestine than stomach. **Functional integrity of GIT:** Increase in peristalsis (increase GI motility) reduces residence time of drug in GIT so reduced absorption, as in case of diarrhoea **pH of drug and pH of GIT:** Weakly acidic drugs remain unionized in acidic pH of stomach and are better absorbed in the stomach. Weakly basic drugs remain unionized in alkaline pH of the intestine and are better absorbed from the intestine. Strongly acidic and basic drugs do not get absorbed well from GIT.	
2	**c)**	**Define excretion. Enlist different routes of excretion of drug with at least two examples of each.** **Definition:** The process of elimination of drugs from the body is called as excretion Important Channels of drug excretion are Kidneys ,Lung, Intestines ,Skin, Bile, Saliva & milk **Kidneys:** Most of the drugs are excreted in urine Weak acids are quickly excreted in alkaline urine & vice versa. Ex. Penicillin, salicylic acid **Lungs:** Excretion of gaseous inhalants. Volatile general anesthetics, alcohol, paraldehyde. Easily detected by breath smell **Intestines**: Purgatives like senna are partly excreted in intestine Heavy metals also through faeces. **Skin:** Metalloids like arsenic, lead **Saliva & milk**: Antibiotics, sulphonamides, morphine excreted in milk. **Bile:** Erythromycin, novobiocin eliminated in bile & reabsorbed in intestine. It prolongs the action.	**1M Def.** **1M Routes** **1M Ex.**
2	**d)**	**Classify various routes of administration of dug. Give advantages and disadvantages of oral route.** **1.Enteral:** Oral	**1M Routes** **1M for any two adv. & Disadv.**

		Sublingual Rectal **2.Parenteral:** **Injections:** Intravenous,Intraarterial,Intramuscular,Subcutaneous,Intraperitoneal,Intrathecal, Intramedullary ,Intraarticular **Inhalations** **3.Local** **Advantages of oral route:** 1. It is simple and most convenient. 2.Self-medication is possible 3.It is cheaper 4. No complications **Disadvantages of oral route:** 1.Slow onset of action 2.100% absorption is not possible &bioavailability is variable & get affected by presence of food, other drugs 3. The irritant and unpalatable drugs can't be given. 4. In case of severe vomiting or in unconsciousness, uncooperative patient ,oral route can't be used. 5. Few drugs which cannot be absorbed from GIT are not given by this route. 6.Drugs which get degraded in GIT can't be given .e.g Insulin	
2	**e)**	**Tetracycline is contraindicated in pregnant women and children.** • Tetracyclines are teratogenic drugs and cross the placental barrier when taken by pregnant females. • It complexes the calcium and makes it unavailable for foetal development which results in bone deformity, staining of teeth etc	**3M**

		• Tetracyclines if taken by children, lead to bone deformity and affect the overall skeletal growth. • It affects the deciduous and permanent teeth formation in children. • Hence it is contraindicated in pregnant women and children.	
2.	**f)**	**Explain how following factors affect drug action:** **i) Sex:** Females require smaller doses of drugs due to their lesser body weight. Drug must be administered with due care in females during menstruation, pregnancy or lactation. **ii) Cumulation:** If excretion rate of particular drug is slow, its repeated administration may built up high concentration in plasma, which is termed as cumulation. Eg: Phenobarbitone in epilepsy treatment, digitalis in CCF **iii) Time of administration:** **Time in relation with food:** Some of the drugs are advised to be taken on empty stomach to get quick action, or to avoid interference of food or to prevent destruction of drugs by digestive enzymes eg: antibiotics like penicillin, tetracycline Most of the drugs are advised to be taken after meal so as to reduce risk of gastric irritation, nausea and vomiting eg salicylates and derivatives **Time in relation with side effects:** Diuretic like drugs should be taken in morning and should not be taken at night as it can cause frequent urination during night	**1M EACH**
3		**Attempt any FOUR of the following**	**12M**
3	**a)**	**What is absorption? Explain active transport process of absorption.** Absorption of drugs means entry of drug in the blood circulation. **ii) Active transport-** it is the transfer of drug against concentration gradient and needs energy. It is carried by specific carrier protein. Compound binds to a specific carrier on one side of the membrane and moves across the cell. The complex then dissociates and the carrier moves back to transport another molecule. Ex. Iron, Sugars , Amino acid , Levodopa etc.	**1M define** **2M Expl.**
3	**b)**	**What is drug antagonism? Explain pharmacological antagonism with suitable**	**1M Def.**

		examples. The opposite action of two drugs on the same physiological system is called as Antagonism. **1) Antagonism at receptor level:-** a) Reversible/ competitive antagonism – the agonist and antagonist compete for Same receptors. By increasing the concentration of agonist the antagonism can be overcome. It is reversible Eg – Acetylcholine and atropine compete with each other at receptor site. b) Irreversible antagonism – Antagonist bids by covalent bonds to the receptor and it dissociates very slowly or not at all. So it blocks action of agonist and blockade cannot be overcome by increasing the dose of agonist so irreversible. Ex. Adrenaline and Phenoxybenzamine at alpha adrenergic receptors. **2) Noncompetitive antagonism:** The antagonist block at the level of receptor effector linkage that is at a different site beyond the receptor and not on the receptor. Ex. Verapamil blocks cardiac calcium channels and inhibits entry of calcium during depolarization so antagonizes effect of Isoprenaline and Adrenaline.	**2M Expl.**
3	**c)**	**Define analgesics and antipyretics. Explain why aspirin is not used in patient with peptic ulcer.** **a)Analgesics:-** These are the drugs which are used for suppression of pain. **b)Antipyretics:-** These are the agents which reduce the elevated body temperature. **Aspirin is not given in peptic ulcer.** 1. In peptic ulcer, there are lesions in the stomach, associated bleeding and pain. 2. Aspirin causes irritation to stomach, gastric erosion, gastritis, gastric ulcer and G.I bleeding. 3. Thus aspirin can worsen the condition of peptic ulcer and hence should not be given.	**1M EACH**
3	**d)**	**Define local anaesthetics. Discuss various methods of producing local anaesthesia.** Definition: Local anaesthetics are pharmacological agents which when applied or	**1M Def. 2M Methods**

		injected, block the conduction as well as generation of impulses in localized area and bring loss of sensation without affecting degree of consciousness. OR They are the compounds that when applied in appropriate concentration, block nerve conduction in the area of application. Examples: cocaine, lignocaine, benzocaine etc. **Methods of producing local anaesthesia**- **(I) By paralyzing of nerve endings:** i) Application to mucus surface, skin, wounds (surface anaesthesia): In this case the LA is just applied on the skin or mucus membrane. ii) By hypodermic injection: LA is injected under the skin layer. iii) By infiltration: Here LA is injected first intradermally, then subcutaneously and then into deeper tissues. **(II) By blocking the sensory impulse:** i) Block anaesthesia: Here the LA is injected close to nerve trunk ii) By spinal anaesthesia: The LA is introduced after lumbar puncture iii) By caudal anaesthesia: The LA is injected into epidural space.	
3	**e)**	**Define anti-parkinsonian drugs. Write the mechanism of action of Levodopa.** **Anti-parkinsonian drugs**:- The dopaminergic or central antimuscarinic drugs which restore balance between excitatory cholinergic and inhibitory dopaminergic nerve impulses at basal ganglia to reduce muscle rigidity and used in parkinsons disease. **Mechanism of Levodopa**: Dopamine is stored and released as a neurotransmitter in dopaminergic neurons. But cannot cross blood brain barrier. Levodopa is precursor of dopamine. Levodopa crosses blood brain barrier and is converted to dopamine by action of DOPA Decarboxylase. Hence it improves the symptoms of Parkinson's disease.	**1M Def.** **2M** **MOA**

3	**f)**	**Give the differences between Drug habituation and Drug addiction.**	**3M**

Drug habituation	Drug addiction
It is a condition resulting from repeated administration of a drug	It is a state of periodic or chronic intoxication produced by repeated consumption of a drug.
There will be desire but not compulsion to continue taking the drug for the sense of well-being.	There will be overpowering desire to continue taking the drug and obtain it by any means.
Little or no tendency to increase the dose.	There is a tendency to increase the dose.
Some degree of psychic dependence but absence of physical dependence and hence of an abstinence syndrome	A psychological and generally a physical dependence on the effect of the drug
If any detrimental effect, it is on the individual. Ex. Tea, Coffee.	The effect is detrimental to the individual and to the society. Ex. Alcohol, Narcotics, Nicotine.

4		**Attempt any FOUR of the following:**	**12M**
4	**a)**	**Write symptoms and treatment of Acute barbiturate poisoning.**	**1M Sym. 2M Treat.**

Symptoms –

Marked excitement, renal failure, pulmonary oedema, cardiac irregularities, cold skin, paralytic dilation of pupil, weak but rapid pulse, respiratory failure.

Treatment –

1) If patient is conscious and within 4 hrs. of ingestion, patient can be induced vomiting with concentrated salt solution or syrup of ipecac. If patient is unconscious, simple stomach wash i.e. gastric lavage is performed.

2) If respiration is slightly affected, oxygen can be given by nasal catheter. If respiration is depressed considerably, endotracheal intubation is done.

3) Forced diuresis- diuretics like mannitol or frusemide is given to increase urinary

		excretion of barbiturates. 4) Alkalinization of urine – Sodium bicarbonate is used for alkalinization of urine which helps in excretion of barbiturates. 5) Prophylactic antibiotics – To prevent infection, antibiotics are used in case of catheterization or tracheostomy 6) Administration of IV fluids –Forced diuresis may result in dehydration. So, administration of fluids is advised.	
4	**b)**	**Classify purgatives with examples. Give mechanism of action of castor oil as purgative.** **Classification:** **I) Stimulant or Irritant purgative** (a) Anthracene group-e.g. Rhubarb, Senna. Aloe. Cascara **(b)** Castor oil (c) Bisacodyl can be given by mouth or as suppository **II) Bulk Purgative:** (a) Saline Laxatives-e.g .Magnesium sulphate, Sodium potassium tartarate, Potassium phosphate, (b) Methyl cellulose, Sodium carboxy methyl cellulose, Plantago , Agar Agar **III) Lubricant / Emollient Purgative:** e.g Liquid paraffin , Dioctyl sodium sulphosuccinate **Mechanism:-** When taken orally, castor oil is hydrolyzed in the intestine by pancreatic lipase to glycerol and ricinoleic acid. The ricinoleic acid stimulates the peristaltic movement of small intestine thus acting as irritant purgative. Full dose of castor oil produces purgation in 2-6 hrs.	**2M Class. 1M MOA**
4	**c)**	**d) What is status asthmaticus? Give its treatment.** • Serious medical emergency due to severe persistent asthmatic attack associated with respiratory failure or insufficiency. It is a medical emergency and needs hospitalization. **Treatment:** • Careful administration of oxygen, salbutamol nebulizer, oral corticosteroids.	**1M Def. 2M Treat.**

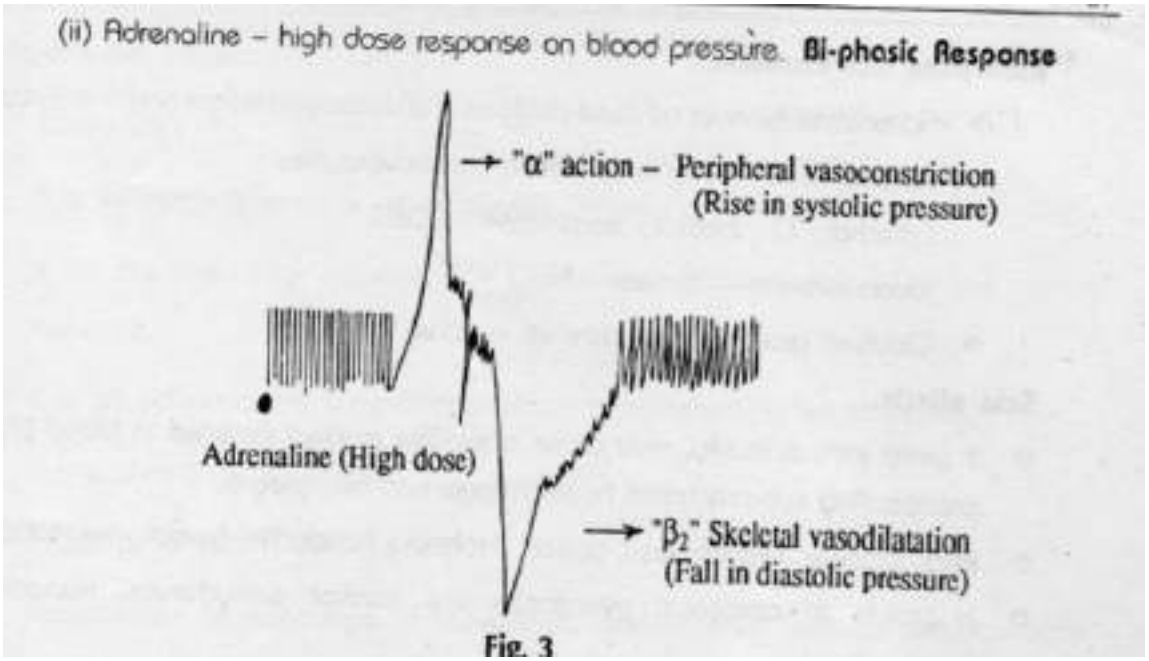
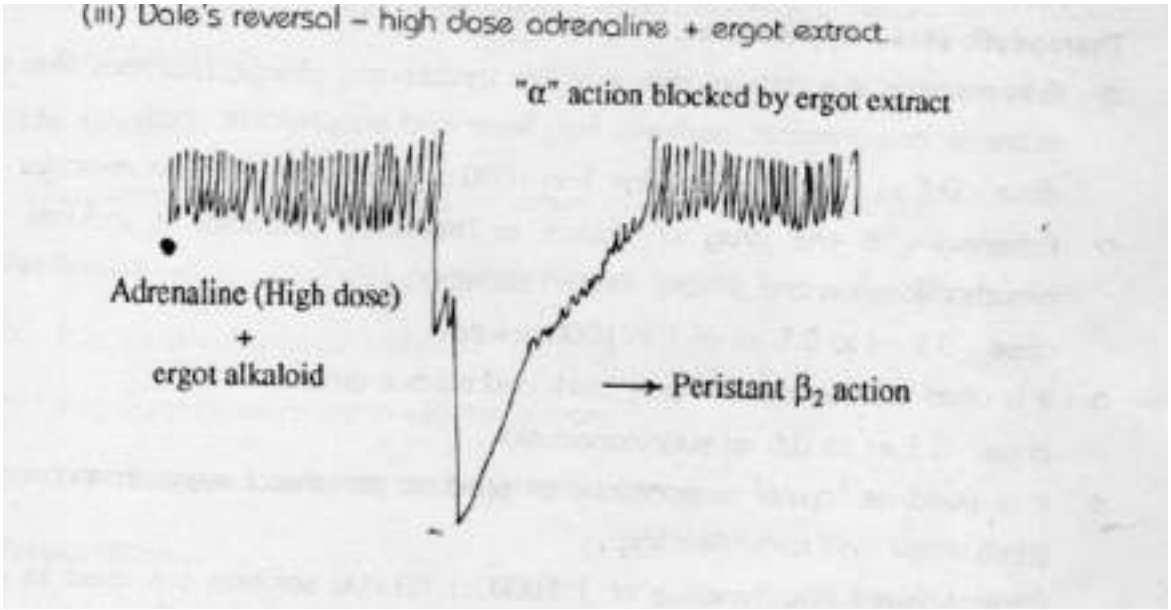
		• If poor response patient is hospitalized. Repeat salbutamol nebulizer every 30 minutes. IV corticosteroids, IV aminophylline or salbutamol, antibiotics are used. If still serious shift to I.C.U. • In case of chronic persistent asthma the drugs should be taken in rotation. Salbutamol & orciprenaline during acute attacks & then corticosteroids.	
4	**d)**	**Define and give two examples of Anthelmintic. Why purgatives are administered with Anthelmintic.** **Anthelmintic:** These are the agents used in treatment of helminthiasis, infestation of worms. Ex. Piperazine,Pyrantel pamoate, Albendazole , Mebendazole,etc. **Why purgatives are administered with Anthelmintic.** Anthelmintics are either wormicidal or wormifugal in action. Thus after killing or paralyzing these worms, worms should be expelled out from intestine. Purgatives are the agents which evacuate the bowel; hence purgatives are advised as supportive treatment with anthelmintics.	**1M Def.** **1M** **Any two** **Ex.** **1M GR**
4	**e)**	**Define anti-arrhythmic drugs. Patients of atrial fibrillation are digitalized before giving quinidine, Why?** **Antiarrhythmic agents:-** These are the agents used to correct cardiac arrhythmia i.e. disturbance in cardiac rhythm. Eg: Quinidine, Procainamide, Propranolol, Lignocaine, Phenytoin, etc. Digitalis corrects heart failure associated with fibrillation. Quinidine therapy alone may lead to rapid ventricular rate during conversion of fibrillation of normal sinus rhythm. In atrial fibrillation where many ventricular premature beats are present, digitalis helps to slow ventricular rate while quinidine abolishes premature beats. (Digitalis and Quinidine both can cause conduction block)	**1M def.** **2M GR.**
4	**f)**	**Define Diuretics. Why diuretics are used along with anti-hypertensive drugs.** **Diuretics:** These are the pharmacological agents which when administered, increase rate of formation of urine as well as excretion of urine. **Antihypertensives are given along with diuretics**. Excess plasma sodium and fluids are present in hypertension. Diuretics inhibit reabsorption of sodium and its equivalent osmotic amount of water and causes its excretion.. This causes decrease in plasma fluid which decreases BP. Diuretics also cause	**1M Def.** **2M GR.**

		vasodilation and decreases BP. Therefore, antihypertensives are given with diuretics.	
5		**Attempt any FOUR of the following:**	**12M**
5	**a)**	**Describe mechanism of action & give therapeutic uses of Digitalis.** Digitalis directly acts on myocardium & increases conductivity, automaticity, rhythmicity & causes forceful contraction of heart. Digitalis derivatives block Na+--K+ ATPase enzymes & improve levels of Na+ & acts as shown below: Digitalis blocks Na+ -- K+ ATPase enzyme ↓ Increases Na+ level ↓ Activates sarcoplasmic reticulum, also stimulates Na-Ca exchange ↓ Releases Ca++ ↓ Increase intracellular calcium ↓ Combines with cardiac muscles ↓ Causes forceful contraction ↓ Leads to complete emptying of heart. Thus relieves congestion It restores myocardial function. Thus heart can do work with less energy expenditure. **Therapeutic Uses Of digitalis**: It is useful in Congestive cardiac failure Left ventricular failure Paroxysmal supraventricular tachycardia Atrial fibrillation Atrial flutter	**2M** **MOA** **1M** **Uses**
5	**b)**	**Define oral contraceptives. Explain different types of oral contraceptives.** **Oral contraceptives**: Are the orally administered agents used for reversible suppression of fertility or agents used for preventing conception. **Types: - Pills are hormonal or non-hormonal.** 1.Combined Pills :Regular contraceptive pill, which contain estrogen and progestin and	**1M Def.** **2M Expl.**

		commonly used pills are taken from 5th day of menstruation for 21 days 2. Mini Pills: Which contain only progestin 3. ECPs (Emergency Contraceptive pills):contains Levonorgestrel .,to be taken only as an emergency, within 72 hours of unprotected sex. 4. Centchroman: Non-hormonal pill, to be taken initially twice a week followed by once in a n week	
5	**c)**	**Define & classify antineoplastic drugs with examples.** **Definition:** Antineoplastic drugs describe a group of medicines that contain chemicals which are toxic to cells, preventing their replication or growth, and so are used to treat cancer. **Classification with examples:** **I. Alkylating agents:** • Nitrogen mustards:E.g.: Chlorambucil, Mechlorethamine • Ethylenimines:E.g.: Triethylenemelamine, Triethylenethiophosphamide • Alkylsulphones:E.g. : Busulphan **II. Antimetabolites:** • Folic acid antagonists:E.g.: Methotrexate • Purine Antagonist:E.g.: 6-mercaptopurine • Pyrimidine Antagonist:E.g.: 5-Flurouracil, Cytosine **III. Radioactive Isotopes:** E.g.: Radioiodine, Radiophosphorous **IV. Antibiotics:** E.g.: Actinomycin-D, Mitomycin **V. Hormones:** E.g.: Androgens, Estrogens, Corticosteroids **VI. Enzymes:**E.g.: L-asparginase **VII. Vinca alkaloids:** E.g.: Vincristine, Vinblastin **Miscellaneous Agents:**E.g.: Hydroxyurea, Cis-platin	**1M Def.** **2M Class.**
5	**d)**	**Give primary goals & different regimens used in treatment of tuberculosis.** **Goals of TB Treatment** 1.To treat M. tuberculosis infection to cure the patient	**1M Goals** **2M Regimens**

		2.Prevention of the development of drug resistance 3..Preventing relapse of disease 4.Prevention of M. tuberculosis transmission **Different regimens used:** **Frequently used combinations are:** Rifampicin + INH Ethambutol + INH Rifampicin + INH + Pyrazinamide Rifampicin + INH + Pyrazinamide + Ethambutol **Short course chemotherapy includes** Rifampicin + INH + Pyrazinamide for 2 months & then Rifampicin + INH for next 4 months. Ethambutol or Streptomycin may also be added.	
5	**e)**	**Write mechanism of action & therapeutic uses of penicillin**. **Mechanism of action:** Penicillin act by interfering with cell wall mucopeptide synthesis so that organisms explode from internal pressure. Thus it is bactericidal in nature. It is effective against multiplying organisms as resting organisms are not making new cell wall. It doesn't interfere with tissue cell wall synthesis in humans. **Therapeutic Uses:** Useful in streptococcal, pneumococcal, staphylococcal infections. Useful in treatment of respiratory tract infections Pneumonia, Pharyngitis, Diphtheria etc. Useful in treatment of venereal diseases like Syphilis, Gonorrhoea. Used in Meningitis, endocarditis ,rheumatic heart condition	**1.5 M EACH**
5	**f)**	**What are anticoagulants? Classify them. Give mechanism of action of Warfarin Sodium** Anticoagulants are the chemical substances that prevent or reduce coagulation of blood, prolonging the clotting time. **Classification:** **In Vitro anticoagulants**: Oxalic acid, Sodium citrate, Sodium Edetate, Heparin **In Vivo anticoagulants:** **Oral:** Coumarin derivatives: Warfarin,acenocoumarol Indanedione Derivatives: Phenindione	**1M EACH**

		Parenteral: Heparin, Heparin derivatives, Hirudin etc **Mechanism of action of Warfarin Sodium:** It acts by interfering with synthesis of vitamin K dependent clotting factors in the liver.	
6		**Attempt any FOUR of the following:**	**16M**
6	**a)**	**Mention different stages of general anaesthesia. Explain Surgical anaesthesia in details.** Stages of anaesthesia i. Stage of analgesia ii. Stage of delirium or excitement iii. Stage of surgical anaesthesia iv. Stage of respiratory paralysis **The Surgical anaesthesia** can be divided into 4 planes. Surgical procedure is done in this stage. **Plane i** - reflexes controlling voluntary muscles begin to go, pupil diameter return to initial size **Plane ii** - respiration becomes more regular and the eyelid reflexes are abolished. **Plane iii**- there is an incomplete intercostal paralysis. thoracic movement is reduced and lags behind abdominal movement. surgery is normally carried out at this stage. **Plane iv** - there is a complete intercostal paralysis. the purely abdominal breathing is rapid and shallow, pupil dilate, the cough and vomiting centres in the medulla are depressed	**1M Stages 3M Expl.**
6	**b)**	**Explain Dale's vasomotor reversal phenomenon in detail.** In low doses, Adrenaline causes peripheral vasoconstriction, increase in resistance, output, and thereby rise in peripheral and systolic BP. In high doses, Adrenaline activates both alpha and beta receptors. It causes peripheral vasoconstriction and leads to rise in systolic BP. This is followed by skeletal muscle dilation of blood vessels, decrease in resistance and output, fall in diastolic BP. This	**4M**

		response of Adrenaline is known as biphasic response. Its vasoconstriction action is blocked by alpha blocker like ergotoxin, Adrenaline causes only fall in BP. This reversal action of conversion of biphasic to monphasic response on Blood pressure is called as Dale's vasomotor reversal. Diagram:  Fig. 3  	
6	**c)**	**Give the significance of plasma protein binding in detail.** On reaching the circulation most drugs bind to plasma proteins. 1. Only free fraction is available for action, metabolism & excretion. Protein binding may delay the drug reaching the site of action.	**4M** **For any four**

		2. Protein binding serves as reservoir of the drug& drug is released when free drug levels fall. 3. It prolongs the half-life & so duration of action 4. Many drugs may compete for the same binding sites, so drug having higher affinity may displace another from the binding sites& result in drug interactions which may lead to toxicity of the displaced drug. 5. Chronic renal failure & chronic liver disease result in hypoalbuminaemia with reduced protein binding leading to raised levels of free drug.	
6	**d)**	**Define & classify anti-hypertensive drugs with examples. Give the uses of propranolol.** **Definition:** Antihypertensive drugs are the agents used in treatment of hypertension. **Classification (According to site of action):** 1. Centrally acting Drugs: Clonidine, Methyl Dopa 2. Drugs acting on autonomic ganglia: Hexamethonium 3. Drugs acting on post ganglionic sympathetic nerve endings a) Adrenergic neuron blockers; Guanethidine b) Catecholamine depletors: Reserpine 4. Drugs acting on adrenergic receptors: a)Alpha adrenergic blockers: Phentolamine b) Beta adrenergic blockers: Propranolol 5. Vasodilators: Hydralazine 6. Drugs acting reflexly by stimulating baroreceptors: Veratrum 7. Oral Diuretics: Thiazides, Frusemide, spironolactone, amilorideetc 8. Calcium Channel Blockers: Nifedipine, Amlodipine, Felodipine 9. Drugs acting on rennin angiotensin system: a) ACE inhibitors: Enalapril, Ramipril b) Angiotensin Receptor Blockers: Losartan, Telmisartan 10.Miscellaneous: MAO inhibitors (Pargyline) **Propranolol is used** To treat tremors, angina (chest pain), hypertension (high blood pressure), heart rhythm disorders, and other heart or circulatory conditions. It is also used to treat or prevent heart attack, to reduce the severity and frequency of migraine headaches**,** and in thyrotoxicosis	**1M Def.** **2M Class.** **1M uses**
6	**e)**	**Classify sulphonamides. Explain by what mechanism Trimethoprim potentiates the**	**2M**

		effects of sulphonamides. Sulphonamides can be classified as: Short acting: Eg Sulphadiazine,Sulphixazole Intermediate acting: Eg.Sulphamethoxazole Long acting: Eg. Sulphadoxine Poorly absorbed: Eg.Sulphasalazine Topical: Sulphacetamide,Silver sulphadiazine Trimethoprim has high degree of selective affinity for bacterial Dihydrofolate reductase. Sulphonamides inhibit conversion of PABA to dihydrofolic acid & Trimethoprim inhibits dihydrofolate reductase & thus prevents reduction of DHF to Tetra hydro folic acid. The two drugs thus block sequential steps in folic acid synthesis & the combination is synergistic & acts as bactericidal. The ratio of trimethoprim: sulphamethoxazole used is 1:5 to attain right plasma concentration.	**EACH**
6	**f)**	**Explain muscarinic actions of acetylcholine in detail.** **CVS:** Acetylcholine slows down heart rate & may produce cardiac arrest. **Blood vessels**: Ach dilates blood vessels & drops B.P. **Other smooth muscles: Causes contraction of smooth muscles** Gastrointestinal tract-Ach increases peristalsis Urinary Bladder-promotes voiding of urine Bronchial smooth muscles- contracted & may cause bronchoconstriction, apnoea. **Glands & secretions**: Ach increases various exocrine secretions such as salivary, respiratory ,gastric secretions etc. **Eyes**: Causes constriction of pupil or miosis by contracting circular muscles of iris	**4M**

Subject Title: Pharmaceutical Jurisprudence **Subject Code:** 0814

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for 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.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Answer any EIGHT of the followings:**	**16M (2x8)**
1	**a)**	**Give Ex-officio members of Joint state Pharmacy Council.** The following are ex-officio members: 1) Chief administrative medical officer of each participating state. 2) Officer in-charge of the Drug Control Organization of each participating state. 3) Government Analyst appointed under D&C Act, 1940 of each participating state.	**2 M**
1	**b)**	**Define Advertisement Under DMR Act 1954** **Advertisement**: It includes i) Any notice, circular, label, wrapper or otherwise such document, and ii) Any announcement made orally or by means of producing or transmitting light, sound or smoke.	**2 M**
1	**c)**	**State any two measures for combating abuse of narcotic drugs and illicit traffic.** Central Government under the provisions of this Act, may take the measures with respect to all or any of the following matters: - i. Co-ordination of actions by various officers, State Government and other authorities under this act or under any other law for the time being in force relating to enactment of the Act. ii. Obligations under the international conventions. iii. Assistance to the concerned authorities in foreign countries and concerned international organizations regarding prevention and suppression of illicit traffic and narcotic drugs and psychotropic substances. iv. Controlling the abuse of narcotic drugs and psychotropic substances. v. Identifying, treating, rehabilitation, education and social re-interaction of addicts. vi. Supplying drugs to addicts where such supply is a medical necessity. vii. Such other matters for effective implementation of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic	**1 M for each, Any two points**

		therein.	
1	**d)**	**How retails price of formulation is calculated under DPCO Act-1995.** By applying the following formula, the retail price of the formulation is calculated: 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. **C.C.:-** Means conversion cost. **P.M**.:- Means the cost of packing material. **P.C.:-** Means packing charges. **MAPE: -** Maximum allowable post manufacturing expenses. MAPE shall not exceed 100% for indigenously scheduled formulations. **E.D.:-** Means excise duty.	**1 M for Formula,** **1 M for Full Form**
1	**e)**	**Give any two difference between Bonded and Non-bonded Laboratory:**	**1 M for Each, Any two points**

Sr No	Bonded Laboratory	Non - Bonded Laboratory
1	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has not been paid.	It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has been paid.
2	Excise duty payable on removal of goods from bonded laboratory.	Excise duty payable at the time of spirit purchase.
3	Bonded laboratory to function under excise staff	No excise staff is required.

		4	License required should be obtained from Excise Commissioner.	License required should be obtained from the officer as the State Government may authorize on this behalf.	
		5	Alcohol on which duty has not been paid shall be used under the excise supervision.	Only the alcohol on which duty has already been paid shall be used.	
		6	Suitable for large scale manufacture.	Suitable for small scale manufacture.	
1	**f)**	**Define Guardian and Owner under MTP Act, 1971.** **Definition of "Guardian"** means 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' {Sec. 2(a)} **Definition of "Owner"** Owner in relation to place, means any person who is the administrative head or otherwise responsible for the working or maintenance of such Hospital or clinic.			**1 M** **1 M**
	g)	**Give the objectives of DMR Act, 1954** Objectives:- i) To control certain types of advertisements relating to drugs & ii) To prohibit certain kinds of advertisement relating to Magic Remedies, which falsely claim & mislead public. iii) To provide matter related therewith.			**2 M**
1	**h)**	**Mention any four conditions of license for sale of Schedule H and schedule X drug under D and C, 1940.** **Sale of Drugs specified in Schedule H and schedule X:** 1)Substances specified in Schedule H and schedule X should not be sold by retail and sold only in accordance with the prescription of RMP. In case of substances specified in			**2 M**

		Schedule X, the prescription should be duplicate, one copy of which is retained by licensee and preserved for at least for two years. 2)Drugs from Schedule H and schedule X, supplied to Registered Medical Practitioner, Hospitals, Dispensaries and Nursing Homes, shall be supplied only against signed written order and such order should be preserved for at least for two years. 3)A prescription of RMP against which drugs from Schedule H or Schedule X, supplied should: i)Be in writing and signed by the person giving it, with his usual signature and be dated. ii)Specify the name and address of the patient or name and address or owner of the animal if drug is for veterinary use. iii)Indicate the total amount of drugs supplied and doses to be taken.	
1	**i)**	**State what does following prescribe under D and C Act, 1940:** **i) Form 20A** **ii) Form 20G** (i) **Form 20A-** License issued in Restricted area For the sale of Drugs other than sch. C, C(1) and X. (ii) **Form 20G-** License issued for Wholesale of Drugs specified in Sch. X	**1 M** **1 M**
1	**j)**	**Discuss any two functions of P. C. I.** **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 standard. (for this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be	**1 M each, Any two**

		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.	
1	**k)**	**Give objectives of Pharmacy Act, 1948** The main objective of Pharmacy Act is- i) To regulate the profession and practice of pharmacy and ii) To raise the status of profession of pharmacy in India.	**2 M**
1	**l)**	**Define "Formulation"** **Formulation** means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but it does not include - (a) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines. (b) any medicine included in the Homeopathic system of medicine; and (c) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.	**2 M**
2		**Answer any FOUR of the followings:**	**12 (4X3)**
2	**a)**	**What is DEC? Give its recommendations.** The Indian Government formed a 'Drug Enquiry Committee' (D.E.C. or Chopra Committee) in 1930 under the Chairmanship of Lt. Col. R. N. Chopra to study problems related to drugs in India. Following are some important recommendations of DEC- 1) Formation of Central Pharmacy Councils & State Pharmacy Councils which would	**1M**

		look after the education & training of professionals. These councils would maintain the register containing the names & addresses of the Registered Pharmacists. 2) Creation of Drug Control Machinery (Departments) at the Centre with the branches in all the states. 3) Establishment of well-equipped Central Drug Laboratory (CDL) with competent staff and experts for an efficient and speedy working of Drug Control Department. It was also suggested that the small laboratories would work under the guidance of Central Drug Laboratory.	**2M, any 2**
2	**b)**	**Define Adulterated Drug under D and C Act, 1948.** A drug shall deemed to be adulterated- i) If it consists, in whole or in part, of any filthy, putrid or decomposed substance, or, ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health, or, iii) If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or iv) If it bears or contains, a colour other than prescribed which may be used for the purpose of colouring only; or v) If it contains any harmful or toxic substance which may render it injurious to health; or vi) If any substance mixed with it so as to render its quality or strength.	**3 M**
2	**c)**	**Define Magic Remedies and give exempted advertisement** **Magic Remedies**- It includes Talisman, Mantra, Kavach and any other charm claiming to possess miraculous power, i. for diagnosis, treatment and prevention of any disease in human being and in animal or ii. for affecting or altering the structure or organic function of the body of human being or animal. **Classes of exempted advertisements**: 1. Any advertisements relating to the drugs printed or published by the Government or any other person with prior permission of the Government.	**1 M for Definition** **2 M, Any 4**

		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 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 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 distributer 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 practitioner, dispensaries, hospitals, medical and research institutions, chemists and druggists or pharmacies.	
2	**d)**	**Discuss the operations controlled by Central government under NDPS Act, 1985.** i) Government shall fix from time to time the limits within which licences may be given for the cultivation of opium poppy. ii) All opium, the product of land cultivated with the opium poppy shall be delivered by	**½ M each, any6**

		the cultivators to the officers authorized on behalf of 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 licenses 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 appeals 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 consistence 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. vii) The rules may provide for the weighment, examination and classification according to the quality and consistence 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. viii)The rules may prescribe the forms & conditions of license for the manufacture of manufactured drugs, the authorities by which such licenses may be granted & fees that may be charged therefore; ix)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. x)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.	

2	**e)**	**Give offences and Penalties under Pharmacy Act, 1948.** **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. **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. **3) Failure to surrender certificate of registration:** Is also punishable with fine upto fifty rupees. **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	**1 M each, any 3**
2	**f)**	**State the various rules prescribed by State Govt. for possession, possession for sale and for sale of poisonous substances under Poison Act, 1919.** 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.	**3 M**

		iv) Maximum quantity of such poison which may be sold any person 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**.**	
3		**Answer any FOUR of the followings:**	**12M(3x4)**
3	**a)**	**Discuss the role of DTAB with its constitution (only Ex-officio members).** **Role of DTAB:** i)To advice the Central Govt. & state Govt. On technical matters arising out of the administration of this Act & ii)To carry out the other functions assigned to it by this act. **Ex-officio members of DTAB:** 1) The Director General of Health Services, who shall be Chairman of the board. 2) The Drugs Controller of India. 3) The Director of the Central Drugs Laboratory, Calcutta. 4) The Director of the Central Research Institute, Kasauli. 5) The Director of Indian Veterinary Research Institute, Izatnagar. 6) The Director of Central Drug Research Institute, Lucknow. 7) The President of Medical Council of India. 8) The President of the Pharmacy Council of India.	**1 M** **2 M**
3	**b)**	**Describe labeling provisions under D and C Act, 1940 for the following:** **i) Hair dyes ii) Vaccines** **(i)Labeling Provisions of Hair dyes** Hair dyes containing paraphenylene diamine or other coal tar dyes or coal tar intermediates should be labeled with the following words (On outer and the inner labels). ‘**’Caution:** This product contains ingredients which may cause skin irritation in certain cases & so a preliminary test according to the accompanying directions should first be made. The product should not be used for dyeing the eye-lashes or eye-brows; as such use	**1½ M**

		may cause blindness''. In addition, the following instructions in English & other local language should appear on each package of Hair dyes. ''This preparation may cause serious inflammation of the skin in some cases & so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap & water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area & allow it to dry. After twenty four hours, wash the area gently with soap & water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each & every application. This preparation should on no account be used for dyeing eyebrows or eye-lashes as severe inflammation of the eye or even blindness may result.'' **ii) Vaccines-** **Labelling Provisions of Vaccines:** **(a) The label on the on the container shall display:** (i) The name of vaccine (Proper name). (ii) the batch number or lot number (iii) The total number of doses in the container or contents in milliliters. (iv) Potency. (v) Expiry date. **(b) In addition to above information, the label on the package shall show:** (i) Proper name. (ii) Contents in Millilitres or doses. (iii) Batch number. (iv) The name and address manufacturer. (v) Manufacturing licence No. (vi) The date of manufacture & date of expiry. (vii) Storage conditions.	**1½ M**

3	**c)**	**Give procedure for price fixation or revision of Bulk drug under DPCO 1995.** Under the provisions of DPCO 1995 to achieve the objectives of this order, Government has power to fix maximum sale price and also to revise the prices of bulk drugs after obtaining necessary information from a manufacturer or importer. While fixing sale prices of such bulk drugs, the govt. shall take into consideration i) A post-tax return of 14% on net worth or ii) A return of 22% on capital employed or iii) For a new plant, a return of 12% based on long term marginal costing iv) In cases where the production is from basic stage, a post-tax return of 18% on net worth or 26% on capital employed, depending upon option for rates of return exercised by manufacturer. No person shall sell a bulk drug at a price exceeding the maximum sale price fixed as per provisions of this order plus local taxes if applicable. After commencement of this order, if any manufacturer commences production of any scheduled bulk drug, he has to furnish the details in form I & any additional information to the govt. within 15 days. After receipt of such information & making necessary enquiry as it deems fit, Govt. may fix the maximum sale price of bulk drug & notify in the official Gazette. Govt. may also fix or revise the price of any non scheduled bulk drug on public interest. Manufacturer or importer of such bulk drug shall not sale such non scheduled bulk drug at a price exceeding the price so fixed or revised	**3M**
3	**d)**	**Explain role of Pharmacist in Healthcare.** i) All the pharmacists working in different fields of profession are directly or indirectly related to nation's health. ii) Community pharmacist and hospital pharmacists are health professionals for the safe and effective use of drugs. iii) Pharmacy occupies an important position in the health care system. So the pharmacist	**3 M**

should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product.

iv) Pharmacist is legally held responsible for the quality of product which ismanufactured and distributed.

v) They supply medicines against prescriptions. They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes.

vi) They provide link between Physician & Patient

vii)They are able to advice patients with minor illness viii)The profession of Pharmacy presently consist of

- Industrial pharmacist
- Hospital pharmacist
- Academic pharmacist
- Community pharmacist

ix)Pharmacist has to play an important role in areas such as:

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

3 **e)** **Differentiate between Law and ethics.** **1M each, any3**

Sr. No.	Law	Ethics
1	Rules of human conduct binding on all persons in a state or nation.	Rules by which a profession regulates action & sets standards for all its members.

			2	Law may prevent one from causing injury to another but it cannot force him to help his neighbor in hours of need.	Helping the neighbour is the function of ethics.	
			3	A law is something you must obey.	Ethics is how society expects you to behave.	
			4	Law deals with actions that are punishable.	Ethics deals with right & wrong.	
			5	Laws are written & approved documents.	Ethics are also written words but they are not carrying legal status.	
			6	If law is broken, a violator may be subjected to punishment, a fine or imprisonment.	If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges.	
3	**f)**	**Define "Cannabis" and "Opium Derivative" under NDPS acr, 1985.** **Cannabis (hemp)** means- i)Charas, which is a resin in crude or purified form obtained from the cannabis plant which includes concentrated preparation & resin known as hashish oil or liquid hashish. ii)Ganja, which comprises of flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops. iii)Any mixture with or without any neutral material of ganja or charas or any drink prepared from them. **Opium Derivative:** It includes i) Medicinal opium. ii) Prepared opium. iii) Phenanthrene alkaloids such as morphine, codeine, thebaine & their salts. iv) Diacetyl morphine (heroin) & its salts. v) All preparations containing more than 0.2% of morphine or any amount of diacetyl morphine.				**1½ M** **1½M**

4		**Answer any FOUR of the followings:**	**12M(3x4)**
4	**a)**	**How Diploma in Pharmacy Institute in India are approved by central council.** **Application by institution/ authority to the Pharmacy Council of India (PCI):** An institution which conducts course of study or hold an examination for the pharmacist, has to apply to the PCI for approval of the course or examination. **Inspection:** i)PCI after receiving such application appoints the inspectors to visit the institution & confirm that whether the institution has the prescribed facilities as per the E R or not. ii) Inspectors may also attend any examination, to judge its standards without interfering with its conduct. iii)The inspector then report to the PCI on the facilities available in the institution & on the conduct & standard of the examinations held. **Approval:** i)On the reports of the inspectors if the PCI is satisfied that the course or examination under consideration is in conformity with ER, it may grant approval to it & ii)The said course of examination shall be considered as approved for qualifying for registration as pharmacist under the act. **Declaration:** Declaration of approval made by resolution is passed at a meeting of the PCI & published in the Official Gazette.	**3 M**
4	**b)**	**Define "Drug Inspector". Give his powers under D and C Act, 1940.** **Drug Inspector** means- i) In relation to Ayurvedic, Siddha or Unani drug, an person appointed by the Central or State Government under section 33-G; & ii) In relation to any other drug or cosmetic, a person appointed by the Central or State Government under section 21	**1 M**

		Powers of Drug Inspector Within the local limits for which the Inspector is appointed, he may: **i) Inspect -** 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. 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-** Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed. From any person, conveying, delivering or preparing to deliver any drug or cosmetic to a purchaser or a consignee. iii) **Search** any person 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 an offence is being committed or has been committed. v) **Stop and search** any vehicle, vessel or other conveyance which he has reason to believe, used for carrying any drug or cosmetic in respect of which an offence has been or is being committed. vi) **Give order** in writing to the person in possession of the drug or cosmetic in respect of which the offence has been or is being committed, not to dispose of any 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, & 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 & seize the same if he has reason to believe that it is an evidence of the commission of an offence under the Act. viii) Exercise any other powers as may be necessary for carrying out the purposes of this	**2M, any4**

		act & the rules made thereunder. If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter he shall be punishable with imprisonment which may extend to three years or with fine or with both.	
4	**c)**	**Give requirements of Bonded Laboratory.** Requirements of bonded laboratory -The bonded laboratory should have - 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. 12) All vessels intended to hold alcohol & other liquid preparations should bear distinctive serial no. with their full capacity marked individually. 13) The vessels for storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.	**3 M**

4	**d)**	**Define "Poison" under Poisons Act, 1919 and give its classification.** **Poison-** Any substance specified as a poison in rule made or notification issued under this Act, is considered to be poison for the purpose of this Act. **Classification of Poisons:** The poison act (12 of 1919) in Maharashtra the rules has been framed as Maharashtra Poisons Rules, 1972 and these include a Schedule giving a list of poisons, Class A and Class B, covered by the Poison Act. Class A poisons generally are those which have medicinal use while Class B poisons do not have any medicinal use. **Class A/ List A poisons**: Aconite, Aconine, Arsenic, Atropine, Belladonna, Cantharides, Chloral hydrate, Coca, Corrosive Sublimate, Potassium cyanide, Diamorphine (Heroin), Diethyl barbituric Acid, Digitalis, Ecogonine, Ergot of Rye, Lead, Nux Vomica, Strychnine, Morphine, Pectrotoxine, Prussic acid, Savin and its oils, Stramonillan, Stropanthus, StropanthinTartar emetic, Tetraethyl lead. **Class B/ List B poisons:** Essential oils of Almonds(unless deprived of prussic Acid), Antimonial wines, all salts of Barium, except Barium sulphate, Tincture of Contharides, Carbolic acid, Chloroform, Mercuric Sulphocyanide, Oxalic acid, Poppies, All oxides of Mercury, Sulphonal, Zinc Chloride. Or **Classification of Poisons:** As per Dr. R. S. Naik professor of Forensic Medicine, M G Institute of Medical sciences, Wardha. No classification of poison is entirely satisfactory, as many poisons fall into more than one group, however the classification given below:- 1)Corrosive :- group consist of strong acids and strong alkalis like, hydrochloric acid, oxalic acids, carbolic acids, salicylic acid, caustic soda, caustic potash 2)Irritants:- chlorine, bromine, iodine, boron, arsenic, antimony, mercury, lead, copper, zinc, magazine. 3)Neurotics:- alcohol, ether, chloroform, barbiturates, organophosphorus compounds, 4) Cardiac:- digitalis, oleander, aconite, tobacco.	**1M -Def** **2M for any classification , any 2 e.g. from each**

		5)Asphyxiants;- irrespirable gases, such as coal gas, carbon monoxide, carbon dioxide, sewer gas and war gases. 6) Miscellaneous :- aspirin, phenacetin, paracetamol, quinine, chlorpromazine, meprobamate, reserpine, amphetamine, LSD, Peyote, mescaline.	
4	**e)**	**Discuss Pharmacist in relation to his trade.** **1) Price Structure** - i) Prices charged from customers should be fair and in keeping with the quality of drugs & medical preparations supplied. ii) The compounding & dispensing charges should be fair & without unduly taxing the purchaser. **2) Fair Trade Practices** - i) No attempt should be made to capture the business of a fellow pharmacist by cut-throat competition, i.e. by offering reduced price, prizes or gifts ii) Labels, trademarks, symbols and other signs of fellow pharmacist should not be copied. iii) Drugs or other ingredients required should always be purchased from reputable source. **3) Hawking of Drugs** - i) Hawking of drugs and medicinal should not be allowed. ii) Any attempt should not be made to collect the orders from door to door. iii) Self-servicing method in pharmacy or drug - stores should not be allowed as it may encourage self-medication which is undesirable & dangerous. **4) Advertising and Displays** - No display or advertisement on the premises, in the newspaper or elsewhere regarding the abilities & services provided the pharmacy. Pharmacist should not make such advertisement which contains- i) Misleading, or exaggerated statements or claims. ii) The word "Cure" in reference to an ailment or symptoms of ill-health.	**3M**

		iii) A guarantee of therapeutic efficacy. iv) An appeal to fear. v) An offer to refund money paid. vi) A prize, competition or similar scheme. vii) A reference to sexual weakness, premature ageing.	
4	**f)**	**Describe the labeling requirement of ophthalmic preparation under D and C Act, 1940.** **Ophthalmic Solutions and Suspensions** – The following additional particulars shall be shown on the label of container- i) The statement 'Use the solution within one month after opening the container'. ii) Name and concentration of the preservative used. iii) The words 'NOT FOR INJECTION'. iv) Special instructions regarding storage, wherever applicable. v) A cautionary legend reading as: **WARNING-** i) If irritation persists or increases, discontinue the use & consult physician. ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions". **Ophthalmic Ointments** i) Special instructions regarding storage wherever applicable. ii) A cautionary legend reading **Warning** - If irritation persists or increases discontinue the use and consult physicians.	**2M** **1M**
5		**Answer any FOUR of the followings:**	**12M(3x4)**
5	**a)**	**Define "Registered Pharmacist" and "Displaced person" under 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. **Displaced person:-**	**1½ M for Each def**

		Displaced person mean i) A person who on account of setting up of dominions of India and Pakistan or on account of civil disturbances or the fear of such disturbances in area now forming part of Pakistan has on or after 1st day of March 1947, left or been displaced from his place of residence in such area and who has since then been residing in India. ii) Any person who on account of civil disturbances or the fear of such disturbances in area now forming part of Bangladesh, has after 14th day of April, 1957 but before 25th day March 1971, left or has been displaced from his place of residence in such area and who has since then been residing in India.	
	b)	**Define "Networth" and "Free Reserve".** **Networth** -It means the paid-up share capital of a company plus free reserve, if any and surpluses excluding outside investment which are not readily available for operational activity **Free reserve-** means a reserve created by appropriation of profits, but does not include reserves provided for contingent liability, disputed claims, goodwill, revaluation and other similar reserves.	**1½ M for Each,**
	c)	**Give various particulars required to be mentioned in application for obtaining license for manufacture in bond.** Following are the particulars which should be submitted in the application for obtaining license to manufacture in bond. i) Name and address of applicant, place and site on which bonded lab is proposed to be built. ii) If the application be a firm, the name and address of all partners of firm. iii) If it be company, its registered the name and address, as well as name and address of directors, managers and managing agent should be specified, amount of capital proposed to be invested. iv) Number and full description of vats, stills and other permanent apparatus and machinery which applicant wishes to set up together with the maximum quantity of alcohol at any one time to remain in the form of finished and unfinished preparations &	**3 M any 6**

		maximum quantities by weight of opium, Indian hemp or other narcotic drugs or narcotics and their contents in finished preparations. v) The approximate date from which the applicant desires to commence the manufacture. Statement whether the laboratory will require a whole time excise officer or part time. vi) List of preparations stating percentage of alcohol contained & license held under D&C Act 1948. vii) Site and elevation plan of laboratory building and similar plans for the quarters of the excise officer together with relevant record.	
	d)	**Discuss objectionable advertisement under Drugs and Magic Remedies Act, 1954.** **1) Advertisement of drugs which may lead to its/their use for the treatment of certain diseases and disorders -** i) For procurement of miscarriage or prevention of conception in women; or ii) For the correction of menstrual disorders in women; or iii) For the maintenance or improvement of the power of human beings for sexual pleasure. Or iv) For diagnosis, cure, alleviation, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the Act. **2) Advertisement of Magic Remedies for treatment of certain diseases or disorders** No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in I as above. **3) Misleading advertisements in relation to drugs, which -** i)Directly or indirectly gives false impression regarding true character of drug or drugs; or ii)Make any false claims for such drug or drugs iii) Is otherwise false or misleading in any material are prohibited. iv) Ayurvedic remedies to cure liver disorders & memory enhancement. **4) Prohibition of advertisements of Magic Remedies for the treatment of certain diseases -**	**3M, any 3**

		Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited	
	e)	**Which are different circumstances under which pregnancy can be terminated under MTP At, 1971?** **1) Consent:-** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except: i) When the pregnant woman is less than 18 yrs. of age or ii) The pregnant woman is lunatic. In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian. **2) Duration of pregnancies:** 1) A pregnancy may be terminated if it is not more than 12 weeks old & a medical practitioner is of the opinion that continuation of such pregnancyi) 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.	**3M**
	f)	**Give the functions of Central Drug Laboratory.** 1) To analyse 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	**3 M , any 6**

		consultation with the DTAB 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:- Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages. 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 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: Anti-sera, Vaccines, (Toxoids, Diagnostic Antigens for veterinary use. 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. 7)In case of **VDRL Antigen (Veneral 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. 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- a) National Institutes of Communicable Disease, Department of Microbiology, Delhi. b) National Institute of Virology, Pune c) 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.	
6		**Answer any FOUR of the followings**	**16M (4x4)**
6	**a)**	**What are Education Regulations? Mention various particular under it.** Subject to the provision of section 10 of Pharmacy Act, 1948, Central Council after approval of Central Government may make regulations prescribing the minimum standard of education required for qualification as a pharmacist is called Education Regulations Education Regulations may prescribe – i) Minimum qualification for admission to the course. ii) Nature & period of course of study. iii) Nature and period of practical training to be undertaken after the completion of 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	**1 M** **Meaning** **3M** **Explanation**
6	**b)**	**What does Sch H and Sch X to the D and C rules prescribed? Give any two example of each.** **Schedule H-** Prescription drugs which are required to be sold by retail only on the prescription of a RMP.	**1M for Schedule**

		Examples- Abacavir,Abciximab, Acamprosate Calcium, Acebutolol Hydrochloride, Aclarubicin, Albendazole, Alclometasone Dipropionate, Actilyse, Acyclovir, Adenosine, Adrenocorticotrophic Hormone (Acth), Alendronate Sodium, Allopurinol, Alpha chymotrypsin, Alprazolam, Amlodipine, Analgin, Androgenic Anabolic, Oestrogenic & Progestational Substances, Antibiotics, , Bacampicillin, Baclofen, Balsalazide, Bambuterol, Barbituric Acid, Basiliximab, Benazepril Hydrochloride, Benidipine Hydrochloride, Benserazide Hydrochloride, Betahistine Dihydrochloride, Bethanidine Sulphate, Bezafibrate, Bicalutamide, Biclotymol, Bifonazole, Bimatoprost, Biperiden Hydrochloride, Biphenyl Acetic Acid, Bitoscanate, Bleomycin, Brimonidine Tartrate, Bromhexine Hydrochloride, , Cabergoline, Calcium Dobesilate, Candesartan, Capecitabine, Captopril, Carbidopa, Carbocisteine, Carboplatin, Carboquone, Carisoprodol, L-Carnitine, Carteolol Hydrochloride, Cefazolin Sodium, Cefuroxime, Celecoxib, Centchroman, Centbutindole, Centpropazine, Cetirizine Hydrochloride, Vinblastine Sulphate, Vindesine Sulphate, Vinorelbine Tartrate, Xipamide, Zidovudine Hydrochloride, Ziprasidone Hydrochloride, Zoledronic Acid, Zolpidem, Zopiclone, Zuclopenthixol, Trapidil, Tegaserod Maleate, Teicoplanin, Telmisartan, Temozolamide, Terazosin, Terbutaline Sulphate, Terfenadine, etc**. (Any other e.g. specified under schedule H to be considered)** **Schedule X-** List of habit forming, psychotropic and other such drugs. **Examples**:- Amobarbital, Ethclorvynol , Phencycidine ,Amphetamine, Phenometrazine Barbital, Glutethimide, Cyclobarbital,Secobarbital ,Meprobamate, Methamphetamine Penobarbital, Methaqualone, Pentobarbital, Dexamphetamine ,Methylphenidate	**& 1M for e.g. any 2** **1M for Schedule & 1M for e.g. any 2**

6	**c)**	**Give offences and penalties under DMR Act, 1954.** Offences & Penalties under Drugs & Magic Remedies (O.A.) Act,1954 **Offence- 1)** Contravention of any of the provision of this Act or Rules- **Penalties:** Imprisonment 6 month or with fine or with both on 1st conviction. Imprisonment 1 year or with fine or with both on subsequent conviction **Offence-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.	**2 M** **2M**
6	**d)**	**Define "R.M.P" under MTP Act 1971. Explain various training and experiences for him under the act.** **Registered Medical Practitioner-** A medical practitioner who possesses any recognized medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 whose name has been entered in a State Medical Register & who has such experience or training in gynecology & obstetrics as the case may be prescribed by rules under this Act. **Experience or training :-** For the purpose of the act, the RMP should possess one or more of the following experience or training in gynecology and obstetrics – a)If he was registered in a state medical register immediately before the commencement of the act, experience in the practice of gynaecology and obstetrics for not less three years. b)A medical practitioner, registered in a state Medical Register on or after the date of commencement , can terminate the pregnancy.	**2 M for def.** **2M Explanation**

		i)If he has completed six months of house surgency in gynaecology and obstetrics; or ii)If he has experience at any hospital for not less than one year in the practice of gynaecology and obstetrics; or iii)If he has assisted a RMP in the performance of twenty five cases of medical termination of pregnancy in a hospital established or maintained , or a training institute approved by the Government, for this purpose. c)In the case of medical practitioner who has been registered in a state medical register and who holds a post graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of degree or diploma is considered.	
6	**e)**	**Explain various ethics to be followed by a person while dealing with the 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.	**4 M**
6	**f)**	**Give penalties for various offences and under NDPS Act, 1985.** Offences and penalties are- **1. Punishment for contravention in relation to poppy straw**. -Whoever, in	**1 M for each, Any**

		contravention of any provisions of this Act or any rule or order made or condition of a license granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw shall be punishable,- (a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees or with both; (b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees; (c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees. Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupee **2. Punishment for contravention in relation to coca plant and coca leaves**.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, cultivates any coca plant or gathers any portion of a coca plant or produces, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses coca leaves shall be punishable with rigorous imprisonment for a term which may extend to ten years or with fine which may extend to one lakh rupees.	**4**

3.Punishment for contravention in relation to prepared opium :-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted there under ,manufactures, possesses, sells, purchases, transports, imports inter- State, exports inter-State or uses prepared opium shall be punishable,

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

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

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

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

4. Punishment for contravention in relation to opium poppy and opium: -Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted there under, cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses opium shall be punishable,

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

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

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

		exceeding two lakh rupees; (c**)** in any other case, with rigorous imprisonment which may extend to ten years and with fine which may extend to one lakh rupees. **5. Punishment for embezzlement of opium by cultivator**. -Any cultivator licensed to cultivate the opium poppy on account of the Central Government who embezzles or otherwise illegally disposes of the opium produced or any part thereof, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh but which may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees. **6. Punishment for contravention in relation to cannabis plant and cannabis**.- Whoever, in contravention of any provisions of this Act or any rule or order made or condition of license granted there under, (a) cultivates any cannabis plant; or (b) produces, manufactures, possesses, sells, purchases, transports, imports inter- State, exports inter-State or uses cannabis, shall be punishable [(i) where such contravention relates to clause (a) with rigorous imprisonment for a term which may extend to ten years and shall also be liable to fine which may extend to one lakh rupees; and (ii) where such contravention relates to sub-clause (b),- (a) and involves small quantity, with rigorous imprisonment for a term which may extend to, one year or with fine, which may extend to ten thousand rupees, or with both; (b) and involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years, and with fine which may extend to one lakh rupees. (c) and involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two	

lakh rupees:

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

7.Punishment for contravention in relation to manufactured drugs and preparations.- Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any manufactured drug or any preparation containing any manufactured drug shall be punishable,

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

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

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

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

8.Punishment for contravention in relation to psychotropic substances:-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any psychotropic substance shall be punishable,

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

(b) where the contravention involves quantity lesser than commercial quantity but

greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees;

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

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

9.Punishment for illegal import in to India, export from India or transhipment of narcotic drugs and psychotropic substances.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license or permit granted or certificate or authorization issued thereunder, imports into India or exports from India or tranships any narcotic drug or psychotropic substance shall be punishable,-

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

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

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

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

10. Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of section 12.-Whoever engages in or controls any trade whereby a narcotic drug or a psychotropic substance is obtained outside India and supplied to any person outside India without the previous authorization of the Central Government or otherwise than in accordance with the conditions (if any) of such authorization granted

under section 12, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but may extend to two lakh rupees:

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

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

12. Punishment for contravention of orders made under section 9A. –If any person contravenes an order made under section 9A, he shall be punishable with rigorous imprisonment for a term which may extend to ten years and shall also be liable to fine which may extend to one lakh rupees:

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

13.Punishment for certain acts by licensee or his servants.-If the holder of any license, permit or authorization granted under this Act or any rule or order made thereunder or any person in his employ and acting on his behalf-

(a) omits, without any reasonable cause, to maintain accounts or to submit any return in accordance with the provisions of this Act, or any rule made thereunder;

(b) fails to produce without any reasonable cause such license, permit or authorization on demand of any officer authorized by the Central Government or State Government in this behalf;

(c) keeps any accounts or makes any statement which is false or which he knows or has reasons to believe to be incorrect; or

(d) wilfully and knowingly does any act in breach of any of the conditions of license, permit or authorization for which a penalty is not prescribed elsewhere in this Act,

he shall be punishable with imprisonment for a term which may extend to three years or with fine or with both.

14. Punishment for consumption of any narcotic drug or psychotropic substance.-
Whoever, consumes any narcotic drug or psychotropic substance shall be punishable,-
(a) where the narcotic drug or psychotropic substance consumed is cocaine ,morphine, diacetylmorphine or any other narcotic drug or any psychotropic substance as may be specified in this behalf by the Central Government by notification in the Official Gazette, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to twenty thousand rupees; or with both; and
(b) where the narcotic drug or psychotropic substance consumed is other than those specified in or under clause (a), with imprisonment for a term which may extend to six months, or with fine which may extend to ten thousand rupees or with both.]

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

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

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

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

		116 of the Indian Penal Code (45of 1860), be punishable with the punishment provided for the offence. (2) A person abets, or is a party to a criminal conspiracy to commit, an offence, within the meaning of this section, who, in India abets or is a party to the criminal conspiracy to the commission of any act in a place without and beyond India which- a) would constitute an offence if committed within India; or b) under the laws of such place, is an offence relating to narcotic drugs or psychotropic substances having all the legal conditions required to constitute it such an offence the same as or analogous to the legal conditions required to constitute it an offence punishable under this Chapter, if committed within India. **19. Preparation**.-If any person makes preparation to do or omits to do anything Which constitutes an offence punishable under any of the provisions of[sections 19,24 and 27Aand for offences involving commercial quantity of narcotic drug or psychotropic substance and from the circumstances of the case, it may be reasonably inferred that he was determined to carry out his intention to commit the offence but had been prevented by circumstances independent of his will, he shall be punishable with rigorous imprisonment for a term which shall not be less than one-half of the minimum term (if any), but which may extend to one-half of the maximum term, of imprisonment with which he would have been punishable in the event of his having committed such offence, and also with fine which shall not be less than one-half of the minimum amount (if any), of fine with which he would have been punishable, but which may extend to one-half of the maximum amount of fine with which he would have ordinarily (that is to say in the absence of special reasons) been punishable, in the event aforesaid: Provided that the court may, for reasons to be recorded in the judgment, impose a higher fine. **20. Enhanced punishment for offences after previous conviction**.-(l) If any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under this Act is subsequently convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, an offence punishable under this Act with the same	

amount of punishment shall be punished for the second and every subsequent offence with rigorous imprisonment for a term which may extend to one-half of the maximum term of imprisonment and also be liable to fine which shall extend to one-half of the maximum
amount of fine.

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

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

(3) Where any person is convicted by a competent court of criminal jurisdiction outside India under any corresponding law, such person, in respect of such conviction, shall be dealt with for the purposes of sub-sections (1) and (2) as if he had been convicted by a court in India.]

21-A-Death penalty for certain offences after previous conviction.-(l) Notwithstanding anything contained in section 31, if any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under39[section 19, section 24, section 27-A and for offences involving commercial quantity of any narcotic drug or psychotropic substance] is subsequently convicted of the commission of or attempt to commit or abetment of or criminal conspiracy to commit an offence relating to-

(2) where any person is convicted by a competent court of criminal jurisdiction outside India under any law corresponding to the provisions of [section 19, section 24 or section 27 A and for offences involving commercial quantity of any narcotic drug or psychotropic substance], such person, in respect of such conviction, shall be dealt with for the purposes of sub-section (1) as if he had been convicted by a court in India.]

22. Punishment for offence for which no punishment is provided.-Whoever contravenes any provision of this Act or any rule or order made, or any condition of any license, permit or authorization issued thereunder for which no punishment is separately

		provided in this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine, or with both.	

Subject Title: Pharmaceutical Jurisprudence Subject Code: 0814

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for 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.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Answer any Eight of the followings:**	**16M**
1	**a)**	**Define 'Adulterated Drug'.** A drug shall deemed to be adulterated i)If it consists, in whole or in part, of any filthy, putrid or decomposed substance, or, ii) If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health, or, iii)If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or iv) If it bears or contains, a colour other than prescribed which may be used for the purpose of colouring only; or v) If it contains any harmful or toxic substance which may render it injurious to health; or vi) If any substance mixed with it so as to render its quality or strength.	**2M** **(Any 2)**
1	**b)**	**Define law. What are the objectives of Pharmaceutical Legislation?** **Law-** Rules of human conduct binding on all persons in a state or nation. **Objectives-** 1) To promote health care by regulating the manufacture, supply & distribution of good quality drugs. 2) To make these drugs available to the public at reasonable prices & through qualified person. 3) To safeguard the people from misleading & false advertisements relating to drugs & remedies 4) To regulate the profession of pharmacy. 5) To promote the Indigenous research technology.	**1M Def.** **1M Object. (Any 2)**

1	**c)**	**Define drug store and chemists as per D and C Act 1940.** **Drug Store:** Licensed premises for the sale of drugs, which do not require the services of a qualified Person. **Chemist and Druggist** Licensed premises for the sale of drugs which require the services of a "Qualified Person" but where the drugs are not compounded against the prescriptions.	**1M Each**
1	**d)**	**Write the functions of Narcotic commissioner of state.** **Functions:-** i) Supervision of cultivation of opium poppy ii) Supervision of production of opium iii) Any other functions as may be performed to him by Government.	**2M**
1	**e)**	**Define Poison. Write objective of Poison Act 1919.** **Definition:-** Any substance specified as a poison in a rule made or notification issued Under the Poison Act,1919 shall be deemed to be a poison for the purpose of this Act. **Objective:-** i) To regulate & control import, possession & sale of poisons. ii) According to the provision of Poison Act,1919 Central Govt. has been authorized to regulate the import of poisons in India. & State Govt. has been authorized to make rules to regulate possession & sale of poison within their respective areas.	**1M Def.** **1M Object**
1	**f)**	**What are education regulations?** Subject to the provision of section 10 of Pharmacy Act, 1948, Central Council after approval of Central Government may make regulations prescribing the minimum standard of education required for qualification as a pharmacist is called Education Regulations Education Regulations may prescribe – i) Minimum qualification for admission to the course. ii) Nature & period of course of study. iii) Nature and period of practical training to be undertaken after the completion of	**2M**

		regular course. (Not less than 500 hrs. covered in a minimum of 3 months in an Institution, Hospital, Pharmacy or Dispensary recognized by Central Govt.) iv) The subjects of examination and the standards to be attained therein. v) The equipment and facilities to be provided by the institutions for the students undergoing approved course of study. vi) Conditions to be fulfilled by institutions giving practical training. vii) Conditions to be fulfilled by authorities holding approved examinations.	
1	**g)**	**Mention different sale licence required for retail and wholesale of schedule C and C_1 drugs.** **Retail sale:** (i)For drugs those specified in schedule C and C_1: **Form-21** **Wholesale sale:** (i)For drugs specified in schedule C and C_1: **Form -21B**	**1M Each**
1	**h)**	**Define 'Dutiable goods', under medicinal and toilet preparations Act, 1955.** **Definition of Dutiable goods:** It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.	**2M**
1	**i)**	**Enlist the objectives of drug and magic remedy Act ,1954(any two)** The Drugs and Magic Remedies Act passed with following main object: i) To control certain types of advertisement related to drugs. ii) To prohibit certain kinds of advertisements relating to magic remedies; which falsely claim and mislead the public, and iii) To provide for matters related therewith.	**2M, Any2**
1	**j)**	**Define under pharmacy Act 1948 'Registered Pharmacist'.** **Registered Pharmacist:** means a person whose name for the time being is entered in the register of the pharmacists of the state in which he is for the time being residing or carrying on his profession or business of pharmacy.	**2M**

1	**k)**	**Give the objectives of drugs and price control order 1995.** **Objectives of DPCO 1995:** i) To achieve adequate production. ii) To secure or regulate the equitable distribution. iii) To maintain and increase the supplies of bulk drugs and formulations and iv) To make these available at fair prices.	**2M**
1	**l)**	**Mention ex-officio members of P.C.I.** Ex-officio members of PCI: i)The Director General of Health Services. ii)The Drugs Controller of India. iii)The Director of the Central Drugs Laboratory.	**2M**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**What are "Loan licenses" and "Restricted licenses" under D and C Act, 1940?** **(i) Loan licence:** It means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee/ manufacturer. (i)Application for the grant or renewal of loan licences to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) & Sch. X shall be made up to ten items for each category of drugs shall be made in Form 24-A accompanied by a licence fee of rupees 6000/- & an inspection fee of rupees 1500/- to the licensing authority. (ii)The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, & facilities for testing, to undertake the manufacture on the behalf of the applicant for a loan licence (iii)Application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an addition fee of rupees 300/- per additional item specified in Schedule M.& M-III (iv)If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost	**1 ½ M Each**

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

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

		ii) Make any false claims for such drug or drugs iii) Is otherwise false or misleading in any material particularly. iv) Ayurvedic remedies to cure liver disorders & memory enhancement. **4) Prohibition of advertisements of Magic Remedies for the treatment of certain diseases**. Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited**.**	
2	**d)**	**What are the requirements of bonded manufactory or laboratory?** **Requirements of bonded manufactory** 1)A Spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory). 2) Separate room/ rooms for the manufacture of medicinal preparations and toilet preparations. 3) Separate room/ rooms for storage of the finished medicinal preparations and finished toilet preparations. 4) Accommodation near the entrance for the officer-in-charge with necessary furniture. 5) The pipes of sink or wash-basins should be connected with general drainage of the laboratory. 6) The gas and electric connection supply should be such that their supply can be cut-off at the end of day's work. 7) Every room should bear a board indicating the name of room and serial numbers. 8) Every window would be provided with specific arrangements of malleable iron rods of prescribed dimensions and window should be covered on the inside with strong wire netting of mesh not exceeding 25mm. 9) There shall be only one entrance to the laboratory and one door to each of its compartments. All the doors shall be secured with excise ticket locks in the absence of officer in-charge. 10) All vessels intended to hold alcohol and other liquid preparations should bear a	**3M**

		distinctive serial numbers and full capacity. 11) The vessels for storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.	
2	**e)**	**Describe the offences and penalties under NDPS Act, 1985.** **Offences and penalties** **1. Punishment for contravention in relation to poppy straw**. -Whoever, in contravention of any provisions of this Act or any rule or order made or condition of a license granted thereunder, produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw or removes or does any act in respect of warehoused poppy straw shall be punishable,- **(a**) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees or with both; **(b)** where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees; **(c**) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees. Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupee **2. Punishment for contravention in relation to coca plant and coca leaves**.-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, cultivates any coca plant or gathers any portion of a coca plant or produces, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses coca leaves shall be punishable with rigorous imprisonment for a term which may extend to ten years or with fine which may extend to one lakh rupees. **3.Punishment for contravention in relation to prepared opium** :-Whoever, in	**1 ½ M Offences, any 3** **1 ½ M Penalties, any 3**

		contravention of any provision of this Act or any rule or order made or condition of license granted there under ,manufactures, possesses, sells, purchases, transports, imports inter- State, exports inter-State or uses prepared opium shall be punishable, (a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both; (b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment for a term which may extend to ten years and with fine which may extend to one lakh rupees; or (c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees which may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees **4. Punishment for contravention in relation to opium poppy and opium**: -Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted there under, cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses opium shall be punishable, (a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both; (b) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees which may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees; (c**)** in any other case, with rigorous imprisonment which may extend to ten years and with	

fine which may extend to one lakh rupees.

5. Punishment for embezzlement of opium by cultivator. -Any cultivator licensed to cultivate the opium poppy on account of the Central Government who embezzles or otherwise illegally disposes of the opium produced or any part thereof, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh but which may extend to two lakh rupees:

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

6. Punishment for contravention in relation to cannabis plant and cannabis.- Whoever, in contravention of any provisions of this Act or any rule or order made or condition of license granted there under,

(a) cultivates any cannabis plant; or

(b) produces, manufactures, possesses, sells, purchases, transports, imports inter- State, exports inter-State or uses cannabis, shall be punishable

[(i) where such contravention relates to clause (a) with rigorous imprisonment for a term which may extend to ten years and shall also be liable to fine which may extend to one lakh rupees; and

(ii) where such contravention relates to sub-clause (b),-

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

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

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

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

7.Punishment for contravention in relation to manufactured drugs and preparations.- Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any manufactured drug or any preparation containing any manufactured drug shall be punishable,

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

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

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

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

Fine exceeding two lakh rupees.

8.Punishment for contravention in relation to psychotropic substances:-Whoever, in contravention of any provision of this Act or any rule or order made or condition of license granted thereunder, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses any psychotropic substance shall be punishable,

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

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

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

		or certificate or authorization issued thereunder, imports into India or exports from India or tranships any narcotic drug or psychotropic substance shall be punishable,- (a) where the contravention involves small quantity, with rigorous imprisonment for a term which may extend to one year, or with fine, which may extend to ten thousand rupees or with both; (b) where the contravention involves quantity lesser than commercial quantity but greater than small quantity, with rigorous imprisonment- for a term which may extend to ten years, and with fine; which may extend to one lakh rupees; (c) where the contravention involves commercial quantity, with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees.] **10. Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of section 12**.-Whoever engages in or controls any trade whereby a narcotic drug or a psychotropic substance is obtained outside India and supplied to any person outside India without the previous authorization of the Central Government or otherwise than in accordance with the conditions (if any) of such authorization granted under section 12, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but may extend to two lakh rupees: Provided that the court may, for reasons to be recorded in the judgment, impose a fine exceeding two lakh rupees **11. Punishment for allowing premises, etc., to be used for commission of an offence**.- Whoever, being the owner or occupier or having the control or use of any house, room, enclosure, space, place, animal or conveyance, knowingly permits it to be used for the commission by any other person of an offence punishable under any provision of this Act, shall be punishable with the punishment provided for that offence.]	

12. Punishment for contravention of orders made under section 9A. –If any person contravenes an order made under section 9A, he shall be punishable with rigorous imprisonment for a term which may extend to ten years and shall also be liable to fine which may extend to one lakh rupees:

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

13.Punishment for certain acts by licensee or his servants.-If the holder of any license, permit or authorization granted under this Act or any rule or order made thereunder or any person in his employ and acting on his behalf-

(a) omits, without any reasonable cause, to maintain accounts or to submit any return in accordance with the provisions of this Act, or any rule made thereunder;

(b) fails to produce without any reasonable cause such license, permit or authorization on demand of any officer authorized by the Central Government or State Government in this behalf;

(c) keeps any accounts or makes any statement which is false or which he knows or has reasons to believe to be incorrect; or

(d) willfully and knowingly does any act in breach of any of the conditions of license, permit or authorization for which a penalty is not prescribed elsewhere in this Act,

he shall be punishable with imprisonment for a term which may extend to three years or with fine or with both.

14. Punishment for consumption of any narcotic drug or psychotropic substance.-

Whoever, consumes any narcotic drug or psychotropic substance shall be punishable,-

(a)where the narcotic drug or psychotropic substance consumed is cocaine ,morphine, diacetylmorphine or any other narcotic drug or any psychotropic substance as may be specified in this behalf by the Central Government by notification in the Official Gazette, with rigorous imprisonment for a term which may extend to one year, or with fine which may extend to twenty thousand rupees; or with both; and

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

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

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

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

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

18. Punishment for abetment and criminal conspiracy.-(l) Whoever abets, or is a party to a criminal conspiracy to commit an offence punishable under this Chapter, shall, whether such offence be or be not committed in consequence of such abetment or in pursuance of such criminal conspiracy, and notwithstanding anything contained in section 116 of the Indian Penal Code (45of 1860), be punishable with the punishment provided for the offence.

(2) A person abets, or is a party to a criminal conspiracy to commit, an offence, within the meaning of this section, who, in India abets or is a party to the criminal conspiracy to the commission of any act in a place without and beyond India which-

(a) would constitute an offence if committed within India; or

(b) under the laws of such place, is an offence relating to narcotic drugs or psychotropic substances having all the legal conditions required to constitute it such an offence the same as or analogous to the legal conditions required to constitute it an offence punishable under this Chapter, if committed within India.

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

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

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

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

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

		(3) Where any person is convicted by a competent court of criminal jurisdiction outside India under any corresponding law, such person, in respect of such conviction, shall be dealt with for the purposes of sub-sections (1) and (2) as if he had been convicted by a court in India.] **21-A-Death penalty for certain offences after previous conviction**.- (l) Notwithstanding anything contained in section 31, if any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences punishable under39[section 19, section 24, section 27-A and for offences involving commercial quantity of any narcotic drug or psychotropic substance] is subsequently convicted of the commission of or attempt to commit or abetment of or criminal conspiracy to commit an offence relating to- (2) where any person is convicted by a competent court of criminal jurisdiction outside India under any law corresponding to the provisions of[section 19, section 24 or section 27 A and for offences involving commercial quantity of any narcotic drug or psychotropic substance], such person, in respect of such conviction, shall be dealt with for the purposes of sub-section (1) as if he had been convicted by a court in India.] **22. Punishment for offence for which no punishment is provided**.-Whoever contravenes any provision of this Act or any rule or order made, or any condition of any license, permit or authorization issued thereunder for which no punishment is separately provided in this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine, or with both.	
2	**f)**	**Define:** **(i)Alcohol** **(ii)Medicinal opium** **(i)Alcohol:** Alcohol means ethyl alcohol of any strength and purity having chemical composition C_2H_5OH. **(ii)Medicinal opium:** Opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other Pharmacopoeia notify in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials;	**1 ½ M Each**

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

3	**b)**	**Define 'Drug' under D and C Act, 1940.** Drugs : it includes 1. All medicines for internal or external use of human beings or animals and all substances intended to be used for; or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes. 2. Such substances other than food intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in the human beings or animals. 3. All substances intended for use as components of a drug including empty gelatin capsules and 4. Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of diseases or disorders in human beings or animals.	**3M**
3	**c)**	**What does Schedule Y and Schedule H to the D and C rules prescribes?** **Schedule Y**: Requirements and Guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials. **Schedule H**: Prescriptions drugs which are required to be sold by retail only on prescription of Registered Medical Practitioner.	**1 ½ M Each**
3	**d)**	**As per as code of ethics explain, how pharmacist is a link between medical profession and public.** A pharmacist under no circumstances, should practice medicine, that is diagnosing diseases and prescribing medicines. However in case of accidents or emergencies, he may render first aid services. A pharmacist should not recommend any particular medical practitioner, unless specially asked for. Pharmacist should never enter into secret agreements with the medical profession, physicians, dentist, and veterinary surgeons to offer them commission or gifts by recommending his dispensary or drug store. Pharmacist should not have any	**3M**

		clandestine or underhand arrangement with any physician. Pharmacist is a link between medical profession and public. He should be constantly in touch with the modern developments in pharmacy and allied fields. He should be expert in the field of pharmacy so that he may advice the physician on pharmaceutical matters. By enlarging his store of knowledge he may be able to educate the public to maintain their health. Pharmacists should neither discuss physician's prescription with customers nor disclose to them the composition of the prescriptions.	
3	**e)**	**Why DEC was formed? Give recommendations of DEC.** **Why DEC was formed (1M)** In the dealing of drugs and medicines, profit rather than service became the main motive. Spurious, substandard and adulterated drugs become more common than standard and the genuine ones. Outside India, drugs were manufactured specifically for India which were of inferior quality. India become platform for quack medicines and adulterated drugs manufactured in all parts of the world. There were very occurrences of offences related to drugs. There was no authority to control such activities. The Indian Government formed a 'Drug Enquiry Committee' (D.E.C. or Chopra Committee) in 1930 under the Chairmanship of Lt. Col. R. N. Chopra was formed to study problems related to drugs in India. **Recommendations of DEC (2M)** 1)Formation of Central Pharmacy Council and the Provincial (State) Pharmacy Council which would look after the education and training of professionals. These councils would maintain the register containing the names and addresses of registered pharmacist. 2)It suggested the creation of drug control machinery (departments) at the centre with the branches in all the states. 3)Recommended the establishment of a well-equipped CDL with competent staff and experts for an efficient and speedy working of Drug Ctrl Department. It also suggested small laboratories which would work under the guidance of CDL.	**1M** **DEC** **2M ,** **Any4**

		4)Setting of test laboratories in all states to control the quality of production of drugs and pharmaceuticals. 5)Appointment of Advisory board to advise Government in making rules. 6)The drugs industry in India should be developed. 7)Setting of courses for training in pharmacy. 8)Prescribing minimum qualification for registration of pharmacist.	
3	**f)**	**Write the difference between Law and Ethics.**	**3M, Any 3**

Sr. No	Law	Ethics
1	Definition- Rules of human conduct binding on all persons in a state.	Definition- Rules by which a profession regulates action & sets standards for all its members.
2	Law may prevent one from causing injury to another but it cannot force him to help his neighbour in hours of need.	Helping the neighbour is the function of ethics.
3	A law is something you must obey	Ethics is how society expects you to behave.
4	Law deals with actions that are punishable.	Ethics deals with right & wrong.
5	Laws are written & approved documents.	Ethics are also written words but they are not carrying legal status
6	If law is broken, a violator may be subjected to punishment, a fine or imprisonment.	If rules of ethics are broken, the professional body may subject the violator to loss of professional privileges

<table>
<tr><td>4</td><td></td><td colspan="3">Attempt any FOUR of the followings</td><td>12M</td></tr>
<tr><td>4</td><td>a)</td><td colspan="3">Differentiate between bonded and non-bonded manufactory or laboratory
<table>
<tr><th>Sr. No</th><th>Bonded Laboratory</th><th>Non-bonded Laboratory</th></tr>
<tr><td>1.</td><td>It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has not been paid.</td><td>It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has been paid.</td></tr>
<tr><td>2.</td><td>Excise duty payable on removal of goods from bonded laboratory.</td><td>Excise duty payable at the time of spirit purchase.</td></tr>
<tr><td>3.</td><td>Bonded laboratory to function under Excise staff.</td><td>No excise staff is required.</td></tr>
<tr><td>4.</td><td>License required should be obtained from Excise Commissioner</td><td>License required should be obtained from the officer as the State Government may authorize on this behalf</td></tr>
<tr><td>5.</td><td>Suitable for large scale manufacture</td><td>Suitable for small scale manufacture</td></tr>
</table></td><td>3M , Any 3</td></tr>
<tr><td>4</td><td>b)</td><td colspan="3">What procedure should be followed by drug Inspectors while sending the samples for test or analysis?
Following is the procedure to be followed by the drug Inspector while sending the samples for test or analysis-
An Inspector taking any samples should pay its fair price and may require a written acknowledgement for the same. If the price tendered is refused or where the Inspector seizes the stock of any drug or cosmetic, he should issue a receipt for the same in the</td><td>3M</td></tr>
</table>

		prescribed form. He should also inform the purpose of taking the samples unless he will fully absents himself and divide the samples into four parts in his presence. Each portion is then sealed effectively and suitably marked. The person from whom the sample is taken should be permitted to add his own seal and mark to all or any of the portions sealed or marked. If the sample is taken from manufacturing premises, it should be divided into three portions only. Where the sample is made up in containers in small volume or is likely to deteriorate or be damaged by exposure, the Inspector should take three or four such containers after suitably marking them and when necessary, sealing them. One portion of the sample should be restored to the person from whom it was taken, the second portion is sent to the Government Analyst for test or analysis, the third one is preserved for production before the court if required, and the fourth portion is sent to the warrantor, if any.	
4	**c)**	**Mention the duties of government analyst.** 1) To analyze or test the samples of drugs & cosmetics sent to him by Drug Inspectors or other persons or 2) To furnish reports of results of such analysis & test. 3) Research work- To forward to the Govt., the report of Analytical & Research work with view to their publication	**3M**
4	**d)**	**Define the following as per DPCO, 1995.** (i)**Bulk drug**- means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to pharmacopoeial or other standards specified in the second schedule to the Drugs and Cosmetics Act and which is used as such or as an ingredient in any formulation. (ii)**Formulation**- means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but it does not include – (a) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.	**1 ½ M Each**

		(b) any medicine included in the Homeopathic system of medicine; and (c) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.	
4	**e)**	**Give the offences and penalties under DPCO, 1995** **Penalties**.—Any contravention of any of the provisions of this order shall be punishable in accordance with the provisions of the essential commodities act. (1) If any person contravenes any order made under Section 3, (a) he shall be punishable,— (i) in the case of an order made with reference to clause (h) or clause (i) of sub-section (2) of that section, with imprisonment for a term which may extend to one year and shall also be liable to fine, and (ii) in the case of any other order, with imprisonment for a term which shall not be less than three months but which may extend to seven years and shall also be liable to fine: Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than three months; (b) any property in respect of which the order has been contravened shall be forfeited to the Government; (2) If any person to whom a direction is given under clause (b) of sub-section(4) of section 3 fails to comply with the direction, he shall be punishable with imprisonment for a term which shall not be less than three months but which may extend to seven years and shall also be liable to fine: Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than three months. or six months, as the case may be. (3) Where a person having been convicted of an offence under sub-section (1) is again convicted of an offence under that sub-section for contravention of an order in respect of an essential commodity, the court by which such person is convicted shall, in addition to any penalty which may be imposed on him under that sub-section, by order, direct that that person shall not carry on any business in that essential commodity for such period, not being less than six months, as may be specified by the Court in the Order.	**3M**

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

		(**ii)Tolbutamide** **(iii)Insulin** **(iv)Ibuprofen** **(v)Barbituric acid** **(vi)Betamethasone** (i)Vasopressin - Schedule H (ii)Tolbutamide – Schedule G (iii)Insulin - Schedule C , Schedule G (iv)Ibuprofen – Schedule H (v)Barbituric acid – Schedule H (vi)Betamethasone – Schedule H	**½ Mark each**
5	**c)**	**Define the following terms as per MTP Act,1971** **(i)Guardian-** **(ii)Minor** **(i) Guardian Definition of "Guardian"** means 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' {Sec. 2(a)} **(ii)Minor** Means a person who, under the provisions of the Indian Majority Act, 1875 is to be deemed not to have attained his majority.	**1 ½ Mark Each**
5	**d)**	**How retail price of drug is to be calculated under DPCO 1995?** 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	**1M**

		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.	**Formula 2M Explanation**
5	**e)**	**Give constitution of state pharmacy council.** 1)Elected members: a) Six members, elected amongst themselves by Registered pharmacists of state. b) One member elected by the members of Medical Council of the State amongst themselves. 2)Nominated members: a) Five members nominated by the State Government of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or be a registered pharmacists. 3)Ex-officio members: a) Chief administrative medical officer of the State. b) The officer in charge of the drug control organization of the state; appointed under D. & C. Act, 1940. c) Government Analyst appointed under Drugs and Cosmetics Act, 1940. If there are more than one such Analyst, one may be nominated by the Government	**3M**
5	**f)**	**Mention the conditions under which name of the pharmacist can be removed from**	

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

		this provision & (iii) Promoting higher education and research in Pharmaceutical Sciences and Technology.	
6	**b)**	**Explain what do schedule N to D and C Act,1940 prescribes?** Schedule N- List of Minimum equipment's for efficient running of pharmacy: 1) **Entrance:** The front of Pharmacy shall bear an inscription, "Pharmacy". 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. A pharmacy shall be provided with supply of good quality water. There shall be separate dispensing department to prevent the admission of the public. **3) Furniture**: A pharmacy shall contain furniture of required size & suitable apparatus. Drugs, chemicals & medicaments shall be kept in a suitable room and suitable containers so as to prevent any deterioration of the contents or of contents of container kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust. 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 &	**4M**

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

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

4) Apparatus and Equipment:

A pharmacy shall be provided with following minimum apparatus:

Balance-dispensing, sensitivity30 mg

Balance-counter, capacity 3 kg, sensitivity 1 kg

Beakers, lipped assorted sizes

Corks assorted sizes and toppers

Cork extractor

Evaporating dishes

Funnel –glass

Litmus paper-blue and red

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

Mortar & pestle

Ointment slab, porcelain

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

Scissors

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

5) Books:

The pharmacopoeia (current edition)

National formulary of India (current edition)

The Drugs and Cosmetics Act, 1940 and Rules, 1945

The Pharmacy Act, 1948

Narcotic Drugs & Psychotropic Substances Act, 1985.

6) General Provisions: A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises. The pharmacist shall always put on clean, white overalls. The premises and pharmacy shall be properly kept and everything must be in good order & clean.

		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. Medicament when supplied shall have labels conforming to the provisions of the laws in force.	
6	**c)**	**Write the functions of pharmacy council of India.** **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 standard. (for this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be recognized or not) **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.	**4M** **(Any 4)**
6	**d)**	**Give the conditions for approval of places for termination of pregnancies. State offences and penalties under MTP Act,1971.** **Conditions for approval of places for termination of pregnancies – (2 marks)** <u>Places where pregnancy may be terminated</u>- i) A Govt. Hospital or	**2M** **Conditio n**

		ii) A place approved for the purpose of this Act of Govt. Place for the termination of pregnancies shall be approved only if – **Conditions :** 1) The Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions and 2) The following facilities are provided - a) An operation table and instruments for performing abdominal or gynaecological surgery. b) Anaesthetic equipment, resuscitation equipment and sterilization equipment. c) Drugs and parenteral fluids for emergency use. **Offences and penalties- (2 Marks)** As per the latest amendments in M.T.P. Act,1971 **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. **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. **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.	**2M Offences & Penalty (any 2)**
6	**e)**	**Describe 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 atleast twice a year, all premises licenced for manufacturing of drugs within the area allotted to him & to satisfy whether the conditions of licence & provisions of the act and rules thereunder are being observed or not. 2) To inspect premises licenced for manufacturing of drugs, specified in Schedule-C & C(1) & to observe process of manufacturing, means employed for standardization & testing of drug & storage conditions & qualification of technical staff and employee & all other details of location, construction, administration of establishment, other things which	**4M**

		may likely to affect potency & purity of the product. 3) To sent after each inspection a detailed report of inspection to the controlling authority with which conditions of licence and provisions of the act & the rules thereunder being observed and which being not observed. 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.	
6	**f)**	**Write the procedure for approval of institution running diploma / degree course in pharmacy** **Application by institution/ authority to the Pharmacy Council of India (PCI):** An institution which conducts course of study or hold an examination for the pharmacist, has to apply to the PCI for approval of the course or examination. **Inspection:** i)PCI after receiving such application appoints the inspectors to visit the institution & confirm that whether the institution has the prescribed facilities as per the E R or not. ii) Inspectors may also attend any examination, to judge its standards without interfering with its conduct. iii)The inspector then report to the PCI on the facilities available in the institution & on the conduct & standard of the examinations held. **Approval:** i)On the reports of the inspectors if the PCI is satisfied that the course or examination under consideration is in conformity with ER, it may grant approval to it & ii)The said course of examination shall be considered as approved for qualifying for registration as pharmacist under the act. **Declaration:** Declaration of approval made by resolution is passed at a meeting of the PCI & published in the Official Gazette.	**4M**

MODEL ANSWER

SUMMER -19 EXAMINATION

Subject Title: Drug Store and Business Management **Subject Code:** 0815

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.

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any <u>FIVE</u> of the following: (2marks for each)**	**10M**
1	**a)**	**Define Budget. Explain in short its objectives. (1 Mark for definition & 1 Mark for any two objectives)** A budget is a written plan covering projected activities of a firm for a definite period of time. **Objectives of Budget: (Any Two)** 1) To provide a realistic estimate of income and expenses for a period. 2) To provide a coordinated plan of action to achieve the target. 3) To provide a comparison of actual results with those budgeted and to indicate courses of corrective actions. 4) To provide a ready basis for making forecasts during the budget period to guide management in making day to day decisions.	**2M**
1	**b)**	**Write at least two advantages and two limitations of 'Financial Statements'(1 Mark for any two advantage & 1 Mark for any two limitations)** **Advantages of Financial statements: (Any Two)** 1) Management can review the up to date progress made by the enterprise and then decide about necessary course of action to be taken in future. 2) The creditors can decide about extending, maintaining or restricting the flow of their credit to the business. 3) On the basis of financial statements, the shareholders are in a position to judge the future prospects of their investment and thus decide either to sell or continue with the ownership of their shares in the firm. 4) The employees union or group can find out the present financial condition of the firm from the financial statements and are thus able to decide whether the firm is in a position to pay higher wages, bonus etc. **Limitations of financial statement: (Any Two)** 1) Interim and not final reports**:** The profit & loss account & the financial position	**2M**

		revealed by the balance sheet cannot be exactly true since these statements are only interim reports. The exact financial position of the business can be known only when the business is either liquidated or sold. 2) The balance sheet does not reveal the exact financial position of the business as it is affected by various factors like fixed assets, going concern concept & convention. 3) The quality of statements depends on the competence & integrity of those who prepare it. 4) It records & reveals only those facts which can be expressed in terms of money.	
1	**c)**	**Define the term 'Account'. Explain its types.(½ Mark for definition & 1 ½ Marks for types of accounts)** **Account:** A formal record of all transactions relating to changes in a particular item. **Types of Account:** **1) Personal account:** It deals with the individual person, firm, company & institutions. e.g. an account of Mr. Ram Gopal, M/S Deep Medical Hall, Glaxo (India) Ltd., M.D. University. The person or firm which supplies the goods/gives money to the business is a creditor and entries made on credit side of his account. Similarly a person or firm which receives the money or goods from business becomes a debtor and the transaction is made on debit side of his account. **2) Real account:** These accounts are maintained to deal with transactions related to building, cash, furniture, land, machinery, stock etc. When an item is purchased or recd., the transaction is recorded on debit side. **3) Nominal account:** These accounts are generally called fictitious accounts. These accounts are maintained to deal with discounts, insurance, rent, wages, salaries, cost of stationery items etc. A separate account is maintained for each type of expenditure. The entries of expenses or losses are made on debit side & of profits or gain on credit side.	**2M**
1	**d)**	**Explain the importance of salesmanship in 'Pharmaceutical Industry' (2 Marks for any four importance)** The success of a firm mainly depends on the performance of their sales force engaged in	**2M**

		salesmanship. It helps producers to increase sales. It also helps consumers to get correct knowledge about the quality of goods and service. Salesmanship not only increases sales but also earns goodwill for the organisation. **OR** The most important functions performed by the salesmen/medical representative in Pharma Industry are as follows: 1. It helps in locating the doctors who will write the prescription. 2. It helps in creating demand for the new products. 3. It provides feedback about the needs etc. it helps to remove the doubt of the doctors. 4. It helps in demonstrating the product. 5. The salesman acts as the consultant for new products. 6. He convinces the doctor to support the products he is selling.	
1	**e)**	**Explain how will you apply VED analysis for drug store.(2 Marks)** This system is based on utility of items. In a drug store VED analysis is useful in controlling & maintaining the stock of various types of formulation of a particular group of drugs. The older the brand, the greater will be its requirement. The best way to calculate the requirements is to classify the different brands of drugs into following categories: The brands are classified into following categories- V= vital. E= essential D= desirable. Accordingly one has to maintain maximum stock of vital items, followed by essential items & then desirable items. e.g acetyl salicylic acid brands available are Disprin, Micropyrine and Anacin hence divide as follows V=vital, Disprin	**2M**

		E= essential, Micropyrine D=desirable, Anacin	
1	**f)**	**Define 'Tender'. Explain 'Open Tender'.(1 mark for definition & 1 Mark for explanation of open tender)** **Tender:** It is a written offer or quotation to do some specified work or to provide required materials at a given price within a prescribed period and under specified condition. 1. **Open Tender:** These tenders are called by advertisement when the sources of supply are many and total value of items to be purchased is large. The tenders are given in leading newspapers.After receiving the tenders from various suppliers, a comparative statement is prepared. The order is placed to the firm with lowest quotation. This method is costly & time consuming.	**2M**
1	**g)**	**Define and classify 'Industry'.(½ Mark for definition & 1 ½ Mark for any three class)** **Definition** It is the part of business activity which relates to production, processing, or fabrication of products. **Classification of Industry** **I) Industries based on type of goods produced** 1) Extractive industries 2) Genetic Industries 3) Construction Industries 4) Manufacturing industry: They are sub classified as, o Analytical industry o Synthetic Industry o Processing industry o Assembly line industry **II) Industries based on Size & amount of investment** i) Light industries ii) Heavy industries	**2M**

		III) Industries based on Capital employed i) Large Scale Industry ii) Small scale Industry **IV) Official classification of industries:** For the purpose of licensing, government made standard classification of industries as given under the first Schedule to the Industries Act, 1951.	
2		**Answer any FOUR of following(3.5 marks for each)**	**14M**
2	**a)**	**Define the term 'firm'. Give advantages of partnership type of organisation.(½ Mark for definition & 3 Marks for any Six advantages)** The persons who have entered into partnership are called partners, individually and collectively called as firm. OR The business organization which runs as a partnership is called a **firm.** **Advantages of partnership type of organisation:(Any Six)** **1)** The formation of a partnership firm is a simple procedure. **2)** The firm's object, mode of operation and policies of the firm can be altered from time to time without any legal formalities. **3)** The partnership firm can raise a larger amount of finance than a sole trader. **4)** Complete business secrecy can be maintained. The profit and loss account and balance sheet of the firm need not be published. **5)** Firm has longer existence as it is not dependent on any one person. **6)** The rights of each partner are well protected in the partnership firm. **7)** Business can be expanded by extending the partnership. (up to 20) **8)** The losses incurred by the partnership firm are divided among the partners. Due to this, each partner's loss will be less than in case of the sole trader. **9)** Profit incurred is distributed among all the partners in the decided ratio. **10)** The division of responsibility and work among the partners leads to specialisation among the partners and firm.	**3.5 M**

		11) Each partner of the firm has unlimited liability. It serves as an important security to creditors who lend money to the firm. **12)** Partners can take quick decision due to firm's size, as compared to that of Joint Stock Company.	
2	**b)**	**What is Drug codification? Explain various methods of drug codification.(1 Mark for definition & 2 ½ Marks for methods for codification)** **Drug codification :**It is the process of assigning of code symbol or a number to a particular material for easy identification Following are the methods of codification **1) Alphabetical method** This is also known as letter code system. E.g Code ' T' represents tablet and code 'C' represents capsules. Not suitable for large number of items. **2) Mnemonic method** In this method code is given to items .e.g. AT represents aspirin tablets etc. The main disadvantage is the materials cannot be recognized without the referring to code index. **3) Numerical method** This method is known as sequence system. Separate no. are given to different classes of items. The new item is given the next higher number in the sequence. **a)Decimal system** In this system the numbers are assigned in such a manner that each digit represents sub group of previous digit. E.g.15.1 represents paracetamol tablet where15 is the analgesic group. The main advantage is this system has capacity to expand to accommodate new items, The main disadvantage is it is	**3.5M**

		cumbersome to use. **b)Block system** In this method the set of numbers are reserved for specified classification. e.g. 101-300 allotted to tab **4) Combination system** In this the mnemonic & numerical methods are combined together. E.g. MT 100 is given to Meftal 250mg. tablets & MT 101 is given to Meftal 500mg	
2	**c)**	**Define market research. Explain various sources for the same.(1 Mark for definition & 2 ½ mark for any Five sources)** Market research is defined as systematic, objective & exhaustive research of the facts relevant to any problem in the field of marketing. **OR** It is the systematic gathering, recording and analyzing the data about the problems associated with the sale of goods and services from manufacturer to consumer. **Primary sources:** The survey techniques are used to collect information from the primary sources. These are **i) Salesmen** If a firm employs salesman to conduct and promote the sale of its products they can be asked to provide an assessment of the consumer and dealers with respect to the firm's product. They will provide first-hand knowledge of the market conditions and distribution system without any additional expense. However the salesmen are not trained for market research and therefore their reports may not be unbiased and accurate. **ii) Dealers:** Dealers may be contacted to provide information regarding the percentage of the sales of the firm's products to the total sale of that kind of products of other firms over a certain period and feedback about the consumer's reaction to the product. But this source does not provide reliable information because the retailers do not have well	**3.5 M**

		organised system of record keeping. **iii) Consumers:** The opinion and attitudes of the consumers is the right source for getting accurate information regarding the quality, price , packaging availability of the firm's product. It needs field survey which is called 'consumer research'. **Secondary sources:** There are certain agencies which gather information after doing the proper survey of the market and present the data in a printed form. 1) **Trade press:** This includes trade journals, economic and financial periodicals, and annual reports published by some business houses and banking companies. 2) **Trade associations:** Many trade associations conduct independent market research and collect useful data pertaining to different trades and markets. 3) **Published surveys:** There are many independent research organisations which publish data contained in reports of the market survey for specific product from time to time. 4) **Government and International publications**: The published periodical reports, journals and bulletins issued by Planning Commission and various Ministries generally contain a lot of useful information for the researcher.	
2	**d)**	**Define Bank. Write its functions.(½ Mark for definition & 3 Marks for any Six functions)** A bank is a comprehensive term for a number of institutions carrying on certain kinds of financial business dealing in money. **OR** Bank is an institution where the transactions of money take place. **Functions of Bank.(Any Six functions)** **Services to depositor:** a) They collect the cheque, demand draft, hundis, local and foreign bills on behalf of their depositor	**3.5 M**

b) They offer discounting facilities in respect of local and foreign bills of the depositor

c) They pay insurance premium subscription and taxes on behalf of the depositor

Services by way of loan:

a) **Overdraft:** The overdraft facility permits the customer to overdraw from his account however the bank fixes the limit beyond which the customer cannot overdraw and the customer is required to pay specific rate of interest on over drawn amount on daily basis. The overdraft facility is allowed only against some security.

b) **Cash credit:** Bank fixes a limit up to which a customer may borrow money from it against some security and interest is charged by the bank on the outstanding amount in cash credit account.

c) **Loans:** The bank gives loans to the customers against some security of mortgage.

d) **Discounting of bills:** The bank encashes the customer's bill before they become due for payment and for this service the bank charges a nominal discount

Miscellaneous services :

a)It buys and sells shares/bonds / debentures on behalf of its customers

b) Lockers are provided to the customers for safe keeping of jewellery and important documents

c) It makes regular payment of subscription, insurance premium, taxes etc. on behalf of its customers

d) It collects interest/dividend on securities and shares belonging to its customers

e) It accepts bills of exchange in respect of imported goods and also purchases bills of exchange

f) It helps people going abroad by arranging for foreign exchange

		g) It provides assistance and advises the customers with regard to investment.	
2	**e)**	**What is accounting convention? Explain various accounting conventions.(½ Mark for meaning of accounting convention & 3 Marks for any three conventions)** **Accounting Conventions:** is used to denote established customs or traditional practices as a guide to the preparation of accounting statements. **Various accounting convention** **1)Convention of disclosure:** The convention of disclosure implies that all material information must be disclosed and the accounts are prepared honestly. **2)Convention of materiality:** The financial statements are expected to disclose all material items, the knowledge of which might influence the decision of the users of financial statements. **3)Convention of consistency:** It means the same accounting methods are followed from one accounting period to the other. The comparison of the result of one accounting period with those of another is possible only if convention of consistency is strictly followed. **4)Convention of conservatism:** Conservatism means a guideline which chooses from acceptable accounting alternatives the one for recording events or transactions which reports the least favourable immediate effect on assets, income and owners' equity. The convention of conservatism provides to play safe. It takes into consideration all prospective losses but leaves out all prospective profits.	**3.5M**
2	**f)**	**Define ledger. Give its importance and format.(½ Mark for definition, 2 Marks for any two importance & 1 Mark for format)** **Ledger:** Ledger is the book which contains, in a summarised and classified form, a permanent record of all transactions of a business. OR **Ledger:** is a book containing all the accounts to which entries are transferred from the books of original entry. **Importance of Ledger:** A ledger is very important and useful in maintaining the account of an organisation because: 1) The management can know on a particular date the amount due from a certain customer or the amount the firm has to pay to a particular supplier. 2) The various transactions pertaining to an account may be spread over in the journal in various pages, but all these transactions are recorded on one page in ledger.	**3.5 M**

3) The accounts are opened in the ledger in some definite order so that these can be included in the same order while preparing P&L account and balance sheet.
4) The accounts can be easily located by going through the index.

Format of Ledger

'Dr' 'Cr'

Date.	Particulars	J.F	Amount Rs	Date	Particulars	J.F.	Amount Rs

3		**Answer any FOUR of following (3.5 marks each)**	**14M**
3	**a)**	**Define budgetary control. Explain in short classification of budget.(1/2 Mark for definition & 3 Marks for classification of budget)**	**3.5M**

Budgetary control: means a constant checking and evaluation of actual results achieved compared with the budget goals, which enables the management to take corrective action where indicated.

Classification of Budget

According to time factor	**According to Flexibility factor**	**Functional classification**.
1. Long-term budget	1. Fixed budget.	1. Sales budget.
2. Short-term budget	2. Flexible budget.	2.Selling and distribution cost budget
3. Current budget		3. Production budget.
.		4. Production cost budget.
		5. Purchase budget.
		6. Labor cost budget.
		7. Production overhead budget.
		8. Capital budget.
		9. Cash budget.
		10. Master budget.

3	**b)**	**Write about any three methods for analysis of 'Financial statement'(3 ½ Marks)** 1 **Comparative financial statement**: These statements contain figures of two or more consecutive years, which give a comparative view of the financial performance of a firm. A comparative profit & loss account gives expenses & revenues of two consecutive years. Similarly, a comparative balance sheet contains the amounts of assets & liabilities at two different points of time. 2 **Common size financial statements:** In these statements, figures are converted into percentages to some common base. For ex. In P& L account, the sales figure is assumed to be 100 and all figures are expressed as percentage of sales. 3 **Funds flow analysis:** It reveals changes in the working capital position of an enterprise. It indicates the sources from which the working capital was obtained & the purpose for which it was used. 4 **Ratio analysis:** It is the most popular method of financial analysis. The term ratio refers to the numerical relationship between two items. The various accounting ratios are: Liquidity ratios, solvency ratios, activity ratios, profitability ratios, Misc. ratios	**3.5M**
3	**c)**	**Define 'Training'. What subject must be covered under training of pharmacist?(1 Mark for definition & 2 ½ Marks for any Five points)** **Training:** Training is the scientific process of improving the knowledge and skill of the employees for doing a particular job The main purpose of the training is to mould the behavior of the new recruits so that they can do their job in a more efficient way. **Training should cover the following subjects.** 1. Rules & policies of the enterprise 2. Routine work of drug store such as, display of inventory, recording methods of sales, maintaining cash book, proper wrapping etc. 3. The technical knowledge of selling of products. 4. Dealing with customers who visit the drug store.	**3.5M**

		5. Highlights of new products should be known to pharmacist. 6. Handling of prescription	
3	**d)**	**Define and classify 'Trade'.(1 Mark for definition & 2 ½ Marks for classification)** **Trade:** Trade means buying, selling and exchange of goods & services. **Classification:** 1) **Internal trade/Home trade:** It consists of sale and exchange of goods within the boundaries of a country. It is further classified as follows • Wholesale trade: It involves sale of goods in comparatively large quantities to those traders who are in direct contact with retailers. • Retail trade: In this trade the retailers supply the requirements of consumers in small quantities as per their needs. 2) **International trade/External trade:** It means the exchange of goods and services between different countries. • Import trade – When a trader of one country purchases goods from the traders of other countries, it is called as import trade. • Export trade: When the trader of one country sells goods to the trader of other countries, this trade is called as export trade. • Entreport trade: When trader purchases goods from one country and sells the same goods to another country, it is called as entreport trade	**3.5M**
3	**e)**	**Explain different types of middlemen involved in the distribution of goods from the producer to consumers.(3 ½ Marks)** **Types of middlemen** **A) Functional middlemen** They help in transfer of goods from the hands of producers to the customers without having an ownership rights. (they do not have title to goods) a) **Brokers**- Their only function is to bring buyer & seller together. If hired by seller then called as selling agent & if engaged by buyer called as buying agent. They get	**3.5M**

		certain % of commission. b) **Commission agent**: They negotiate the sell of goods, take possession & make arrangement for transfer of the goods. So he has to arrange for warehousing, grading, packing, assembling & disposal. c) **Auctioneers**: They collect goods display & invite bids from buyers. Bid means the price which the buyer is willing to pay for the goods being auctioned. The buyer making the highest bid gets the goods. **d) Del credre agent**: They find the buyer & also guarantee the payment of price on their behalf. The agent has to pay the sum if the buyer fails to pay. Del credere agents charge higher than normal commission rates. **B) Merchant middlemen** Merchant middlemen purchase the goods to resale them for a margin of profit. They take possession & become owner of the products and transfer title of ownership to the buyer when the goods are sold. They are classified as follows: a) **Wholesaler**: Wholesalers are the merchants who act as intermediaries between the manufacturers and retailers. They buy goods in large quantity from producer & sell them to retailers. They are of three types - Manufacturer wholesaler ,Wholesaler proper & retailer wholesaler b) **Retailers:** They are the middlemen between wholesaler & consumers. Retailing is the final stage of distribution of goods and involves selling to the ultimate consumers. There are two types of retailers – itinerant and fixed shop retailers	
3	**f)**	**Define sales promotion. Give various techniques of sales promotion.(1 Mark for definition & 2 ½ Marks for any five techniques of sales promotion)** Sales promotion includes the marketing activities other than personal selling, advertising & publicity that stimulate the consumer purchasing such as window display, shows, demonstration etc. **<u>Techniques of sales promotion</u>** **1) Free samples**-The medical representatives give free samples to the doctor. This method is useful for new products. It is an expensive method and used only by big organizations.	**3.5M**

		2)Trading stamps-The stamps are issued in proportion to the purchase. The customers collect the stamps& exchange it for free product. **3)Coupons -**Coupons entitle the holder to save certain amount on purchase of specific product. The coupons may be sent via post, magazine, newspaper or retailers. The retailers give discount to the customers. The firm reimburses the retailers for the same, **4)Premium or Bonus offer:** In this the firm gives certain quantity of the product free of cost on purchase of a specified quantity of the product • **With pack premium**: The free product is given along with the product purchased by the customers. • **A reusable container**: The product is packed in a container that has utility for the customer after it is consumed. • **Free in the mail premium**: Free gift is given to the customer on producing a proof of purchase i.e. cash memo or wrapper of the product. **5)Prize contest**: The contests are held for customers, salesmen and dealers. They are required to write slogan or complete sentence about the utility of the product. The best entry gets the prize. **6)Fairs and exhibitions:** These are organized to display and popularize product of the firm.	
4		**Answer any FOUR of following (3.5 marks each)**	**14M**
4	**a)**	**Explain 'Petty Cash Book 'along with its format.(2 Marks for explanation & 1½ Marks for Format)** **Petty cash book** Large number of small payments, such as, for conveyance (bus, taxi), stationery, postage, telegrams, cartage and other miscellaneous expenses is made in any business organisation. If all these payments are handled by the cashier and are recorded in cash book, the procedure is found to be very cumbersome. To avoid this, a petty cashier is appointed. The petty cashier works on the imprest system that is definite sum known as imprest money is given to petty cashier to make small payment out of it. All small payments are handles by the petty cashier and are recorded in cash book. When he has spent a major portion of his imprest money he gets reimbursement of the amount spent from main cashier. The reimbursement may be	**3.5M**

made to the petty casher on weekly, fortnightly or monthly basis depending on the frequency of payment's made.

Dr Cr

Date	Particulars	Total amt Rs	Date	Particulars	Voucher number	Total amount Rs	Conveyance Rs	Stationery Rs	Postage & telegram Rs	Cartage Rs	Misc Rs	Remarks

4 b) What do you mean by 'Balance Sheet'? Give its format and objective.(1Mark for meaning, 1 ½ Marks for any three objectives & 1 Mark for Format) **3.5M**

Balance sheet is a statement of accounts prepared for the purpose of ascertaining the exact financial position of the business on the last date of the financial year under review.

Objectives –

1. It provides information as to the total amount of money involved in running the business enterprise
2. It shows the financial state of the business firm as on a particular date
3. It gives information regarding the nature and the cost of assets of the firm
4. The information regarding nature and cost of firm liabilities is available from a balance sheet

Format

Dr Cr

Liabilities	Amount Rs	Assets	Amount Rs

4 c) Define economics. Write about different types of economic systems. **3.5M**

Economics: It is a social science concerned with proper use of allocation of resources for achievement of various human needs.

OR

Economics is the social science concerned with the employment of scarce resources of society, having alternative uses to produce goods & services.

		There are three types of economic systems – capitalist, socialist and mixed • **Capitalist system** – There is freedom for the producers to acquire any property and to produce any product. The consumers are also free to use any product in any amount, they are at liberty to spend their income. The means of production and distribution are generally in the hands of private owners. The role of government is to protect the producers and consumers so as to avoid unhealthy competition and also to provide essential services to the public economically. • **Socialist system** – The large and basic industries are owned and controlled by the government, even the distribution is controlled by the govt. • **Mixed system** – The activities of both the systems capitalist and socialist are used. It means some economic activities are controlled by the government and certain other economic activities are kept open for the public.	
4	**d)**	**Write disadvantages of 'Sole proprietorship' type of business.(½ Mark each for any seven disadvantages)** **Disadvantages:** 1. The individual proprietor generally suffers due to lack of financial resources. So, it is difficult to expand the business. 2. It is very difficult for a single person to look after all aspects of business. Eg, - production, sale, finance, advertising, keeping accounts competently 3. The business is usually run on small scale. The benefits of large-scale business cannot be enjoyed as this may raise the cost of business. 4. The liability for business debts is unlimited. 5. The business ends with the death of the proprietor if the heirs are not qualified or competent to run the business 6. There are no checks and control on the sole proprietor. 7. The benefits of division of labour are not enjoyed by sole trader. 8. The financial resources of a sole trader are generally limited.	**3.5M**
4	**e)**	**Define 'Scrap and Surplus'. Give its disposal procedure. (1 Mark each for definition of scrap & surplus and 1 ½ mark for Disposal procedure)**	**3.5M**

		Scrap: Scrap is residue incidentally obtained from manufacturing process. It is usually a small value and is recoverable without further processing. Eg powder and fine granules obtained in processing of tablets, non-returnable containers and packing cases. **Surplus items:** Surplus items are those items which are not required by the organisation..Eg rejected components, defective parts, obsolete material etc **There are two methods of disposal of scrap & surplus** • It can be reprocessed into useful raw material for subsequent production • It is sold if it cannot be recycled into useful material.	
4	**f)**	**Write about various qualities of successful salesmen.(3 ½ Marks)** **Qualities of good salesman:** **A) Personal qualities:** • A good salesman must have an attractive personality. • He must possess good health & sound physique • He should have a clear voice & his tone of speaking should be natural. • He should also be well dressed as it adds to his charm. • He must have good stamina. **B) Mental qualities:** • A good salesman should possess a sound memory, presence of mind, imagination, foresightedness, sound judgement & initiative. • He should be intelligent enough to understand the nature & requirements of potential buyers. • He must have the imagination to look at things from the viewpoint of the customer. • He should be persuasive, tactful and convincing. **C) Social qualities:** • A good salesman must have a liking for people & the ability to mix with them.	**3.5M**

		• He must not be shy & of reserved nature. • He should be sincere, dependable, co-operative & honest. • He should have patience to listen to his customers & resolve their objections. • He should always be polite & courteous while dealing with his customers. • He must help the customers in selecting the right type of goods. **D) Vocational skills:** • A good salesman must have specialized knowledge of selling techniques. • He should have a thorough knowledge of the products, customers & competitive products already available in the market. • He should be fluent in different languages.	
5		**Answer any FOUR of following (3.5 marks each)**	**14M**
5	**a)**	**What is 'Profit and Loss Account'? Give its objective and format.(1Mark each for meaning & format and 1 ½ for objectives)** **Profit and loss account**: is an account that reveals the net profit earned or net loss suffered by a firm in course of its business operations during the accounting period. It is prepared at the end of the financial year of the business. **Objectives of profit and loss account:** 1. It provides information about net profit or net loss in the business during the accounting period. 2. It helps in comparing the net profit or net loss of current year with the net profit or net loss of the previous year. From this comparison the businessman can come to know whether the performance of the business over the years is improving or declining. 3. It guides in controlling expenses incurred in running the business enterprise & in sale of goods, thus eliminating wastage & improves future profitability.	**3.5M**

Format of 'Profit and Loss Account'

Dr Cr

Particulars	Amount (Rs)	Particulars	Amount (Rs)

5 b) What is journal? Give its format and advantages.(1 mark each for meaning & format and 1 ½ marks for any three advantages) **3.5M**

Journal is the basic book of original entry. The journal provides a chronological record of all transactions with details of the accounts debited & credited & the amount of each transaction. The transactions from this book are posted in the ledger.

Date (1)	Particulars (2)	L.F. (3)	Debit (4)	Credit (5)
	Narration			

Advantages of journal: (Any Three)

1) It is book of original entry, which provides date-wise record of all business transactions.
2) Each journal is a complete reflection of rule of double entry.
3) It reduces the chances of error in accounting.
4) Narration gives a brief explanation of particular transaction.
5) As the transactions are recorded immediately in journal as & when they take place, it eliminates the necessity of posting ledger immediately after the transaction.
6) The page number of the ledger is given in L.F. column in journal, which helps in locating the transaction posted in ledger.

		7) Courts recognize the journal as evidence in proving or disproving claims.	
5	**c)**	**What do you mean by 'Joint Stock Company'? Give its two advantages and two disadvantages.(1 ½ for meaning and 1 Mark each for any two advantages & disadvantages)** A 'Joint Stock Company' is a form of business organization formed and registered under Company Act, 1956. A Joint Stock Company is organised to carry on a business on a large scale. **Advantages: (any two)** 1) Large no. of investors are available for the capital, so a business can be organized on a large scale. . 2) Well qualified & experienced persons can be appointed for effective management which helps the company to earn increasing profits. 3) The shares of the company can be transferred easily & can also be easily converted into cash which attracts investors. 4) The management of the company is conducted on democratic principles. The company is run by board of directors elected by members in general body meeting of the Co. 5) The liabilities of the members of a company are limited to the nominal value of the shares held by them. 6) Risk of each member is reduced because it is diffused and spread over several members of the company. 7) Since a company pays income tax at flat rates, it bears low tax- liability on higher profits as compared to others. 8) Insolvency, insanity or death of its members has no effect on existence of company **Disadvantages: (any two)**	**3.5M**

		1) Formation of company is costly, time consuming & number of formalities are required. 2) Company cannot take prompt decisions, due to time lag between board meetings & difficulty in getting requisite quorum. 3) It is not difficult for an unscrupulous management to indulge in malpractices & to cheat the investors. 4) Company is not managed by proprietors (shareholders.) Directors sometimes misuse their positions. 5) Secrecy of the business affairs cannot be maintained. 6) A Joint stock company may gain exclusive control over the production or distribution of a commodity which may lead to exploitation of consumers. 7) Persons controlling the company may attempt to influence economic & political decisions made by the government.	
5	**d)**	**Define management, pharmaceutical management. Mention various functions of management.(1 Mark each for definition of management & Pharmaceutical management and 1 ½ for Functions)** **Management**: Management is the process of conducting and managing various business activities. It is the art of securing maximum results with the minimum efforts so as to secure maximum prosperity and happiness both for the employer and employees and at the same time to provide best possible service to public. **Pharmaceutical management**: When the principles and practices of management are applied to pharmaceutical industry and drug store, it is called as Pharmaceutical management. **Functions of management:** 1. Planning 2. Organizing	**3.5M**

		3. Staffing 4. Directing 5. Controlling 6. Coordinating	
5	**e)**	**Give advantages of departmental store.(3 ½ Marks)** 1. It provides great convenience in shopping as customers can get their all requirements at one place. 2. It keeps a large variety of goods, thus offering a good choice to customers, when they buy the required goods. 3. The departmental stores are located mainly in the central part of the city. So it is convenient for all types of consumers to visit it. 4. It buys its requirements in large quantities which reduces its cost & increases the profit. 5. Due to huge sale in departmental stores, the selling cost per unit becomes very low. 6. It provides telephone facilities, recreation facilities & free home delivery facility to its customers. 7. It can afford to employ competent sales persons to attend to its customers. This leads to efficiency & increased customer satisfaction.	**3.5M**
5	**f)**	**Enlist the qualities of the approved supplier. (3 ½ Marks for any seven qualities)** An approved supplier possesses following qualities: (any seven) 1. The price is lowest or reasonable as compared to competitors. 2. Has a good reputation in the market. 3. Has a sound financial position. i.e can supply the material on credit. 4. Possesses manufacturing capabilities of a range of materials. 5. Has proven record to supply at a short notice.	**3.5 M**

		6. Provides after sales service or technical assistance as and when required. 7. Supplies the required consignment according to the delivery schedule. 8. Quotes agreeable terms & conditions of payment.	
6		**Answer any FOUR of the following: (3.5 Marks for each)**	**14M**
6	**a)**	**What is 'Trial Balance'? Explain two methods for preparation of Trial Balance along with its format.(1 Mark each for definition & any one format and 1 ½ Marks for methods for preparation)** **Trial balance**: is a statement prepared to check the arithmetical accuracy of the book-keeping entries up to the date stated at the head of the trial balance. It ensures that both the aspects of each transaction have been duly recorded. **Balance method:** In this method, all the ledger accounts are first balanced. This is done immediately after postings have been made from books of original entry to the ledger. For this purpose, the debit & credit sides of each ledger account is totalled & balance on debit as well as credit side is obtained. The balances are then recorded on the debit or credit side of the trial balance. If the grand total of debit & credit balances tally, it shows arithmetical accuracy in the books. **Trial Balance as on 31st March 2019**	**3.5M**

Particulars	*Balance*	
	Dr	*Cr*

		Total amount methods: In this method the total on debit side of every ledger account is entered under debit column of the trial balance & the total on the credit side of each ledger account is recorded under credit column of the trial balance. A grand total of both debit and credit side is then taken. In case grand total on both sides tally, it indicates arithmetical accuracy of the trial balance. **Trial Balance as on 31st March 2019** Particulars | Debit total(Rs) | Credit total(Rs) | | |	
6	**b)**	**What is 'Day-Book'? Explain in short various types of Day-Books.(½ Mark for meaning and 3 Marks for any three day books)** There are large numbers of transaction of similar type. In order to maintain a proper record of all such transaction the firm maintains special journal known as day book. **Following 'Day-Books' are commonly used:** 1) **Purchases journal/book**- It is also called 'Invoice book' & is used for recording purchase of goods on credit. The entries into purchases are recorded from the invoices or bills received from the supplier of goods. Trade discount & other details are not recorded. **2) Sales journal/book-** It is used for recording of sale of goods on credit. The entries into sales journal are recorded from sales invoices or bills issued by the firm to the customers. **3) Purchases return journal/book-** It is used for recording transactions relating to return of goods purchased on credit. When goods are returned to the supplier, a debit note is prepared in duplicate. **4) Sales return journal/book-** It is used for recording transactions relating to return of	**3.5M**

		goods sold by a firm to customers on credit. On receipt of goods from customer, a credit note is prepared in duplicate.	
6	**c)**	**Give salient features of Multiple Shop.(3 ½ Marks for any seven features)** **Following are the salient features of multiple shop:** 1. They are group of shops in the same branch of retail trade. 2. There is fixed price & std. quality of goods available. 3. The branches can be easily identified due to uniformity in decoration 4. The middlemen profit is avoided as there is direct contact bet. Producer & customer. 5. The goods can be transferred to other branches if needed. 6. The sale is on cash payment. 7. The supply of items to various branches is made direct from head office 8. A single firm's branches are situated at different locations in the city or different parts of the country. 9. They provide shopping facilities near the residence of would be customers. 10. Each branch deals in similar line of goods. 11. Purchasing, assembling, transporting, advertising & financing for all multiple shops is made by central office.	**3.5M**
6	**d)**	**List the documents required for getting the license of starting wholesale trade.(3 ½ Marks)** The documents required for getting the license of starting wholesale trade are as follows: 1. Application in duplicate on Form 19 of The Drug & Cosmetics Rules. One copy for biological drugs & other for non-biological drugs. 2. A fee of Rs. 1500/- per license (Total Rs. 3000/-) to be deposited in State Bank of India/Government Treasury on challan form in specified head for grant of wholesale license. 3. (a) Attested copy of Diploma in Pharmacy from any institution duly recognized by Pharmacy Council of India. (b) Attested copy of registration certificate issued by State Pharmacy Council &	**3.5M**

		Certificate on the basis of which registration was done with State Pharmacy Council. (c) Attested copy of the 'Experience certificate' of minimum of 4 years in sale/distribution of drugs after Matriculation on salary basis. OR Attested copy of the 'Experience certificate' of minimum of one year in dealing with drugs after graduation, in any discipline, from a recognized university on salary basis. (d) Attested copy of matriculation certificate/graduate degree certificate. (e) Affidavit of the qualified person if the qualified person is an employee of the firm. 4. Affidavit to be given on non-judicial stamp paper duly attested by first class magistrate by each partner in case of partnership concern & by proprietor himself/herself in case of proprietorship concern. 5. Plan of the premises on blue print. 6. Rent receipt in case of rented premises or affidavit if the person is himself/herself the owner of premises. 7. Copy of the partnership deed in case of a partnership concern. 8. Receipt showing the purchase of refrigerator.	
6	**e)**	**Write note on perpetual method of inventory control along with its advantages.(2 Marks for short note and 1 ½ Marks for any three advantages)** This is a method of recording the store balance after every receipt and issue to facilitate regular checking and to prevent closing down for stock-taking. The perpetual inventory systems comprises of- 1.Bin Card 2.Stores ledger 3.Continuous stock-taking	**3.5M**

		Bin Card- This is a document maintained by the store-keeper in his store to keep record of all items of materials and goods in his store. So bin card serves the purpose of providing ready references. It shows quantities of each material received, issued and in stock. **Store ledger**- It is kept in the cost accounting department. The stores ledger is generally maintained in the form of loose leaf cards because they can be easily removed and inserted. **Continuous stock taking** : Under this system only a limited number of items are verified on a day. The selection of the items of materials should be such that each item of material gets checked up at least a certain number of times in a year & checking of a particular item is evenly distributed during the period. The selected number of items are counted daily or at frequent intervals and compared with the bin card and stores ledger by the store keeper. The bin card and store ledger record the balances and their correctness can be verified by means of physical verification .In case any difference between recorded and actual balances, it has to be pointed out to the management. **Advantages of perpetual method of inventory control** 1) Balance of stock can be known at any time during the year 2) It is helpful in formulating proper purchase policies 3) Detail & more reliable check can be obtained 4) Errors & shortages of stock are discovered & can be avoided in future 5) Capital investment in material will be controlled 6) Continuous stock verification makes store keeper more efficient. **OR** 1) It helps in detection & immediate rectification of errors & discrepancies. 2) It ensures reliable checking of the items in a systemic way without disturbing routine work. 3) Timely action can be taken on serious shortage. 4) There is a moral check on the staff. 5) It helps in compilation of profit & loss account & balance sheet. 6) Overstocking & under stocking is avoided.	
6	**f)**	**Define financial planning. Give various sources for collection of finance.(1 Mark for definition and 2 ½ Marks for sources)** **Financial planning**: is defined as the process of deciding the financial activities or goals of	**3.5M**

organization.

Various sources of collection of finance are:-

1. **Owned capital**- It is contributed by owner & remains invested in business.
2. **Loan capital**- It may be raised from individual banks or financial institutions. It involves periodical payments of interest at a fixed rate & repayment of loan capital after the expiry of the stipulated period. It is available against mortgage or pledge of property of borrower.

   On the basis of duration, sources of finance are classified into:-

   1. Long term finance (ten years or more)
   - a. Shares- Preference shares, Ordinary shares
   - b. Debentures
   - c. Ploughing back of profits
   - d. Financial Institutions- IFCI, IDBI, ICICI, IRBI, NSIC, SFC's, SIDC's, UTI

   2. Medium term finance (three to ten years)

   a. Issue of preference shares

   b. Public deposits

   c. Mortgages

   d. Issue of debentures

   e. term loans from bank

   f. Assistance from special financial institutions.

   3. Short term finance (less than two years)
   - a. Trade credit
   - b. Bank credit
   - c. Installment credit
   - d. Customer advances

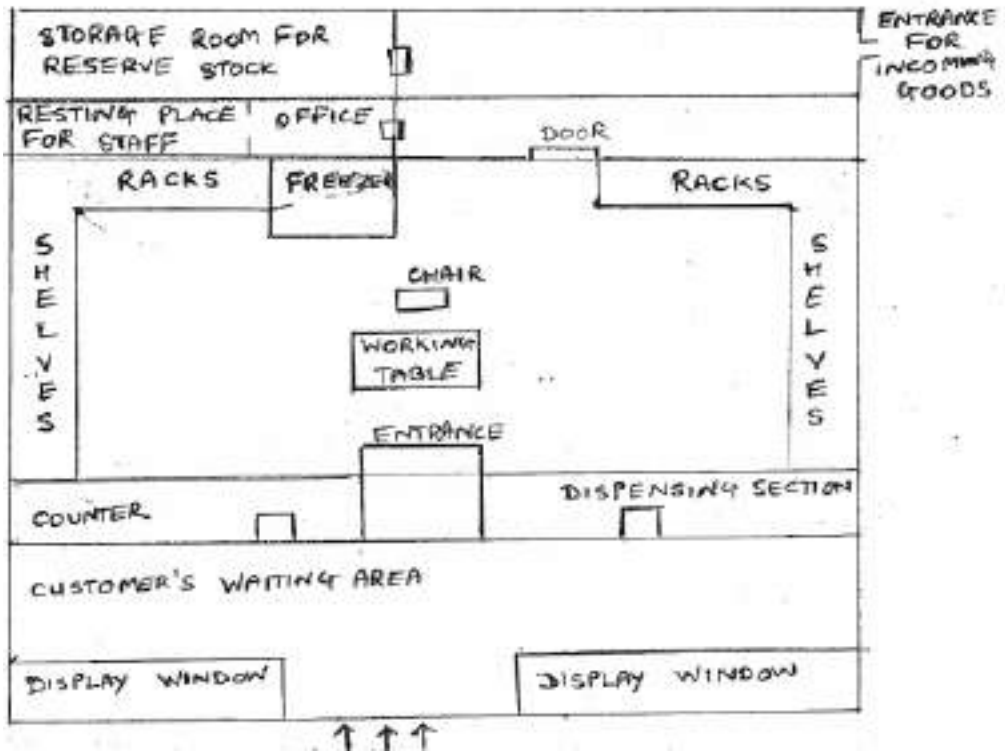
Subject Title: Drug Store & Business management Subject Code: 0815

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.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Answer any Eight of the followings:**	**16M**
1	**a)**	**Define the term: (**1 M each) **i) Recruitment –** is the process of exploring the source of supply of the required personnel and stimulating the prospective employees to apply for jobs in the organization. ii) **Training -** is the scientific process of improving the knowledge and skill of the employee for performing a particular job.	2M
1	**b)**	**What do you mean by Book of Original Entry? Give two examples of it.** **(1 M for meaning, 1 M for egs)** **Book of Original Entry** – These are books for account in which a transaction is recorded for the first time from source document is called book of original entry. Examples – 1. Journal 2. Cash book 3.Other day books a) Sales day book b) Purchase day book c) purchase return book d) sales returns book	**2M**
1	**c)**	**Define inventory control. Enlist different techniques of inventory control.** **(1 M definition, 1 M for any 4 techniques)** Inventory control is a process of maintaining optimum level of inventory by using any technique of inventory control. **OR** It is a systematic control, constant checking & evaluation of stored inventories. **Techniques of Inventory Control** 1. ABC analysis	2M

		2. Economic Order Quantity 3. Perpetual Inventory system 4. Review of slow and non-moving items 5. Input output ratio analysis 6. Setting of various level 7. Use of Material Budgeting 8. Establishing an effective purchase procedure 9 Scrap & surplus disposal 10 VED analysis	
1	**d)**	**Define Trade. Enlist various aids to trade.** **(1 M definition, 1M for any 4 aids to trade)** Trade means buying, selling and exchange of goods and services. **Aids to trade** • Banking • Transport • Insurance • Warehousing • Packaging • Advertising and publicity	2M
1	**e)**	**State the channel of distribution in Pharmaceutical industry.** **Direct selling:** i) Manufacturer - Consumer **Indirect selling of drugs to consumer includes following intermediates.** i) Manufacturer – Distributors- wholesaler - Retailer (pharmacist)- Consumer. ii) Manufacturer - Wholesaler - Retailer(pharmacist) - Consumer iii)Manufacturer -Wholesaler (pharmacist)- Consumer iii) Manufacturer - Retailer (pharmacist)- Consumer	2M

1	**f)**	**Mention basic principles of effective window display.** **(2 M for any 4 principles)** 1. There should be insignia (green cross). 2. It should display seasonal items. 3. It should show the price of the items. 4. The items should be changed frequently to give fresh look to the display. 5. The window should be well lit during night. 6. It should include moving objects if possible. 7 There should be decorative background, using wall papers etc.	2M
1	**g)**	**Sketch typical layout of ideal retail drug store.** 	2M
1	**h)**	**Define business. Enlist distinct forms of business organisation.** **(1 M definition, 1M for forms)** Business means any kind of activity that keeps a person busy, includes all individuals and group activities, directed toward earning money acquiring wealth through production and	2M

		exchange of goods and services **Various Types of business organisations.** ➢ Sole proprietorship – Ex. Small scale retail shop ➢ Partnership Ex. Large scale retail shop. ➢ Joint Stock company Ex. Cipla Pharma, Sun pharma, Ranbaxy etc. ➢ Cooperative society Ex. Swadesh, Sahakari Bhandar	
1	**i)**	**What is 'Ordering Cost' and 'Inventory Carrying Cost'?** **(1 M each)** **Ordering Cost:** are the expenses incurred to create and process an order to a supplier. It consist of cost of paper work which consist of use paper, typing, posting, filing etc. It also includes salaries of staff involved in work, incidental cost like follow up, receiving, inspection etc. **Inventory carrying cost:** Refers to the total cost of holding inventory. It includes rent on storage, cost of insurance and taxes, salaries of the store keeper, losses in store due to pilferage, wastage, breakage etc.	2M
1	**j)**	**What is the meaning of Accounting concept and convention in Accountancy? (1M each)** **Accounting concept** mean the necessary assumption or conditions upon which accounting is based. **Accounting conventions** is used to denote established customs or traditional practices as a guide to the preparation of accounting statements	2M
1	**k)**	**Define finance. Enlist various sources of finance.** **(1M each)** **Finance**:- Finance is the provision of money at any time when business requires it. **Various sources of finance are**: **1) Long term finance**: a) Shares b) Debentures	2M

		c) Ploughing back of profits d) Financial institutions. **2) Medium Term finance:** a) Shares b) Debentures c) Ploughing back of profits d) Financial institutions e) Public deposits f) Mortgages **3) Short term finance:** a) Trade Credit b) Bank Credit c) Installment credit d) Customers advances.	
1	**l)**	**Define the term financial statements.** The term financial statements means the two statements prepared at the end of the accounting period of the enterprises.	2M
2		**Attempt any FOUR of the following**	**12M**
2	**a)**	**Define recruitment. What are the different methods of recruitment of a pharmacist?** **(1 M definition, 2 M for methods)** **Definition:-** Recruitment is a process of exploring the source of supply of the required personnel & stimulating the prospecting employees to apply for jobs in the organisation. Methods employed in recruiting a pharmacist: 1) By State or central Government agencies, such as ‘ Service selection board’ 2) For the job of a salesman, recruitment is done either by the owner of the drug store or by the personnel department of the pharmaceutical house or the sales manager of the firm. 3) An advertisement is given in leading newspapers, popular magazines and professional journals. The detailed description of the post is given and the interested candidates are required to submit their application along with their bio-data, before the last date.	**3 M**

		4) Present pharmacy employees are requested to recommend suitable registered pharmacy candidates. **5)** By advertising on notice board of institute. **6)** Through professional association & clubs.	
2	**b)**	**Explain : 'perpetual inventory control system' in detail.** **(1M for each)** This is the method of recording the store balance after every receipt and issue to facilitate regular checking and to prevent closing down for stock-taking. The perpetual inventory system comprises of– a. Bin card b. Stores Ledger c. Continuous stock-taking **Bin card** - This is a document maintained by the store-keeper in his store to keep records of all items in his store. So bin card serves the purpose of providing ready references. It shows quantities of each material received, issued and in stock. A bin card is used for each material. Each receipt, issue or return is recorded on bin card in a chronological order and the latest balance is shown after each receipt and issue. The format of bin card is as follows	**3 M**

Aroma Pharmaceutical Pvt. Ltd.

BIN CARD

Description of Material: Bin No.:
Code No.: Normal quantity to order:
Stores ledger folio No.: Maximum stock level:
Re-order stock level:

Date	Receipt		Issue		Balance quantity
	G.R. No.	Quantity	S.R. No.	Quantity	

Store ledger - It is kept in the cost accounting department. The stores ledger is generally maintained in the form of loose leaf cards because they can be easily removed and inserted. The format of the stores ledger is as shown as under-

Aroma Pharmaceutical Pvt. Ltd.

STORES LEDGER ACCOUNT

Description of material: Maximum stock:
Code No.: Minimum stock:
Bin No.: Re-order level:
Location: Ordering quantity:
Unit:

Date	Receipts				Issue				Balance			Stock Verified		
	G.R. No.	Qty.	Rate	Amt	S.R. No.	Qty.	Rate	Amt	Qty.	Rate	Amt	Date	Initial	Remarks

G.R. No. means Goods Receipt Number S.R. No. means Stock Receipt Number

Continuous stock taking- Under this system only limited number of items are verified on a day. The selection of the items of materials should be such that each item of material gets checked up at least a certain number of times in a year and the checking of a particular item is evenly distributed during the period. The selected number of items are counted daily or at least at frequent intervals and compared with the bin card and stores ledger by the store keeper.

2	**c)**	**Define term budget. What are objectives of budgetary control?** **(1 M for definition, 2 M for any 2 objectives)** A budget is a written plan covering projected activities of a firm for a definite period of time. The main objectives of budgetary control are given below: **1) Planning:** A sound planning is necessary for the success of any firm. So it is very	**3 M**

		essential to prepare the budget and draw the detailed programmes relating to production schedule, raw materials costs, sales targets, research programmes, advertising programmes etc. In fact, budget is a plan of action. The budgetary control will force the management at all the levels to plan in time all the activities to be done during the future period. **2) Co-ordination:** For effective planning and implementation co-ordination between different departments and management is very necessary. It helps to co-ordinate the various activities of the firm and secure co-operation of all concerned so that the common objectives of the firm may be successfully achieved. **3) Control:** It is necessary to ensure that all the plans and objectives are implemented and achieved successfully. This is only possible through budgetary control which makes the control possible by comparing the actual performance with the pre-determined plans and reporting the shortcomings to the management for the corrective action. No control of performance is possible without pre-determined standards.	
2	**d)**	**Discuss advantages and disadvantages of 'Joint Hindu family business'.** **(1.5 M for any 3 advantages and any 3 disadvantages)** **Advantages –** 1. Karta has full freedom to run the business he has the right to take decision without any interference of others. 2. The business is just like insurance cover for children, widows, disabled and sick members of the family. 3. All the co-parceners have limited liability except 'Karta'. 4. The business can be run smoothly with the help of all the male members of the family. 5. Every co-parcener gets share in the profit of the business irrespective of his contribution in successful running of the business. 6. The business has no effect of insanity or death of any member. **Disadvantages –** 1. The resources of the joint family business are limited in comparison to other business organisations. 2. Karta has limited authority to run the business. The initiative and sincerity of	**3 M**

		young members of the family has no place. 3. That continuity of the joint Hindu family business depends upon the continuity of the joint Hindu family itself. 4. All the members have the right to get share in income and profits of business irrespective of their involvement in the business. This may make the members of the family irresponsible and lazy.	
2	**e)**	**Discuss various plans of compensating an efficient employee to continue with his job.** 1) Adequacy- The amount of compensation should be in proportion to the responsibility of his job and it should be sufficient to maintain a reasonable standard of living. 2) Simplicity- the compensation plan should be simple so that it can be easily understood by the employees. 3) Incentive- The plan should stimulate the employees to find out ways and means to make profitable drug sales over a long period of time. 4) Proportionate award- The plans are framed in such a way that the pay of the employee should be proportionate to the volume of sales made by him. 5) Flexibility- The plan should be flexible enough to operate effectively throughout the year. 6) Promotion- A provision should be made in the compensation plan to provide promotion in pay and reward for continuous long and devoted service of an employee 7) Uniform earning- The plan should enable the employee to earn a reasonable uniform income each month.	**3 M**
2	**f)**	**Define Balance sheet. Give specimen format of balance sheet.** **(1 M definition, 2 M format)** Balance sheet is a statement of accounts prepared for the purpose of ascertaining the exact financial position under review. **Format of Balance sheet** Dr. Cr.	**3 M**

Liabilities	Amount	Assets	Amount

3		**Attempt any FOUR of the following**	**12M**
3	**a)**	**Define Advertising. Give its disadvantages.** **(1 Mark for definition & 2 Marks for Any Four disadvantages)** **Advertising:** It is an art, used to familiarize public with the product by informing of its description, uses, its superiority over other brands, sources of its availability and price**.** **Disadvantages:** 1)It multiplies the needs of the people by inducing them to buy things which they do not really need or cannot afford to buy 2) It increases the cost of product. 3) Many times, the facts are misrepresented in the advertisement. 4) It involves huge wasteful expenditure, because majority of advertisements either escape the attention of people or are ignored by them. 5) It does not increase the demand and the sale of the product. It only shifts demand from one seller to another.	**3 M**
3	**b)**	**What are the different methods of determining the price of drug material to be charged from a customer?** **(1 M each for any three methods)** Different methods of determining the price of drug material are as follows - **1) FIFO Method: (First In First Out Method):** Under this method, the materials which are received first are issued first. The issues materials are priced at the cost price of oldest consignments till it gets exhausted. As oldest lot is exhausted, the issues materials are priced at the cost price of next of oldest lot in the sequence. The closing stock is valued at the latest purchase price. 2) L**IFO Method: (Last In First Out Method):** Under this method, the price of latest consignment in the stock is used for calculating the value of issue until that consignment is exhausted, then the next lot of pricing is used and so on through the successful lots. **3) Average Cost Method:** Under this method, when the new stock of the goods are received the total value of goods in stock is divided by the total quantity in hand and this will gives the average price. All issues	**3 M**

		of the goods will be made at this price until a new consignment is again received. Then the new price will be calculated. Instead of simple average, where only unit cost is considered for calculating the average cost to be charged to the issues, weighted average cost also be used. Under weighted average cost, along with unit cost the quantity of units also considered. **4) Replacement Price Method:** Also known as "Market Price Method". Under this method, the materials are priced at the prevailing market price on the date of issue. According to this method, the replacement price is determined each time when the material is issued. The main advantage of this method that it considers the current market price, for pricing policies. **5) Inflated Price Method:** This method is used for those goods which are subjected to some wastage. The total amount paid is divided by the quantity expected to be finally available for use and the rate is used for the sale of goods. Wastage may be due to loss on breaking the bulk, evaporation, etc. The cost of such normal wastage is included while charging the price when such material is sold. **6) Standard Price Method:** Under this method, the materials issues are charged at a pre-determined or estimated price which reflects a normal or an effected future price. The standard price is generally fixed after careful examination of the current market price, trend of price and market condition etc. The standard price ia made applicable for definite period of time.	
3	**c)**	**Define:** **(One Mark for Each Definition)** **(i) Over Draft facility:** The facility to draw the cheque, more than the amount standing to the credit of his account against some security. **(ii) Cash Credit facility:** The facility to borrow the money up to certain fixed limit against some existing security or guarantee. **(iii) Discounting of Bills:** It is the process of encashment of customer's bills before they become due for payment.	**3 M**

3	d)	**Define Purchasing. What are the various steps involved in purchase procedure?** **(1M for Definition & 2 M for steps)** **Purchasing:** Purchasing is the business activity which is responsible for the procurement of the raw materials, supplies, tools, machineries and services to produce certain goods. OR Purchasing is the business activity to procure raw materials, goods and services of desired quality and quantity at lowest price and at desired time. **Steps involved in Purchase Procedure:** 1) **Purchase Requisition:** When the existing stocks are depleted and come to a minimum limit, the store Incharge fills the requisition form and sends it to the purchase department. The purchase requisition indicates the type, quantity and quality of purchase items. 2) **Selection of the Suppliers:** A list of items to be purchased is sent to the various suppliers or the tender is invited through leading newspapers. The comparative statement of all received quotations from different suppliers is prepared. The supplier who quoted the lowest rate is generally selected. Apart from price other consideration like ability to supply the required volume, maintenance of quality of goods, ability to deliver the goods as per schedule and the terms of payment are taken into consideration. **3) Placing the Order:** After selection of supplier, the order is placed on 'Supply Order Form' which contain detailed specification of items, quantity required, price and other terms and conditions of the supply. It is signed by authorised person. Generally 5-6 copies of supply order are prepared. Two copies sent to supplier, One copy sent to store In charge, One copy sent to accounts department and One copy remains with purchase manager. **4) Receiving and Checking of Material:** The material which is received from the supplier is inspected for its quantity and quality. The goods are compared with invoice or bill sent by the supplier. **5) Checking of Invoice or Bill:** If goods are received in satisfactory condition, the invoice or bill is checked before it is	**3 M**

		approved for the payment. **6) Recording of Bills in Books:** The bills are sent to the Accounts section to make the entries of the bills into the account books. **7) Releasing the Payment to the Supplier:** According to terms and condition of the supply order, the payment is released by the account section to the supplier.	
3	**e)**	**What are Trial Balance? Write various objectives and method of preparation of Trial Balance.** **(1M for Definition, 1 M for Objectives & 1 M for any one Method)** **Trail Balance:** It is a statement prepared to check the arithmetical accuracy of the book-keeping entries up to the date stated at the head of the trial balance. **Objectives of Trial Balance:** a) To ascertain the arithmetical accuracy of the ledger accounts. b) To help in locating errors. c) To help in the preparation of final accounts. d) Aid to management **Methods of preparation of Trial Balance:** **1) Balance Method:** In this method all the ledger accounts are first balanced. For this, the debit and credit side of each ledger account is totalled and the balance on debit and credit side is obtained. The balances are then recorded on the debit or credit side of the trial balance. If the grand total of debit and credit balances tally, it shows that the books are accurate arithmetically. 2) **Total Amount Method:** In this method the total on debit side of every ledger account is entered under the debit column of the trial balance and the total on the credit side of each ledger account is recorded under credit column of the trial balance. The grand total of both debit and credit side is taken. In case grand totals on both sides tally, it indicates arithmetical accuracy of the trial balance.	**3 M**

<table>
<tr><td>3</td><td>f)</td><td>What do you mean by scrap? Describe procedure for disposal of scrap and surplus.
(1 M for Definition & 2 M for Disposal Procedure)
Scrap: Scrap is residue incidentally obtained from manufacturing process. It is small value and recoverable without further processing.
E.g. Powder and fine granules obtained in processing of tablets, non-returnable containers and packing cases.
Procedure for disposal of Scrap and Surplus:
a) The scrap and surplus materials can be reprocessed into useful raw material for subsequent production of basic products.
b) The scrap and surplus materials are sold if it cannot be recycled into useful material.</td><td>3 M</td></tr>
<tr><td>4</td><td></td><td>Attempt any FOUR of the followings</td><td>12M</td></tr>
<tr><td>4</td><td>a)</td><td>Differentiate between Profit and Loss Account and Balance Sheet. (Any Six Difference, 0.5 Mark for each)
<table>
<tr><th>Sr. No.</th><th>Profit and Loss Account</th><th>Balance Sheet</th></tr>
<tr><td>1</td><td>In this Account the Nominal Accounts are shown.</td><td>In Balance Sheet Personal Accounts and Real accounts are shown.</td></tr>
<tr><td>2</td><td>It provides the information regarding Net profit or net loss.</td><td>It provides the information regarding financial position of the business.</td></tr>
<tr><td>3</td><td>It is a ledger account and provides the information about debits and credits.</td><td>It is only a statement of assets and liabilities.</td></tr>
<tr><td>4</td><td>It is an Account so the words “To” and “By” are used.</td><td>It is a statement so the words “To” and “By” are not used.</td></tr>
<tr><td>5</td><td>The balance of this account indicates the profit or loss of the business</td><td>The totals of both the side of the balance sheet are always same.</td></tr>
<tr><td>6</td><td>The account shows profit or loss made by the business as on a fixed date.</td><td>It shows the financial position of the business enterprise on a fixed date.</td></tr>
</table></td><td>3 M</td></tr>
</table>

4	**b)**	**Explain how maximum stock level is fixed.** **(Any Six factors)** A Maximum stock level is generally fixed by taking into consideration the following factors-- **1)** Rate of consumption of the materials. **2)** Availability of Storage Space. **3)** Amount of Capital needed and available. **4)** Nature of Material. **5)** Market Trend. **6)** Fashion Habits. **7)** Government Restrictions. **8)** Risk involved due to fire, obsolescence and deterioration. **9)** Lead Time from the date of placing the order.	**3 M**
4	**c)**	**Explain various legal requirements to start Retail Drug Store.** **(1 M each)** **1) Minimum Qualification:** **a)** Diploma in Pharmacy from a recognized institute. b) Registered pharmacist with the state pharmacy council. c) A person who has sufficient capital can do so by appointing a registered pharmacist on full time basis. **2) Minimum Space:** **a)** The store should fulfil all the requirements of schedule N of the D & C Act and Rules, 1945. b) Minimum desirable area to open a new Retail drug store is 10 sq. m. **3) Storage Arrangement:** **a)** There should be sufficient number of racks to store drugs & pharmaceuticals. **b)** Refrigerator is mandatory to store antibiotics vitamins, vaccines, sera, enzymatic preparations, etc.	**3 M**

4	**d)**	**Mention salient features of partnership business.** **(3 M for any Six salient features,)** **1)** In Partnership business, two or more persons, maximum up to Twenty (Ten in case of Banking Firm) join together to share any profit. **2)** Each partner of the firm has unlimited liability. **3)** A partner cannot transfer his shares to an outsider without the consent of the other partners. **4)** Partnership is formed on the basis of an agreement between the concerned persons. **5)** Any profit made by the partnership must be distributed among the partners in the agreed ratio, usually in the proportion of capital amount invested by each partner in the firm. **6)** A partnership is dissolved automatically when the term for which is expires or when a partner dies or retires. **7)** If and when the partnership is dissolved, the firm does not. It depends on the remaining partners whether to continue the firm. Dissolution of the firm takes place in following circumstances:---- a) If the partners agree that the firm be dissolved. b) In the event of all the partners becoming insolvent. c) If the business becomes illegal. d) In case the court issues the orders that the firm be dissolved.	**3 M**
4	**e)**	**Define Bank. What are the different kinds of Bank? Mention functions of Bank.** **(0.5 M for Definition, 01 M for Different Kinds of Bank & 1.5 M for Functions of Bank)** **Bank:** A bank is a comprehensive term for a number of institutions carrying on certain kinds of financial business dealing in money. OR Bank is an institution where the transactions of money take place. **Kinds of Bank:** 1. Commercial bank 2. Savings bank 3. Land development bank	**3 M**

4. Co- operative bank
5. Industrial bank
6. Exchange bank
7. Mixed bank

Functions of Bank:

1.Services to Depositor:

a) They collect the cheques, demand drafts, hundis, local and foreign bills on behalf of their depositor.

b) They offer discounting facilities in respect of local and foreign bills of the depositor.

c) They pay insurance premium subscription and taxes on behalf of the depositor.

2. Services by way of Loan:

a) **Overdraft:** The overdraft facility permits the customer to overdraw from his account however the bank fixes the limit beyond which the customer cannot overdraw and the Customer is required to pay specific rate of interest on over drawn amount on daily basis. The overdraft facility is allowed only against some security.

b) **Cash credit:** Bank fixes a limit up to which a customer may borrow money from it against some security and the interest is charged by the bank on the outstanding amount in cash credit account.

c) **Loans:** The bank gives loans to the customers against some security or mortgage.

d) **Discounting of bills:** The bank encash the customer's bill before they become due for the payment and for this service the bank charges a nominal discount

3. Miscellaneous Services:

a) It buys and sells shares/bonds / debentures on behalf of its customers.

b) Provides the Lockers to the customers for safe keeping of jewellery and important documents.

c) It makes regular payment of subscription, insurance premium, taxes etc. on behalf of its customers.

e) It accepts and pays the bills of exchange in respect of imported goods and also purchases the bills of exchange.

f) It helps people going to abroad by arranging foreign exchange for them.

		g) It provides assistance and advises the customers with regard to investment.	
4	**f)**	**Define Term: (One Mark for Each Definition)** **(i) Debenture:** A debenture is a document or certificate issued by the company acknowledging loan and also gives an undertaking to repay the specified borrowed sum along with interest to the debenture holder on a prescribed date. **(ii) Petty Cash Book:** The Cash book maintained by a petty cashier which is used to record small day to day expenses or cash payments. **(iii) Capital:** It is the investment by the owner for the use in the firm. It is equal to total assets minus total liabilities.	**3 M**
5		**Attempt any FOUR of the followings**	**12M**
5	**a)**	**Discuss various qualities of good salesman.** Qualities of a salesman personal qualities mental qualities social qualities vocational skills **Personal qualities** 1. He should have attractive personality, 2. Good health, good physique, as the job involves lot of physical strain. 3. He should have clear voice, & his talk should impress people. 4. He should be well dressed. **Mental qualities** 1. He should have good memory, imagination, presence of mind, good judgment. 2. He should be intelligent to understand the nature & requirement of the buyers. 3. He should be able to think from the view of the customer. **Social qualities** 1. He should have liking for people & should be able to mix with them. 2. He should not be shy & reserved. 3. He should be a patient listener. 4. He should be polite & courteous.	**3 M**

		Vocational skills 1. He should know various selling technique. 2. He should have knowledge of the product, customers, & competitive products.	
5	**b)**	**Write short note on warehousing.** .Warehouses are places meant for storage of products. There are three types of warehouses Private, Public, Bonded. Private warehouses are owned by big business concerns or wholesalers for the storage of their own stocks. Public warehouses are operated by business firms which provide storage facility to the public for a certain charges. The bonded warehouses are used to keep imported goods for storage until the payment of custom duty is made. The warehouses are required for following reasons. 1. It removes hindrance of time. 2. Maintains stability of price. 3. ensures continuous availability of goods throughout the year in spite of the fact that the same grows or is produced only during a particular season. 4. There is always a time gap between production of goods & its subsequent sale. To ensure continuous availability of goods in the market, its proper storage is essential. 5. It maintains enough reserve stock. 6. It prevent damage to the drugs, chemicals & perishable foods.	**3 M**
5	**c)**	**Define Codification. Explain different methods used for codification**. **(1M for definition, 2M for methods)** Codification is a method to assign a code symbol or no. to the item for its easy identification. **<u>Methods of codification</u>** **1) Alphabetical method**	**3 M**

This is also known as letter code system. e.g. T represents tablet.

Not suitable if large no. of items are present.

2) Mnemonic method

In this method code is given to items .e.g. AT represents aspirin tablets etc.

The main disadvantage is the materials cannot be recognized without the referring to code index.

3) Numerical method

This method is known as sequence system.

Separate no. are given to different classes of items.

The new item is given the next higher no. in the sequence.

this system involves use of ,

Decimal system & Block system.

Decimal system

In this system, the no. are assigned in such a manner that each digit represents sub group of previous digit.

E. g. 15.1 represents paracetamol tablet where 15 is the analgesic group.

the main advantage is this system has capacity to expand & accommodate new items,

the main disadvantage . Is it is cumbersome to use.

Block system

In this method the set of no. are reserved for specified classification.

e.g. 100-300 allotted to the tablets.

4) Combination system

In this the mnemonic & numerical methods are combined together.

e.g. MT 100 is given to Meftal 250mg. tablets

& MT 101 is given to Meftal 500mg. tablets.

<table>
<tr><td>5</td><td>d)</td><td>Differentiate between departmental store & Multiple Shops.
(3M for any 6 points)
<table>
<tr><th>Departmental store</th><th>Multiple shops</th></tr>
<tr><td>Wide variety of products are available</td><td>Particular type of product are available</td></tr>
<tr><td>No uniform pricing system.</td><td>Uniform pricing in all the branches</td></tr>
<tr><td>Control over the activity is easier.</td><td>Control is difficult</td></tr>
<tr><td>provide no. of services to the customer.</td><td>No other services to the customer</td></tr>
<tr><td>No uniformity in decoration</td><td>uniformity in decoration</td></tr>
<tr><td>Sale of goods in cash & credit</td><td>Sale is only on cash basis</td></tr>
<tr><td>Stores mainly for rich people.</td><td>For general public</td></tr>
<tr><td>Located in the center of the city.</td><td>Located in various localities of city.</td></tr>
</table></td><td>3 M</td></tr>
<tr><td>5</td><td>e)</td><td>Explain money measurement concept & cost concept of accountancy.
(1.5M for each)
Money measurement concept- According to this concept all business transactions are required to be recorded in terms of money. Those transactions that are not capable of being recorded in terms of money are not recorded in the accounting books, because the monetary unit is relevant, simple and understandable. By expressing all assets and liabilities in terms of money, it is possible to include them during the preparation of financial statements.
Cost concept: According to this concept, all transactions are recorded at their monetary cost of acquisition. The majority of assets and liabilities are recorded in the account books at the price paid to acquire the same. However they are carried forward from year to year at</td><td>3 M</td></tr>
</table>

		acquisition cost, irrespective of any subsequent increase or decrease in their cost. Another important feature is, it is not necessary to show the assets year after year for an indefinite period at the cost price. The assets recorded at cost price at the time of purchase are systematically reduced due to depreciation till their economic life is over. i.e. they have been fully depreciated and sold as scrap. The concept is applicable to fixed assets only and current assets are not affected by it.	
5	**f)**	**Define share. Explain different types of shares**. (**1M for definition,2M for types)** The capital required is divided into large no. of equal parts & each part is considered as a share. The shares are of two types **preference share &** **ordinary shares** **Preference shares** They carry preference both regarding dividend & return of capital. These shares are preferred by those people who do not like to risk their capital & yet want an higher income than that if invested in other scheme. These shareholders get a fixed dividend &preference in return of the capital in case of winding of the business. **Ordinary shares or equity shares** Ordinary share holders are the real owner of the organisation as a company is controlled by them. They have voting rights to elect the director of the company. The dividend is paid after the dividend of the preference shareholder. They have a risk as they get the money only after the clearance of all other claims. They get higher rate of dividend.	**3 M**
6		**Attempt any FOUR of the followings**	**16M**
6	**a)**	**Differentiate between slow moving, dormant material & obsolete items. Enlist the steps taken to detect these.** **(1M for each item, 1M for steps),** Slow moving items are those which are moving at a slow rate. Dormant items are those which are moving temporarily due to seasonal production. Obsolete items are those which have become useless due to change in the design, method of	**4 M**

		mfg. ,process etc. **The steps taken to detect these.** • prepare periodic report • identify obsolete items • find moving ratios **periodic report** A monthly or quarterly report on the stocks of nonmoving items is prepared which indicates purchase, consumption & balance in hand. **obsolete items** Many slow & non-moving items become useless with the time. A good method should be designed to locate these items so that it can be utilised or its further purchase can be stopped. **moving ratio** By calculating the moving ratio, we can determine slow moving, dormant or obsolete items.	
6	**b)**	**Explain window display as Silent salesman**. In Window display the goods are exhibited in the artistically laid down windows in front of the shops or at busy centres like bus stop ,railway stations. • The main aim of window display is to attract customers & thus promote sales. • It creates good impression about the retail pharmacy. • As it displays seasonal items, price of the items & due to brilliant lighting during night people will get attracted easily. • As the items displayed in the window are changed frequently to give freshness & newness to the display, hence it attract people regularly. • The colour plays important role in window display. It helps in arresting the attention of passersby and creates a pleasing impression . • As without communicating with customers, window display attract customers It acts as silent salesman	**4 M**

6	c)	**Classify different types of middleman involved in the distribution channel. Write in brief about each middleman.(1M for classification, 3M for description)** **Types of middlemen** **1 Functional middlemen** – a.Brokers b.Commission agents c.Auctioneers d.Del credere agents **2 Merchant middlemen** a Wholesalers b Retailers **Functional middlemen**- They help in transfer of goods from the hands of producers to the customers without having an ownership rights. (they do not have title to goods) **Brokers**- Their only function is to bring buyer & seller together. If hired by seller then called as selling agent & if engaged by buyer called as buying agent. They get certain % of commission. **Commission agent** - They negotiate the sale of goods , take possession & make arrangement for transfer of the goods. So he has to arrange for warehousing, grading, packing, assembling & disposal. **Auctioneers** They collect goods display & invite bids from buyers. Bid means the price which the buyer is willing to pay for the goods being auctioned**.** The buyer making the highest bid gets the goods. **Del credre agent-** They find the buyer & also guarantee the payment of price on their behalf. The agent has to pay the sum if the buyer fails to pay. **Merchant middlemen** **Wholesalers** He is the middleman between the manufacturer & retailers**.** They buy goods	**4 M**

		in large quantity from producer & sell them to retailers.. The wholesaler is called as stockist if he deals in items manufacturerd by a single firm or company. **Retailers** Is the middlemen between wholesaler & consumer. The retailers buy goods in large quantity from the wholesalers & sell them to consumers.	
6	**d)**	**Discuss various requirements of effective Budgeting**. **(4M for any 4)** The following are the requirements are of a good budgeting system: 1. **Cooperation of top management**: This requires commitment of the top management and policies underlying it. 2. **Clearly defined organisation**: In order to carry out budgeting in a manner that will provide maximum benefits, a good organisation within the business has to be developed. 3. **Accurate accounting system** The accounting system in the business should be such also hold each part of the organisation to its responsibilities. 4. **Unambiguous policy**: A budget programme is always based on certain fundamentals the collection of which is called the policy of the business. So no programme can be prepared without knowledge of the business policy to be adopted during the period covered by the budget 5. **Preparation by responsible executives** The responsibilities for the preparation of the budget estimates should rest on those executives who are responsible for performance of the budget. This guaranties proper implementation of the programme contained in the budget. 6. **Constant vigilance**: An effective system of budgetary control requires a constantat all levels. As soon as unfavourable trends are detected, immediate remedial action must be taken. 7. **Budget committee**: A budget committee has to be established consisting of a budget director, chief executive officer & executives of various departments of the organisation for successful implementation of the budget. 8. **Cost of operation**: The budget system should not cost more to operate that it is worth.	**4 M**

9. **Reasonably attainable goals:** Budget figures should be realistic **and represent reasonably attainable goals to gain maximum profit.**
10. **Continuous budget education:** In order to achieve success of budgeting, it is important that budget education should be provided to those who are engaged in preparing the budget proposals.

6 e) From the information given below, prepare profit & loss account of M/S Sandeep Medical Hall for the year ending 31st March 2017. **4 M**

Profit & loss account of M/s Sandeep Medical Hall for the year ended 31st March 2017

Dr **Cr.**

Particulars	**Amount (Rs)**	**Particulars**	**Amount (Rs)**
To Rent	8000	By gross Profit b/d	60000
To Salary	25000	By Discount recd	4000
To commission paid	4000		
To Interest on loan	3000		
Advertisement	7000		
To printing & stationary	3000		
To Legal charges	4000		
To bad Debts	2000		
To net profit	8000		
	64000		**64000**

6 f) Draw format of Journal & Ledger. Explain types of accounts. **4 M**

(1M for each Format,2M for types)

format of Journal

Date	Particulars	LF	Debit (Amount)	Credit (Amount)

format of Ledger

Dr. **Cr.**

Date	Particula	J.F.	Amount (Rs.)	Date	Particular	J.F.	Amount (Rs.)

Types of Account:

1) Personal account: It deals with the individual person, firm, company & institutions. e.g. an account of Mr. Ram Gopal, M/S Deep Medical Hall, Glaxo (India) Ltd., M.D. University. The person or firm which supplies the goods/gives money to the business is a creditor and entries made on credit side of his account. Similarly a person or firm which receives the money or goods from business becomes a debtor and the transaction is made on debit side of his account.

2) Real account: These accounts are maintained to deal with transactions related to building, cash, furniture, land, machinery, stock etc. When an item is purchased or recd., the transaction is recorded on debit side.

3) Nominal account: These accounts are generally called fictitious accounts. These accounts are maintained to deal with discounts, insurance, rent, wages, salaries, cost of stationery items etc. A separate account is maintained for each type of expenditure. The entries of expenses or losses are made on debit side & of profits or gain on credit side.

Subject Title: Hospital and clinical pharmacy **Subject Code:** 0816

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.

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any EIGHT of the following: (2marks each)**	**16M**
1	**a)**	**Define : (1M each)** **i) Hospital Pharmacy** **ii) Teratogenicity** **i)Hospital Pharmacy-** It is service department of hospital which receives drugs and supplies, stores, dispenses them to inpatients and outpatients under supervision of qualified registered pharmacist. **ii) Teratogenicity-** The administration of certain drugs to pregnant woman, specifically during the first trimester of pregnancy results in foetal abnormalities is called as Teratogenicity	**2M**
1	**b)**	**Give the normal physiological value of: (any four) (½ M each)** **i) Haemoglobin-** Male-15.5 +/- 2.5gm% Female- 14+/- 2.5gm% ii) **Blood Cholesterol-**150-240 mg% **iii) Clotting time of blood**: 4-10 minutes **OR** Slide and Capillary tube method.-3-6 minutes. **iv) Sperm count-** 60 to 150 millions/ cc of semen **v)Heart rate-** 70- 80/ min	**2M**
1	**c)**	**Translate into English: (any four) (½ M each)** **i) Guttae**- A Drop **ii) Unus**- One **iii) Charata**- A powder **iv) Bis in Die**- Twice a day **v) Omni nocte**- Every night.	**2M**
1	**d)**	**What is the full form of following: (any four) (½ mark each)** **i) WFI**- Water For Injection **ii) DIC**- Drug information Centre **iii) PTC**- Pharmacy and Therapeutic Committee	**2M**

		iv) CUDD- Centralized unit dose dispensing **v) EEG**- Electro Encephalogram	
1	**e)**	**What advice will you give to patients about following drugs-(Any two) (1 mark each)** **i)Spermicidal jellies & cream-**" Should be applied 10 to 30 minutes before sexual intercourse & remains in vagina 6 to 8 hours afterwards" **ii)MAO- Inhibitors-** " Avoid Cheese, alcoholic beverages and liver and yeast extract" iii) **Salicylates-**" Do not take on empty stomach"	**2M**
1	**f)**	**Name two preservatives used in parenteral preparation. (any 2 -1 mark each)** **i. Chlorocresol** **ii. benzalkonium chloride** **iii. benzyl alcohol** **iv. phenyl mercuric nitrate**	**2M**
1	**g)**	**Define the term- Referred patient, Ambulatory patient. (1 mark each)** **i) Referred patient-** He is referred directly to outpatient department by his attending medical/ dental practitioner for specific treatment, other than an emergency treatment, and who later returns to the practitioner for further treatment. **ii) Ambulatory patient-** An ambulatory patient is 'able to walk' and receive primarily health care and walk off from the hospital.	**2M**
1	**h)**	**Give any two reasons for patient noncompliance. (any 2 reasons – 1 mark each)** **1.In appropriate packaging** : Some time design or size of container make difficulty to remove the medicament .Many elderly patient ,arthritis patient have difficulty with unit dose pack or foil wrapping while removing medicament **2. Poor labelling**: Poorly hand written label are difficult to read or follow for the patient/pharmacist. Many prescriptions contain direction which are inadequate like take when required or use as directed that may produce confusion. **3. Multiple drug therapy**: Greater the number of drugs patients is taking the higher is the risk of non compliance. **4. Asymptomatic nature of patient**: In case of asymptomatic patient, it is difficult to convenience a patient by explaining the value of drug therapy results in non compliance. **5. Measurement of medication:** Many times there is confusion to the patient in measuring liquid preparations or number of tablets.	**2M**

		6. Cost of medication: Because of high cost of drugs, poor patients are not purchase such drug. **7. Frequency of medication**: Regular schedule of dosage intake cannot be followed due to work load. **8. Duration of therapy**: Long duration treatment lead to patient noncompliance. **9. Illness:** The nature of patient's illness may contribute to non-compliance like chronic hypertension, mental illness.	
1	**i)**	**Give the uses of: (Any two) (1 M each)** **i) Ryle's tube** i) To give fluid or drugs to those patients who can't imbibe enough amount. ii) To give stomach wash in case of poisoning. iii) For gastric juice analysis. ii)**CT scan-** CT stands for computed tomography. It is an advanced technique used for morphological examination of neurological organs, head, eyes, neck, spinal cord etc. **iii)X-ray machine-** It is used to take internal photographs of body. For e.g. to check a fracture of bone or to check the status of TB in lungs.	**2M**
1	**j)**	**What are the benefits of unit dose dispensing? (any 4 benefits – ½ mark each)** 1. The patients are charged for those which are administered to them. 2. It reduces the medication error since the pharmacist checks the copy of physician's original order. 3. It avoids drug losses, no pilferage of drug. 4. Less space is required as compared to bulky floor stock. 5. Patients receive the nursing service 24 hrs a day. 6. It avoids duplication of orders and extra paper work.	**2M**

		7. It enhances more efficient utilization of personnel 8. It eliminates labelling error. 9. Drug accounting become easier. 10. Better financial control means credits are eliminated.	
1	**k)**	**Classify Hospital on the basis of its bed size.** **i) Large Hospitals-** Bed capacity 1000 and above e.g.- J.J.Hospital Mumbai **ii) Medium Hospitals**- Bed capacity 500-1000 e.g.- Bombay hospital **iii) Small hospitals**- Bed capacity 100-500 e.g.- Breach candy hospital Mumbai **iv) Very small hospital**- Bed capacity below 100 e.g.- Any private hospital	**2M**
1	**l)**	**Name four quality control tests for parenterals. (½ M each)** **1.** Sterility Test **2.** Pyrogen Test **3.** Clarity Test. **4.**Leaker Test **5.** Assay	**2M**
2		**Solve any FOUR : (3 marks each)**	**12M**
2	**a)**	**Name various methods of sterilization. Give principle of Hot air oven and autoclave.** **Methods of sterilization- (1 M)** I) Physical method- i) Moist heat sterilization ii) Dry heat sterilization iii) Radiation II) Chemical method- i) Gaseous sterilization ii) Heating with bactericide III) Mechanical method i) Sterilization by filtration	**3 M**

		Principle of Hot air oven- (1 M) All microorganisms including bacterial spores can be destroyed .Dry heat kills the microorganisms by oxidation of cell proteins. **Principle of Autoclave- (1 M)** Autoclave is used to carry out steam sterilization. It works on the principle of utilization of saturated steam under pressure. The steam has more penetrating power and thermal capacity than dry heat. Saturated steam under pressure causes coagulation of cell protein leading to the destruction of microorganisms. The steam penetrates in the spores and capsules of bacteria, ruptures it and the escaping protoplasm is coagulated.	
2	**b)**	**Write in brief about bed side pharmacy.** **Bed-side pharmacy-** Hospital pharmacy is becoming increasingly patient oriented nowadays. Hence he/she must work in close association with the nursing and medical staff. Personally each pharmacist in the hospital should visit the wards, go to each patient's bedside and discuss with them regarding the medicines and drugs they take. This is called as Bed-Side pharmacy. Following points are considered to become bedside pharmacy, 1. The pharmacist should build an inter-professional team of the physicians, nurses and pharmacists. 2. Ward visit:-Daily in the morning, he visits the wards and enquires about the progress of health etc. 3 Take medication history of each patient during the visits. 4. He interacts with the physicians about medicine and with nurses regarding storage, handling and safe use of the medicine. 5. Pharmacist carrying out such visits must have thorough knowledge about drug food reactions, allergies, side effects and adverse reactions of drugs. 6. He/she should give counselling to the patients regarding their food habits and ways of administration of drug. 7. He/she guides the patient about the treatment to be continued after discharge and how the drugs should be stored at home to avoid its degradation.	**3M**

		8. Medication at Bed-Side: Lifesaving drug--Nitroglycerine tablet is kept at bedside, if ordered by physician. 9. Not more than one strip/10 tablet shall be left with the patient.	
2	**c)**	**What is prepackaging of medicines? Give its advantages. (2 M for explanation, any 2 advantages- 1 M)** Pre-packaging increases the standard of practice of hospital. The following factors should be considered while pre-packaging- • Demand and turnover of the items • Availability of containers. • The labelling to be done. • The process of packaging. • The stability of items. • Cost of prepackaging. It is useful for IPD & OPD. The size of pre-packaging is decided by consultation with the pharmacy, medical and nursing staff. The data for pre-packaging of various dosage forms and therapeutic agents is obtained from Hospital formulary. In OPD the size of pre-packaging is decided by call cycle of patient. But there is major drawback of pre-packaging that the patient is taken off the drug that has been pre-packaged the remaining quantity will sheer waste. Pre-packaging operation is carried out either by pharmacist or under his direct supervision. **Advantages-** • It is suitable for fastest moving items whose demand is very high and also for those items which takes long time for compounding and packaging. • It offers convenience. • It is labour saving. • It is time saving.	**3M**

2	**d)**	**Enlist the abilities required for hospital pharmacist. Explain any two.** **(To enlist 1 M, 2 Mark for any 2 abilities)** The hospital pharmacist should possess following abilities: 1. Administrative ability 2. Technical ability 3. Manufacturing ability 4. Research ability 5. Teaching/Training ability 6. Ability to Control **1. Administrative ability**-Hospital pharmacist should be thoroughly familiar with organisation of hospital, with staff and with appropriate channel of communication. Hospital pharmacist should be capable of planning and integrating services, budgeting, inventory control, cost-review, cost-effectiveness, audit, maintenance of records and preparation of reports. **2. Technical ability**- Hospital pharmacist must have ability to use his basic knowledge of effect of drug on biological systems, in assessing drug absorption, distribution, metabolism and pathophysiology, therapeutics and patient care techniques. **3. Manufacturing ability**-Hospital pharmacist must be able to develop formulations not available commercially. Hospital pharmacist should possess an adequate understanding of the principle involved in formulations and preparation of dosage forms. **4. Research ability**-Hospital pharmacist must be prepared to participate in clinical research initiated by medical staff and to conduct pharmaceutical research himself. Hospital pharmacist must be able to establish database for drugs being used and patients participating in studies. Hospital pharmacist must have ability to collect appropriate data interpret them and make conclusion from data. **5. Teaching/Training ability**- Hospital pharmacist is responsible for training of new personnel and for carrying out continuous educational programme for pharmacist and	**3M**

		pharmacy supportive personnel. Hospital pharmacist must be able to develop well planned and co-ordinate training programme and able to deliver lectures. **6. Ability to Control-**Hospital pharmacist must be able to develop quality assurance programme for quality services of pharmacy department and products dispensed. Hospital pharmacist must be able to develop control programme for distribution of drugs throughout the hospital.	
2	**e)**	**Give the functions of PTC. (any 6 functions – ½ mark each)** 1) To advise the medical staff and hospital administration in matters related to the use of drugs 2) To establish and develop suitable educational schemes to improve the professional staff on the matters related to the use of drugs. 3) To develop and compile formulary of drugs and prescription accepted for use in hospital. It also minimizes the duplication of the same type of drugs or products. 4) To study problems related to the distribution and administration of drugs used in hospital. 5) To review adverse drug interaction occurring in hospital. 6) To initiate and promote studies on drug use and review the results of such studies. 7) To recommend about the drugs to be stocked in hospital patient care areas. 8) To advise the pharmacy in the implementation of effective drug distribution and control procedures	**3M**
2.	**f)**	**Discuss drug food interaction. (any 6 examples- ½ mark each)** Food affects the absorption of the drug. It may be attributed to 1) Dilution of the drug 2) Adsorption or complexation of drug 3) The alteration of gastric emptying. **Examples:** 1) Food reduces the absorption of aspirin, isoniazide, tetracycline, benzyl penicillin, amoxicillin, Ampicillin, levodopa and Rifampicin 2) Food increases the absorption of hydralazine, nitrofurantoin, lithium citrate, riboflavin, carbamazepine, metoprolol, propanolol, and spironolactone.	**3M**

		3) Iron absorption is reduced if food has been taken within the previous two hours. On the other hand, nausea is more likely if iron is taken on empty stomach so iron tablets are often given with food. 4) Nitrofurantoin is given with food to avoid GIT irritation. 5) Meals containing high fat increase the absorption of fat soluble drug Griseofulvin. Fat containing drug increases degree of ionization of Griseofulvin, so increases its absorption. 6) The diuretic effect of tea takes place rapidly if given before meals but diuresis is delayed if it is given after food. 7) The absorption of nitrazepam, glibenclamide, metronidazole, oxazepam, theopylline is unchanged by food. 8) Monoamine oxidase (MAO) is an enzyme which breaks down catecholamines such as or epinephrine. When the enzyme is inhibited, there are increased levels of nor epinephrine in adrenergic neurons. Thus, MAO inhibitors are used as antihypertensive. Certain food like cheese, chocolate, alcoholic beverages, liver, yeast extract contain tyramine. Tyramine is metabolized by MAO. When the patients being treated by MAO inhibitors also take tyramine containing food, tyramine reaches the systemic circulation causing severe hypertension. 9) Milk reduces absorption of tetracycline by forming an insoluble complex	
3		**Solve Any <u>FOUR:</u> (3 marks each)**	**12M**
3	**a)**	**Which are the equipments for manufacture of pills and compressed tablets as per Drugs and cosmetics Act & Rules? (3 marks)** **Requirements for Tablets and Pills** For effective operations, the tablet production department shall be divided into four distinct and separate sections as follows: - **(a) <u>Mixing, Granulation and Drying section</u>** (1) Disintegrator and sifter (2) Powder mixer (3) Mass mixer/Planetary mixer/Rapid mixer granulator. (4) Granulator (5) Thermostatically controlled hot air oven with trays (preferably mounted on a trolley)/Fluid bed dryer. (6) Weighing machines. **(b) <u>Tablet compression section.</u>**	**3M**

		(1) Tablet compression machine, single/multi punch/rotatory. (2) Punch and dies storage cabinets. (3) Tablet de-duster (4) Tablet Inspection unit/belt. (5) Dissolution test apparatus (6) In-process testing equipment like single pan electronic balance, hardness tester, friability and disintegration test apparatus. (7) Air-conditioning and dehumidification arrangement (wherever necessary) **(c) Packaging section (strip/blister machine wherever required).** (1) Strip/blister packaging machine. (2) Leak test apparatus (vacuum system) (3) Tablet counters (wherever applicable) (4) Air-conditioning and dehumidification arrangement (where ever applicable). **(d) Coating section (wherever required).** (1) Jacketed kettle (steam, gas or electrically heated for preparing coating suspension). (2) Coating pan (stainless steel) (3) Polishing pan (where applicable) (4) Exhaust system (including vacuum dust collector) (5) Air-conditioning and dehumidification arrangement. (6) Weighing balance.	
3	**b)**	**Name any four surgical instruments with their uses. (any 3 instruments – 1 mark each)** Surgical instruments are used for different activities like incision, cutting, holding etc. **1.Scalpels:** The scalpel is used to make incision. **2.Scissors:** It is an instrument which helps in cutting and dissecting. **3. Tissue forceps**: Tissue forceps are used to hold tissues for traction or opposition having good grip on the tissue. **4. Haemostatic forceps** : **(any 1)** 1.To achieve haemostasis. 2. to catch bleeding of periosteal vessel	**3 M**

		3. To hold bleeding in fibrous background. 4. In appendectomy to pass ligature around the appendicular artery **5. Swab holding forceps: (any 1)** 1. To hold fundus of gall bladder during cholecystectomy. 2. As a tongue holding forcep 3. For swabbing a cavity 4. To hold ovum. **6.Needle holder** : It is used for holding the needle. **7. Sharp curate**: It is used for dilation of cervical and uterine curate. **8. Cusco's speculum**: It is a female gonadal instrument mainly used to retract the vaginal walls for examination of internal structures. **9. Kocher's intestinal clamp** : it is used to hold the intestine	
3	**c)**	**What are the functions of Modern Hospital? (any 3 functions – 1mark each)** **Functions of Modern Hospital:-** 1. **Patient care**: It includes services for diagnosis, prophylaxis and treatment of diseases to the sick or injured patients. It is a centre of community health and contributes a great deal to preventive and social medicine. 2. **Public health**: The hospitals are required to support all the activities carried out by various public health and voluntary agencies such as immunization programme, blood donation camps, social and economics rehabilitation, health education etc. by providing facilities and advice. 3. **Medical research**: Research is an important activity in the hospital that helps in developing the new methods of treatment and improving the hospital services. Some of the common areas of research in the hospital are development of new techniques in surgery, laboratory diagnostic procedures, evaluation of investigational drugs in diseases. 4. **Educational training:-** This facility , particularly for medical students , pharmacists , nursing staff, medical technologist and allied health professional helps to fulfil their curriculum requirement. Hospital also educates the general public through lectures and demonstrations on the preventive aspects of common and serious diseases. Hospital provides the methods by which the persons can work together in groups with the object of care of	**3M**

		patient and community. 5. **Counselling and patient advice**: It is a modern concept adopted in big hospitals for the wellbeing of the patients. During these counselling sessions pharmacists educate people on communicable diseases, epidemics and family welfare etc.	
3	**d)**	**Describe signs, symptoms and pathophysiology of Rheumatoid Arthritis or Diabetes** **Pathophysiology: (1 ½ marks)** Rheumatoid arthritis is an autoimmune disease. In these diseases, body's immune system no longer accepts certain body proteins and reacts as if they were foreign antigen and produces antibodies against them. It is observed that patient's body considers human gamma globulin (IgG) as the antigen and produces antibodies against them, known as 'Rheumatoid factors". The antigen reacts with antibody to form immune complex, which then reacts with complement. Complement is a series of proteins, which helps to stimulate the inflammatory process. Thus, the immune complex reacts with the complement in the joints, which leads to the inflammatory response. **Signs and symptoms (1½ marks)**: 1. Fatigue, anorexia, weight loss and fever 2. Inflammation of peripheral joints, most frequently the small joints of hand and feet, and the writs, larger joints may also be involved. 3. Morning stiffness is a common symptom. The stiffness generally lasts more than 30 minutes and may last for many hours. 4. Chronic inflammation of joints results in erosion at the margins of the bones. 5. Deformities may develop, mainly of the fingers and neck etc. Joints may ankylosed with complete loss of motion. 6. Around 20- 30 % patients show formation of rheumatoid nodules. They occur commonly in the elbow or along the extensor surface of forearm. 7. Inflammation of organs than joints like heart, lungs, eyes, may also occur. **OR** **Diabetes:** **Pathophysiology (1 ½ Marks)** Diabetes is a chronic disorder of carbohydrate, fat and protein metabolism, in which the body either fails to produce sufficient amount of insulin or responds abnormally to insulin. In a diabetic person, due to abnormal insulin metabolism, the body cells and tissues do not	3M

make use of glucose from the blood, resulting in an elevated level of blood glucose, hyperglycemia. Over a period of time, hyperglycaemia can lead to severe complications, such as eye disorders, cardiovascular diseases, kidney damage and nerve problems.

Type I diabetes mellitus results from immune mediated destruction of pancreatic β -cells. Hyperglycemia occurs when 80-90% of β-cells are destroyed. It results in secretion of no insulin from pancreas. It is insulin dependent diabetes.

In Type II diabetes mellitus, there is a normal production of insulin hormone, but the body cells are resistant to insulin. Since the body cells and tissues are non-responsive to insulin, glucose remains in the blood stream. Insulin resistance is manifested by increased lipolysis and free fatty acid production. The liver metabolises free fatty acid into ketone bodies that results in ketoacidosis.

Sign and symptoms:(1 ½ Marks)

1.Polyuria (frequent urination), polydipsia (increased thirst) and polyphagia

2. Hyperglycaemia, poor wound healing and maximum. Susceptibility to infection and weight loss. Nocturia, blurred vision, vascular complications, numbness in feet, itching and drowsiness occur

3.In case of chronic patients, it leads to Kidney failure, lesions in the eye and high frequency of gangrene.

3	**e)**	**Explain what happens when the following drugs are prescribed together: (1 ½ Marks each)** **i) Digitalis with Diuretic** **ii) Warfarin and Phenylbutazone** **i)Digitalis with Diuretic-** Diuretic causes loss of potassium from body results in hypokalemia and if digitalis is administered it may produce digitalis toxicity. **ii)Warfarin and Phenylbutazone:** Phenylbutazone displaces the warfarin from its binding sites resulting in increased amount of free form of warfarin causing haemorrhage.	**3M**
3	**f)**	**Define Hospital formulary? Write the guiding principles while using Hospital Formulary.(1 Mark for Definition, 2 marks for guiding principles- any 4 points)** **Hospital formulary-** Hospital formulary is revised compilation of pharmaceutical preparations and ancillary drugs which reflects current clinical judgment of medical staff of the hospital. **Guiding principles for preparation of Hospital Formulary: (any 4 points)** The following principles will serve as guide to all those utilizing the formulary system: 1. The medical staff of the hospital shall appoint P and T Committee and outline its scope, purpose, organization and function. 2. The formulary system will be sponsored by medical staff based upon recommendations of P and T Committee. 3. The medical staff shall adopt the written policies and procedures of the formulary system. 4. Drugs should be included in the formulary by their nonproprietary names and should be prescribed by the same name. 5. Limiting the number of drugs available from pharmacy can produce substantial patient care and financial benefits. These benefits can be greatly increased by using generic equivalents. Generic equivalent- The drugs containing identical active compounds. E.g Two brands of tetracycline.	**3M**

		Therapeutic equivalent- The drugs differing in composition but having very similar pharmacological or therapeutic effects. E.g: two different antacid products. 6. The management of the hospital shall inform all the medical and nursing staff about the existence of the formulary system, procedures of the operation of the system and any changes in those preparations. Copies of formulary must be readily available at all times. 7. Provision shall be made for the use of drugs not included in the formulary, by the medical staff. 8. The pharmacist shall be responsible for specification as to quality, quantity, and source of supply of all the drugs used in the diagnosis and treatment of patients.	
4		**Solve Any <u>FOUR:</u> (3 marks each)**	**12M**
4	**a)**	**What is Idiosyncrasy and Allergy? (1 ½ Marks each)** **<u>Idiosyncrasy</u>-** The term idiosyncrasy (Greek idios means 'one's own and synkrasis, a mixture together') is used to denote abnormal drug response. Idiosyncrasy covers unusual, bizzare or unexpected drug effects which cannot be explained or predicted in individual recipients. It also includes drug induced foetal abnormalities, **e.g. (any 1 example)** 1. phocomelia which developed in the offspring's of mothers exposed to thalidomide. 2.Individuals with deficiency of Glucose 6 phosphate dehydrogenase enzyme are at more risk of developing haemolysis after use of antimalarials, antibiotics, sulphonamides, salicylates 3. Analgesics may induce tumours of kidney and pelvis in patients with renal disease. 4. Long term therapy with immune suppressive agents like azathioprine, cyclophosphamide may induce lymphoid tumours **<u>Allergy:</u>** These reaction are common but unpredictable which ranges from mild skin reaction to major anaphylaxis and death occurring very rarely. The term "allergy" is used to indicate an immunological reaction. Drug or its metabolites (simple structure) combine with body proteins. These stable drug protein complex acts as antigen .Simple chemicals which are capable of binding firmly with a	**3M**

protein to form antigenic product, are term as 'haptens'.

When an individual comes in contact with such antigenic complex .there occurs formation of antibodies; i.e sensitized. Such sensitized individual when re exposed to the drug or haptens, antigens reacts with antibodies. Antigen –antibody complex triggers the release of mediators like histamine from mast cells and cause allergic drug reaction. Now manifestations of allergic reaction occurs which are characteristic of the mediator and not the drug.

(any one example)

Allergic reaction	**Causative drugs**
Anaphylaxis	Penicillin, Dextran, Iodine containing compound.
Skin rashes	Sulphonamide, penicillin, Barbiturates
Hemolytic anemia	Sulphonamide, penicillin, Quinidine and methyl dopa.
Hepatitis	Phenothaiazines, methyldopa
Leucopenia	Sulphonamide, thiouracil, henylbutazone
Nephritis	Methicilin, oxacillin, nafcillin

4 b) Define clinical pharmacy. What is the scope of clinical pharmacy? (1mark for definition and 2 marks for any 4 points) **3M**

Definition of Clinical pharmacy – Clinical pharmacy is a new-born discipline that carries traditional hospital pharmacist from his product oriented approach to more healthier patient oriented approach, so as to ensure maximum well-being of the patient while on drug therapy.

OR

It is the branch of pharmacy which is concerned with various aspects of patient care & deals not only with dispensing of drug but also advising the patients on safe & rational use of drugs.

Scope of clinical pharmacy— (any 4 points)

1. Medication history- it includes past and present of prescription and non – prescription drug, dietary supplements, dietary habits, drug and estimate of patient compliance with the drug therapy.

2. Monitoring drug therapy- it includes evaluation of patient pharmacokinetics and pharmacodynamics parameters, lab. Findings, medical problems and communicating relevant

		findings to physician. **3. Participation in ward rounds**- The clinical pharmacist with physicians should participate in ward rounds, observe individual patient and decide the drug therapy. **4. Drug information**- The clinical pharmacist establish drug information center. The drug info. Is available at this centre and utilized suitably. This data is send to physician as per their requirements. **5. Patient counselling**- it involves providing information to the patient about drug therapy and illness. The pharmacist acts as resource for information about health promotion and disease prevention. **6. Participation in new drug investigation**- clinical pharmacist along with physician participates in investigation of new drugs. Data of this investigation is complied, analyzed and maintained at drug information centre. **7. ADR management**- Along with physician clinical pharmacist's activity is involved in reporting of management of ADR. **8. Educational Programme-** clinical pharmacist organized educational programs for nursing and education related to safe and effective use of drugs. **9. Tailoring drug therapy**- the clinical pharmacist after the diagnosis of physician formulates drug therapy as per clinical need of individual patient.	
4	**c)**	**Enlist the different softwares used in Hospital pharmacy. Explain the use of computer in Inventory control. (1 mark to enlist any 2 software , 2 marks for 2 systems of inventory control)** **Softwares (any 2)-** Micromedex, PubMed, MEDLINE, MEDLARS, BIOSIS, MEDIPHOR, PAD. The computer can be effectively used for inventory control in the hospital pharmacy as follows: **i) Periodic inventory control system**- In this system, inventory of goods is manually checked, the amount of stock in hand, minimum and maximum, can be found out by feeding the data to the computer. Once the stock is entered in the computer, it is helpful for placement of order to each supplier. **ii) Perpetual inventory control- In** this system, computer maintains running balance of all drugs in the stock. All drugs are entered into the database. When they arrive in the pharmacy,	**3M**

		they are added in the initial stock, so as to update the current stock. The current level of each drug is found out by subtraction from the inventory balance. Thus, the computer can list out minimum order quantity of each drug. In this way computer can help in inventory control- - To detect the items those have reached minimum order level. - To prepare the list of drugs to be ordered and their quantities. - To prepare the purchase order and avoid duplicate orders. - Keeping the inventory records for accounting aspects, audit inspections and legal requirements. - For automatic updating of price - For evaluation of demand. - To detect infrequently purchased items for possible return of elimination from pharmacy's drug supply.	
4	**d)**	**How surgical cotton is evaluated as per I.P? (any 3 test as per IP – 1 mark each)** **Evaluation of Absorbent Cotton Wool I.P.** **1. Identification test:** (a) When treated with iodinated Zinc Chloride solution, the fibres become violet. (b) Microscopic examination shows the length of each fibre to be up to 4 cm and the width up to 40 μm, the shape being flattened tube with thick rounded matter, and twisted. Only occasionally one foreign fibre is observed. **2. Alkalinity or Acidity:** Thoroughly saturated about 10 g with 100 ml of recently boiled and cooled water, then with the aid of glass rod press out two 25 ml portions of water into white porcelain dishes. To one portion add 3 drops of phenolphthalein and to the other portion add 1 drop of methyl orange. No pink colour develops in either portion. **3.Surface active substances:** Shake 10ml of the solution 30 times vigorously in 10 sec, allow it to stand for 1 min .after 5 minutes the height of froth should not exceed 2 mm above the surface of liquid. **4. Sinking time:** Pack 5 gm of Absorbent cotton loosely in the basket and drop it at the height of 10mm on the surface of water, contained in a beaker. Should not be more than 10 seconds. **5. Water holding capacity:** After evaluating the sinking time remove the basket from the water and drain it for 30 seconds in horizontal position. Weigh it and calculate the weight of water retained by the sample .It should not be less than 23 g of water / gm of sample . **6. Neps:** Spread thin layer 5 g of Absorbent cotton for an area of 450 sq cm .uniformly	**3M**

		between two glass plate and view by naked eye under transmitted light. Should not be more than 500 neps/gm of absorbent cotton. **7. Water soluble substances:** Not more than 0. 5 % **8. Ether soluble substances:** Not more than 0. 5 % **9. Sulphated ash**: Not more than 0. 5 % **10. Loss on drying :** To check % w/w of volatile & moisture substances. Not more than 8.0 % w/w **11.Fluorescence Test-** A 5mm thickness layer examine under 365 nm u.v. lamp. It shows only a slight brownish violet fluorescence & few yellow particles. Not more than few fibres show an intense blue fluorescence.	
4	**e)**	**Define Hallucinogen. Give the effects and treatment of LSD. (1 mark each for definition , effects and treatment)** Hallucinogens are agents that act on CNS to produce a state of perception of matters/objects with no reality or feeling with no external cause. **OR** Hallucinogens are a group of naturally occurring and synthetic compounds capable of producing distortion of reality resulting in confusion, delirium, amnesia and loss of sense of direction, space and time. **Effects of LSD:** A person on LSD may experience physiological effects, including raised blood pressure and heart rate, dizziness, loss of appetite, dry mouth, sweating and tremors; but the drug's major effects are emotional and sensory. The user's emotions may shift rapidly from fear to euphoria, with transitions so rapid that the user may feel several things simultaneously, including panic and extreme terror. Panic and terror can lead a user to run across a busy street. LSD also has dramatic effects on the senses. Colors, smells, sounds and other sensations appear highly intensified. **Treatment**: - It includes supportive environment and the extreme agitation is controlled by Antianxiety and tranquilizer diazepam.	**3M**
4	**f)**	**Define DIB. Write sources of drug information. (1 mark – Definition , 2 marks – sources)** **Drug information Bulletin**: The drug Information Centre may publish a journal or periodical	**3M**

or any booklet about current or amendment information on drugs, Various technical aspects and modernization of hospital practices for all the health professional which is referred as "Drug information Bulletin"

1.Primary sources –

Information obtained from basic researches and developments which is published in brief for first time. Information on internet, website, C.D ROM.

2.Secondary sources –

Information in the form of abstracts, journals, periodicals, references and official books is called secondary sources.

i) Journals and periodicals – American journal of hospitals pharmacy, Indian journal of hospitals pharmacy, Journal of clinical pharmacology.

ii) Text books – Text book of hospitals pharmacy, clinical toxicology.

iii) Reference books- Remington's pharmaceutical science, Merck index

iv) Pharmacopoeias – The Indian Pharmacopoeia, British Pharmacopoeia

v) Formularies – National formulary of India, National formulary of America.

3) Tertiary Sources - It include dictionaries, encyclopaedias, desk references

The Chemist and Druggist directory

Indian Pharmaceutical Guide- which gives the manufacturers or suppliers catalogues and price list.

Medical register and Directory of Pharmaceutical Chemists.-Statistical Table and Mathematical table to provide scientific data.

5		**Solve any <u>Four</u>: (3 marks each)**	**12M**
5	**a)**	**Differentiate between Drug Addiction and Drug Habituation. (any 6 points, 3 marks)**	**3M**

Drug Addiction	**Drug Habituation**
1. It is a state of periodic or chronic intoxication produced by repeated administration of drug.	1.It is a condition resulting from repeated administration of drug.
2.It is accompanied with physical and psychological dependence	2.It is accompanied with psychological dependence only
3.Tolerance is developed	3.Tolerance is not developed
4.Tendency to increase the dose	4.No Tendency to increase the dose
5. Withdrawal symptoms are severe and require medical treatment.	5. Withdrawal symptoms are not severe and are very less.
6.Person shows compulsion to take the drug	6. Person has strong desire but not compulsion to take the drug.
7.Detrimental effect on both person and society	7. No Detrimental effect on society.
e.g-Morphine, alcohol	e.g.- Tea, coffee

5	**b)**	**Classify antidotes with examples : (any 3 types of antidotes with any 1 example – 1 mark each)**	**3M**

The antidotes are of 4 types.

<u>1. Physical antidote.-</u>

These substances inhibit the absorption of poison. e.g. Demulcents such as fats, oils and egg albumin. The demulcents form the coat on the mucous membrane and inhibit the absorption of poison.

Banana is used for glass poisoning

Charcoal – alkaloidal poisoning.

2.Chemical antidote :-

It is substance which interacts chemically with poison to form an insoluble precipitate which is nontoxic.**(any 2 examples)**

Poison	**Antidote**
Acid	Mg oxide, Cal oxide
Carbonic acid	MgSo4
Lead	Sulphates of alkali
Oxalic acid	Lime
Phosphorus	Copper sulphate
Alkaloids	Tannins

3 Physiological Antidote: It produces opposite action to that of poison without interacting chemically.**(any 2 examples)**

Poison	**Antagonist /Chelators**
Morphine	Caffeine, Naloxone
Organophosphorus compounds	Atropine
Strychnine	Chloroform
Arsenic	BAL, EDTA
Lead	BAL, EDTA, Penicillamine
Mercury	BAL, Penicillamine
Iron	Desferrioxamine B
copper	BAL, Penicilliamine

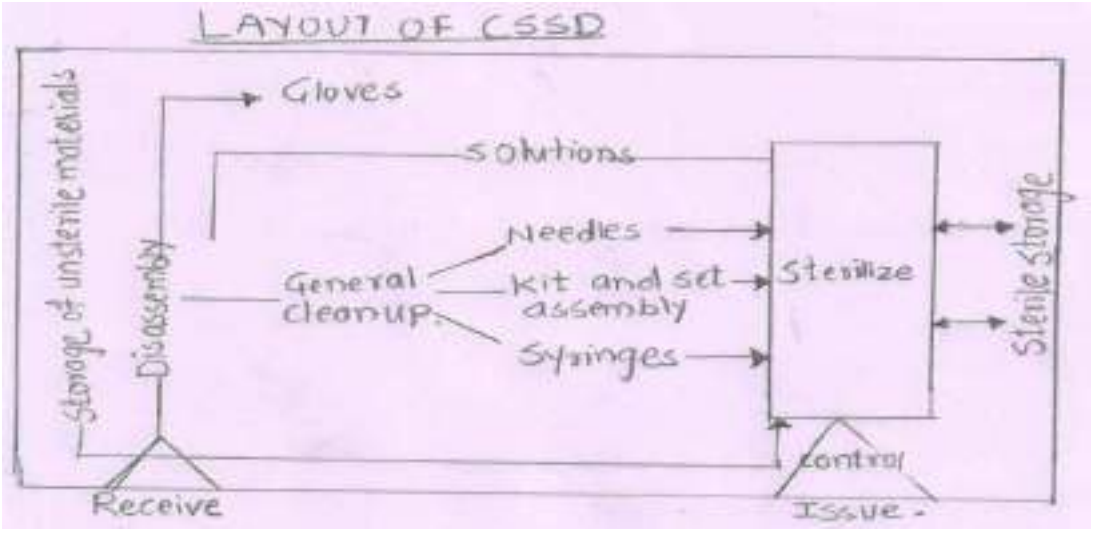
4.Universal Antidote: When nature of ingested poison is unknown, the universal antidote is used.

	Ingredients	**Quantity**
1.	Powdered charcoal	2 parts
2.	Magnesium oxide	1 part

		3. Tannic acid 1 part	
5	**c)**	**Define Bioequivalence. Explain first pass effect.** **Definition: (1 mark)** A product is considered bioequivalent if its rate and extent of systemic absorption does not show a significant difference from the pioneer drug product when administered at same dose of active ingredient by the same route and under the same experimental conditions. **First pass effect: (2 marks)** Orally administered drugs go to the systemic circulation via hepatic portal system, which first present the drugs to the liver. Thus the entire absorbed dose of the drugs is exposed to the liver during first pass through the body. The drug, if it is rapidly metabolized in the liver, a small fraction only will reach the systemic circulation. This is known as first-pass affect and may cause significant reduction in bioavailability. Route of administration highly affects first-pass metabolism effect. Bioavailability of propranolol, oxyphenbutazone, chlorpromazine, and aspirin undergo first pass effect.	**3M**
5	**d)**	**What are the objectives and functions (any three of each) of Hospital pharmacy?** **Objectives: (any 3 points, 1 ½ marks)** 1. To professionalize the functioning of pharmaceutical services in a hospital. 2. To ensure the availability of the right medication at the right time, in the right dose, at the minimum possible cost. 3. To teach the hospital pharmacist about the philosophy and ethics of hospital pharmacy and guide them to take responsibility of professional practice. 4. To strengthen the management skills of hospital pharmacist working as the head of the department 5. To strengthen the scientific and professional aspects of practice of hospital pharmacy such as his consulting, teaching role and research activities. 6. To utilize the resources of hospital pharmacy for the development of profession. 7. To attract the greater number of pharmacist to work in the hospital. 8. To promote the payment of good salaries to pharmacist. 9. To establish drug information services 10. To participate in research projects carried out in hospital. 11. To implement decisions of Pharmacy and Therapeutics Committee **Functions: (any 3 points, 1 ½ marks)**	**3M**

		1. Dispensing of drugs, chemicals and pharmaceutical supplies. 2. Dispensing of all narcotic drugs, alcohol & maintaining running stock account of the same. 3. Filling and labelling of all drug containers. 4. Inspection of all pharmaceutical supplies. 5. To maintain satisfactory system of record and book keeping of all products available in hospital pharmacy. 6. To maintain stock of approved drugs. 7. To maintain adequate control over dispensing of all drugs. 8. To maintain correct specification of drugs. 9. To maintain correct costing of drug. 10. To prepare large volume parenterals & other parenteral preparations & to maintain aseptic condition while manufacturing. 11. To check quality of manufactured product. 12. To give information concerning to medicines to physicians, interns & nurses. 13. To prepare periodic & annual report about working of Hospital pharmacy. 14. To implement decisions of PTC. 15. To implement programme of education for pharmacist, nurses and interns.	
5	**e)**	**Define outpatient. Explain the Receipt and Issue system to outpatient.** **Definition: (1 mark)** Outpatient means the patient who does not occupy bed in the hospital and is offered consultation, diagnosis and receives treatment. **OR** An outpatient may receive general or emergency treatment which could be diagnostic, therapeutic or preventive without being admitted in the hospital. **Receipt and Issue system: (2 marks)** 1. Patient in his first visit to OPD goes to registration counter .Take case paper after paying nominal fees. 2. Then patient goes to general check-up counter –guided for medical department on the basis of clinical symptom.	**3M**

		3. Physician write prescription for patient and he submitted it to pharmacy dept. where prescription is compounded and dispensed by pharmacist. 4. Pharmacist numbers the prescription, monitors it and assembles the materials and equipment for compounding. 5. Pharmacist gives token to the patient so patient and prescription can be identified. 6. Compounded prescription filled in suitable container, packaged, labelled and priced reasonably. 7. Pharmacist records prescription in a register for accounting purpose. 8. While dispensing and compounding the drug correct delivery is ensured by checking token number. For his next visit prescription is given back to the patient.	
5	**f)**	**Define and classify poisons.(definition 1 mark, classification 2 marks for any 4 classes)** **Poison** is any substance taken in the body by ingestion, inhalation, injection or absorption that interferes with normal physiological function. **OR** A poison can be defined as a chemical substance which when administered, inhaled or Swallowed is capable of producing harmful or lethal effect on the body. **Classification:**Depending upon mechanism of action of poison, these are classified as **1) Corrosives-(any one example)** a) Strong acids- sulphuric acid, nitric acid, hydrochloric acid b) Organic acids- oxalic acid , carbolic acid c) Concentrated alkalies- caustic potash, caustic soda, carbonates of sodium, calcium and potassium 2**) Irritants- (any one example)** a) Inorganic: 1. Non- metallic- Phosphorous, chlorine , bromine, Iodine 2. Metallic- Lead, Mercury, copper, zinc, arsenic , manganese b) Organic: 1. Animal origin- Snake, scorpion, Insects, Cantherides 2. Vegetable origin- Ergot aloe, capsicum, castor oil seeds etc. c) Mechanical- Powdered glass	**3M**

		3**) Neurotics-(any one example)** a) Cerebral poison- opium , sedatives and hypnotics, insecticides, cocaine and hyoscyamus b) Spinal poisons- Nux vomica c) Peripheral poisons- curare alkaloids, conium 4) **Cardiac- (any one example)** e.g. Digitalis , stropanthus, aconite, tobacco 5) **Pulmonary depressants**- Substances acting on lungs e.g. Gases such as carbon monooxide, coal gas 6) **Miscellaneous**- Analgesics, antipyretics, stimulants, antidepressants, antihistamines, hallucinogens.	
6		**Solve any FOUR : (4 marks each)**	**16M**
6	**a)**	**Describe the location and layout of central sterile service room.(location 1 mark, layout 3 marks)** **Location**: It should be centrally located in the hospital or near a place where bulk of the supplies are required as operation theatres which contributes about 75% of the work of this department. The store and laundry should be very near. **LAYOUT**  It consists of series of working station in dirty,non sterile area which are separated from sterile by Autoclaving and different sterilizing equipment. In layout, sterile area is established having	**4M**

		different sterilizers i) At the entrance, Non sterile items like gloves, syringe and needle, rubber gloves, surgical instrument and dressing, urine and blood collection sets, etc are received. ii)The Non sterile item then passes for sorting and disassembly purpose iii) It goes for general clean-up process for washing purpose, powdering process for gloves and all this assembled according to types of items. Linen material goes to the linen storage section iv) Then these items pass through partition zone to sterile area for sterilization in different sterilizer. v) Finally the sterilized item comes to the sterile storage area. vi) From this area, these items are issued or distributed to various departments through clear area. The purpose of such layout is to minimize cross flow of non-sterile item with sterile item thereby eliminating the possibility of error of contamination.	
6	**b)**	**What is (ADR) – Adverse Drug Reaction? Give the classification of ADR. Give the reasons for ADR. (definition 1 mark, classification 1 mark, any 4 reasons 2 marks)** Adverse drug reactions (ADR) – "Any response to a drug which is noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy". **Classification of ADRs:** **A) Predictable ADRs:** 1. Excessive Pharmacological effect. 2. Secondary Pharmacological Effects. 3. Rebound response on discontinuation. **B)Unpredictable ADRs:** 1. Allergic drug reaction and Anaphylaxis. 2. Idiosyncrasy. 3. Genetically determined Toxicities. 4. Toxicity following drug withdrawal.	**4M**

Reasons for ADR:

1.Medication errors:

• Self medication of OTC drugs by patient leads to over use or misuse of drug. It may result into excess pharmacological action or complications.

• Over prescribing of potent medicament to the patient e.g oral hypoglycemic, antihypertensivess etc.

2.Inadequate monitoring of the patient:

Drugs like cardiotonics, Diuretics, corticosteroids needs therapeutic monitoring with continuing the administration beyond therapeutic end point which leads into adverse reactions.

3.Sudden withdrawal of drugs: Therapy with drugs like corticosteroids and harmones cannot be suddenly stopped. Such drugs therapy is gradually stopped by decreasing the dose.

4.Bio-availability variations: There are number of brands of the same drug which leads to variations in bio-availability of drugs.

5.New potent drugs : The ever increasing number of new potent drugs along with brands ,may cause hypersensitivity reactions in particular individuals.

6.Drug interaction and drug food interaction: This type of interaction occurs when two or more drugs or presence of food may inactivate or alter the absorption of drug results in inactivation.

7.Some drug having narrow margin of safety: Difference between therapeutic dose and toxic dose is very narrow in some drugs,e.g- .Digitalis if not prescribed carefully leads to its toxicity.

8.Patient factors:

a) Age: Young and old patients are more susceptible to adverse drug reactions as compare to the adults, because of pharmacokinetics pattern at this age.

b) Disease state: Mainly patients with hepatic or renal dysfunction are prone to adverse effect of drugs.

c) Genetic factors: Some people are sensitive to even low doses of drugs, while others are not. This may be due to defects into either enzyme deficiency, or abnormal enzyme system.

Ex. In people with Glucose -6 –phosphate dehydrogenase (G-6PD) deficiency, antimalarial therapy can develop haemolytic anaemia.

		9.Discontinuation of therapy /treatment due to : High cost of medicine, Lack of faith on physician or Noncompliance.	
6	**c)**	**Write the role of pharmacist in patient counselling.(any 8 points, 4 marks)** **Role of Pharmacist in patient counselling-** **1) Name of the drug and its action**- The pharmacist should inform the patient about not only the name of drug but also its other name .He must explain the use of that drug and action on the body. **2) Route of administration-** It is important for the pharmacist to inform the patient about the route of administration of drug, whether the drug is to be taken orally or it is to be applied locally or to be used into eye, ear or nose or inserted rectally or vaginally. The pharmacist should be sure that the patient understands how to use ophthalmic preparations and suppositories. **3) Time of administration-** The pharmacist should instruct the patient when to take the medication e.g. some drugs should be taken on empty stomach i.e. about 1 hour before meal or 2-3 hours after meal to ensure adequate absorption of drug. . **4) Duration of therapy**- The pharmacist should encourage the patient to continue taking the medicine for the prescribed duration of the treatment. He should explain that the course of treatment must be completed to achieve best results. **5) Storage of drugs**- The pharmacist should instruct the patient regarding storage of drugs as per label on the container. The patient should advise to store the drugs in a separate cabinet where children will not reach. **6) Adverse effects of drugs-** The patient should be informed about the adverse effects of the drugs, but it not necessary to inform about all the side effects e.g. .Headache. The patient should be informed of those side effects which will allay fears and help him to avoid injury to himself e.g. change in colour of urine, drowsiness. **7) Restrictions**- The patient should be informed well that he should avoid certain drugs and foods during the therapy. E.g. Restriction of Tyramine containing food in patients on MAO inhibitor therapy **8) Allergic reactions**- Before dispensing the drugs like penicillin or sulphonamide, the pharmacist should ask the patient about his allergic reactions in the past. It helps in avoid in further complications of treatment. **9) Removal of drug from package**- The patient is not familiar with the packing of the	**4M**

		product as the pharmacist. Hence, the pharmacist should demonstrate the method of removal of drug from the package to the patient so that he can handle it properly. **10) Refill information-** The patient should be informed the patient verbally, whether the prescription is refillable, or not. If it is, then for how many times it may be refilled and length of time during which it may be refilled. If it is not refillable, he should be instructed such, so that he may contact the physician for the same drug if needed.	
6	**d)**	**Discuss four important factors governing make or buy decision. (4 marks for 4 factors)** Four important factors are: 1) **QUALITY**-The quality of outside purchases & the quality that could be possibly achieved when manufactured within the hospital are compared. If there are no wide variations between these two, it is not an important consideration .if there is a wide variation, it becomes crucial factor. If a better quality results from in-house manufacturing, the matter should be probed further. Why do the outsiders fail to come up to the desired quality level? Also, is the hospital competent to produce the desired quality? Does it have the necessary infrastructure? Most of the times, as in case of large volume fluids, the hospital favors in-house manufacturing as it has a legitimate apprehension that an outsider may compromise with the quality of his supplies. 2) **QUANTITY**-Generally, those items whose orders are too small to purchase it from an outside supplier are manufactured within the hospital. Similarly, items which are required every day for use in hospitals, in large quantities, are generally decided to be manufacture. Break-even analysis gives the hospital the break-even quantity of production. Break-even is at a point where there are no profits and no losses. 3) **COST**-Here we compare the costs of buying from outside with the cost of in-house manufacturing. The cost of manufacturing the items within the hospital is estimated by drawing up a cost-sheet. It is important to allocate over-heads correctly. Cost and quantity together considered for making the decision. 4**) SERVICE:** Generally, a supply is more assured when a hospital makes an item then when it buys it. Assured supply is often a valid reason for manufacturing. Interruption in supplies may affect the major clinical series of the hospital. Unfair practices of outsider make a hospital opt for making rather than buying.	**4M**

6	**e)**	**Describe procurement or purchase procedure step-by-step. (4 marks)** **1. Purchase request form/purchase requisition**-Pharmacist or person authorized by him prepares and fills purchase request form. This form provides information to purchase dept. regarding description, packaging, specifications, price, quantity needed, inventory balance and anticipated monthly use. The original copy of this form is sent to administrator for approval. After his approval it is forwarded to purchasing officer. A copy of this form is retained by pharmacist for his record to indicate that the process of procurement is going on. **2. Quotation invitation**-On the receipt of purchase request form, purchasing officer invites quotations from different suppliers. **3. Purchase order form**- Purchasing officer scrutinizes the quotations received. He checks the quantity to be supplied in consultation with pharmacist and prepare purchase order form. **Seven copies of purchase order are prepared** – 1) a copy for the supplier for supply of materials 2) a copy for the account section for audit 3) a copy for the purchase section for filing 4) a copy for the department from where purchase requisition originated 5) Two copies for the receipt section of stores out of which one is used once the goods arrive for checking and the other when the goods are returned 6) a copy for history with the purchase section to ascertain the rates and other information in future. **4. Receipt of goods**- When the ordered goods comes in dept. the quantities and prices are checked. Invoice of supplier is compared to the purchase order. Received goods bill sent to the account section where bill is entered in purchase record register. If a part of order is returned to supplier, it contains Goods Returned Note (1 copy to supplier and 1 to the department) **5. Release of payment to supplier.**	**4M**
6.	**f)**	**Explain floor stock system. (2 marks for explanation, 1 mark each for any 2 merits and any 2 demerits)** The medicines or drugs are stored in pharmacy and supplied or distributed to the wards or rooms on order and kept under the supervision of registered nurse at nursing station are called floor stock drugs. It is classified further into	**4M**

		a)Charge floor stock drug:- Drugs which are stocked on the nursing station at all time and are charged to the patient account .An envelope is used to dispense the drugs to the nursing station. **b) Non Charge floor stock drug**:- Drugs which are placed at the nursing station at all time and for which there may not be direct charge to patient's account. The cost is calculated in the per day cost of hospital room. Drug basket method or Mobile dispensing unit is used to dispense the drugs to the nursing station. **Merits: (any 2 Merits – 1 mark)** 1. The deteriorated, out dated and non-approved drugs and drug samples may be removed quickly through the routine checking of the cabinets. 2. The nursing station drug cabinets are under the continuous supervision of the pharmacist. 3. Less number of pharmacy staff is required. 4. Ready availability of required drugs. 5. Minimization in patient prescription orders at pharmacy. **Demerits: (any 2 Demerits – 1 mark)** 1. It consumes nursing personnel time. 2. There are chances of medication errors because personally pharmacist cannot take review of requirement of medications. 3. Increase in drug inventory at nursing stations. 4. Special facilities are required in nursing stations for storage of drug.	

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.

Q. No	Sub Q. N.	Answer	Marking Scheme
1		**Solve any EIGHT Questions : (2 marks each)**	**16M**
1	a)	**Define the following terms: (any two) (each definition - 1 mark)** i) **Drug abuse**- It is an inappropriate and persistent use of drugs beyond medical need. ii) **Pyrogens**- Pyrogens are metabolic products of micro-organisms which produce rise in body temperature on injection. iii) **Hospital-**It is the complex organization utilizing combination of specialized scientific equipments and functioning through a group of trained people educated to a problem of modern medical science and maintenance of good health. **OR** The hospital is defined as the 'an institution of community health. 'Its function embrace the entire spectrum of medical care prevention, diagnosis, therapy, rehabilitation, education and research.	**2M**
1	b)	**Give normal values with significance: (any two) (1 mark each for normal value and significance)** **i) Blood cholesterol** **Normal value:** 150-240 mg/dL or mg % **Significance:** **Total cholesterol — Diseases** 300-400 mg% — Coronary thrombosis 400-500 mg% — Diabetes 500-600 mg% — Obstructive jaundice 600-700 mg% — Nephritis Below 80-100 mg %, it could be hyperthyroidism and pernicious anaemia	**2M**

		ii) ESR **Normal Value: Westergren Method:** Male 0-15 mm at end of one hour Female 0-20 mm at end of one hour **Wintrobe Method** : Male 0-9 mm at end of one hour Female 0-20 mm at end of one hour **Significance: -** Increase in ESR suggests possible pathological conditions like rheumatoid arthritis, TB, pneumonia, allergy, malignant tumour, syphilis etc. ESR decreases in polycythaemia, sickle cell anaemia, protein shock, burning case etc. **iii) Sperm count** **Normal value:** 60 -150 millions/ml of seminal fluid **Significance:** Persons with low counts (less than 60 millions/cc) might show infertility.	
1	**c)**	**Translate into English: (any four) (½ mark each)** i) **Collyrium**– an eye lotion ii) **Tussis**– a cough iii) **Dolore urgente** – when the pain is severe iv) **Unus** - one v) **Hora somni** - at bedtime	**2M**
1	**d)**	**State the meaning of: (any two) (each meaning 1 mark)** i) **Carminatives** – these are the drugs which expel gases from stomach and intestine and are used to relieve flatulence and in intestinal colic. ii) **Anorexia**– loss of appetite iii) **Necrosis** – death of cells or tissues	**2M**
1	**e)**	**What advice must be given to patients while using following drugs? (any two) (each drug 1 mark)** i) **Haematinics** – may colour faeces reddish brown to black.	**2M**

		ii) **Diphenhydramine**- It may cause sedation or drowsiness so do not drive. iii) **Amoxycillin**– 1. 'May cause diarrhoea'. 2. It should be taken on empty stomach i.e-1hour before or 2 hours after meal. 3. Complete the course otherwise reoccurrence may be occur	
1	**f)**	**What is first pass effect? (2 marks)** Orally administered drugs go to the systemic circulation via hepatic portal system, which first present the drugs to the liver. Thus the entire absorbed dose of the drugs is exposed to the liver during first pass through the body. The drug, if it is rapidly metabolized in the liver, a small fraction only will reach the systemic circulation. This is known as first-pass affect and may cause significant reduction in bioavailability.	**2M**
1	**g)**	**What do these abbreviations stand for? (½ mark each)** i) **CCF** – Congestive Cardiac Failure ii) **BAL** – British Anti-Lewisite iii) **ECG** – Electrocardiogram iv) **LAL** – Limulus Amoebocyte Lysate	**2M**
1	**h)**	**Write one example of each poison:(½ mark each for any 1 example)** (i) **Corrosive**- Sulphuric acid, nitric acid, hydrochloric acid, oxalic acid, sodium hydroxide, potassium hydroxide, carbonates of sodium, calcium, potassium,caustic soda,caustic potash. (ii) **Irritant** -Phosphorous, chlorine , bromine, Iodine, Lead, Mercury, copper, zinc, arsenic , manganese, Snake, scorpion, Insects, cantharides, Ergot, aloe, capsicum, castor oil seeds. (iii) **Neurotic**- opium , sedatives and hypnotics, insecticides, cocaine and hyoscyamus, nux vomica, curare alkaloids, conium (iv) **Mechanical**-Powdered glass, Asbestos, Diamond dust, Chopped hairs	**2M**

1	**i)**	**Write uses of (any two) (1 mark each)** i) **CT scanner -** It is an advanced technique used for morphological examination of neurological organs, head, eyes, neck, spinal cord etc. ii) **Foley's catheter** – It is used to decompress urinary bladder or to drain bladder in case of urine retention. iii) **Scalpel** – It is used to make an incision.	**2M**
1	**j)**	**Mention doses of (any two): (1 mark each)** i) **Dimercaprol -**It is administered in a dose of 3-5mg/kg I.M at the interval of 4 hours for first 2 days, interval of 4 to 6 hours for additional 2 days and interval of 6 to 12 hours for additional 7days ii) **EDTA -** Dose-75 mg/kg 24hrs I.M given in 3-6 divided doses for 5 days may be repeated for a second course after a minimum of 2 days, iii) **Desferrioxamine**-Oral 8 to 12 grams in 40 to 60 ml distilled water I.V. 2 gram in 5% laevulose solution	**2M**
1	**k)**	**Name four quality control tests for parenterals. (each test ½ mark)** • Sterility test. • Pyrogen test. • Clarity test. • Leaker test.	**2M**
1	**l)**	**State meaning of (any two):** i) **Cold –** temperature between 2 to 8 ^{0}C ii) **Cool**– temperature between 8 to 25 ^{0}C iii) **Freeze**– temperature 0 ^{0}C or below 0 ^{0}C	**2M**

2		**Solve any FOUR questions: (3 marks each)**	**12M**
2	**a)**	**Classify hospitals on the basis of ownership.(3 marks for classification)** On the basis of ownership hospitals classified as 1) Public 2) Private **1) Public hospitals are owned by Government.** **a) Central Government Hospitals** - Military hospital - Railway hospital - All India Institute of Medical sciences, New Delhi. -JIPMER **b) State Government Hospitals** - J.J. Hospital- Mumbai - Sassoon hospital-Pune - Ghati hospital- Aurangabad - ESIS Hospital- Mulund -Victoria hospital- Bengaluru -Stanley hospital- Chennai -Civil hospital- Jalgaon **c) Local-Self Government Hospitals** - BMC Hospital-Sion,Mumbai - KEM Hospital- Parel, Mumbai	**3M**

- Cooper hospital- Vile Parle, Mumbai

-Bhagwati hospital-Mumbai.

2) Hospitals owned by Private:

a) Private Trust hospital

- Bombay hospital-Marine lines , Mumbai

- Jaslok hospital- Mumbai

- Rajasthan hospital- Ahmedabad

-Jindal hospital- Bengalaru

b) Hospital owned by Religious Trust/bodies

- Hindu Mission Hospital- Chennai

- Al-Ameen Hospital- Bengalaru

- Christian Medical College Hospital – Vellore

-Minakshi Mission Hospital- Madurai.

c) Private Company Hospitals

-Fortis Hospital-Bengalaru

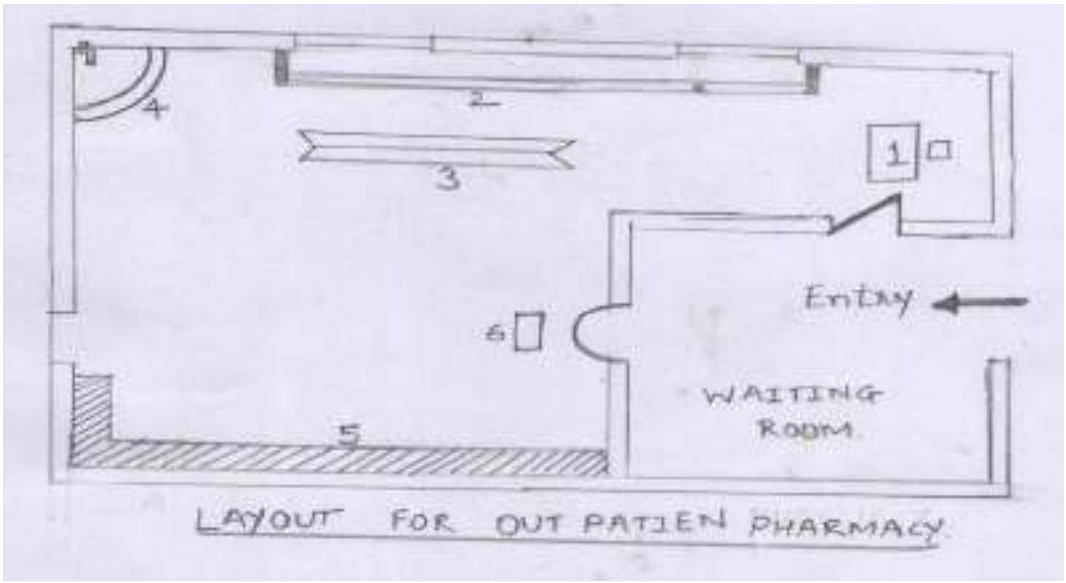
- Apollo Hospital- Chennai

-Medinova Hospital- Gujarat

-HMT Hospital- Hyderabad.

g) Private Clinics/Nursing Homes

Such clinics are owned by an individual doctor or a group of doctors in towns or big cities and serve for 24 hrs.

2	b)	**Draw a layout of outpatient pharmacy.(3 marks)**  1. Table and chair 2.Preparation table 3.Storage rack 4. Sink with tap 5. Medicine platform 6.Dispensing window	**3M**
2	c)	**Differentiate between drug addiction and drug habituation.(any 6 points, 3 marks)**	**3M**

Drug Addiction	**Drug Habituation**
1. It is a state of periodic or chronic intoxication produced by repeated administration of drug.	1. It is a condition resulting from repeated administration of drug.
2.It is accompanied with physical and psychological dependence	2. It is accompanied with psychological dependence.
3.Tolerance is developed	3.Tolerance is not developed
4.Tendency to increase the dose	4.No Tendency to increase the dose
5. Withdrawal symptoms are severe and require medical treatment.	5. Withdrawal symptoms are not severe and are very less.

		6.Person shows compulsion to take the drug	6. Person has strong desire but not compulsion to take the drug.	
		7.Detrimental effect on both person and society	7. No Detrimental effect on society.	
		e.g-Morphine, Alcohol	e.g.- Tea, Coffee	
2	**d)**	**Write pathophysiology, signs and symptoms of Tuberculosis OR Hepatitis.** Tuberculosis is infectious disease caused by several species of Mycobacterium tuberculosis. They collectively termed as tubercle bacilli. **Pathophysiology :- (1 ½ marks)** The bacillus that causes TB is tiny rod shaped germ. These germs are protected by an outer layer of wax which prevents the normal defence of the body from destroying them. TB may attack any part of the body such as bones, joints, glands, lymph nodes, eyes, kidney etc. but it especially attack on lungs causing pulmonary TB. These germs can live for months in any place especially in a damp area. Tuberculosis is spread through the air, when people who have the disease cough, sneeze, or spit. When the germs enter into the lungs, the body defence, i.e. W.B.C surround the germs and swallow them .But because of waxy coat, many germs continue to live for months. The larger WBCs then move in building a wall of resistance against the invaders. This is known as 'tubercle'. Reactivation of bacilli due to decreased immunity, as in malnutrition or old age or due to imunosuppressants. The tubercle may disappear leaving a hole or cavity. Large masses of scar tissue may form around this area. This hinders the flow of blood and interferes with normal functioning of lungs.	**3M**

Signs & Symptoms: (1 ½ marks)

Primary Tuberculosis:

-Initial infection does not produce any signs & symptoms. Incubation period is 4-8 weeks.

-Mild fever and malaise may occur.

Secondary or Pulmonary tuberculosis:

Fever up to 40^{o}c in late afternoon or evening & sweat at night

- General malaise, fatigue & weight loss
- Cough in early morning. Green or yellow sputum with blood streaks.
- Chest pain and dyspnoea.
- If pulmonary artery in tubercular region ruptures,-massive haemorrhage.
- The infection may spread to pericardium. It causes inflammation and restriction in motion that may lead to heart failure.

Chronic/ Miliary tuberculosis:

In this case lesions are found at lymph node kidney, meninges, spleen, bone marrow and other organ. Difficulty in breathing, weight loss, fatigue and GIT disturbances.

OR

Hepatitis: (pathophysiology of Hepatitis A OR Hepatitis B) (1 ½ marks)

Pathophysiology of Hepatitis –A

Viruses enter liver cells & cause degenerative changes. Fibrous tissue develops in the damaged area. Effect depends on the amount of fibrous tissue formed.
Once the virus enters the circulation, accumulation of virus takes place in hepatocyte

		& hepatic sinusoids. The viral particle replicate within hepatocytes that causes degenerative changes means swelling of liver cell and subsequent necrosis may occur. Infective viral particle spread into blood, bile & other body secretions, Hepatotropic viruses cause hepatic injury. Damage to liver cells is caused by fibrosis (Blood clot) in the liver. **OR** **Pathophysiology of Hepatitis B** Virus replicate in liver and its fragment get incorporated in liver cell membrane. There is production of antibody like IgM, IgG against the virus. This antibody attack foreign plasma membrane of liver cell and thus cellular immunity develops which damage the liver. The manifestations are because of immune response infection. **Signs and symptoms : (1 ½ marks)** 1. Uneasiness, nausea vomiting with fever. 2. Loss of appetite and body weight. 3. The epigastric discomfort described as a sense of fullness or pain is common. 4. Changes in smell, taste and sense with pharyngitis and cough. 5. Elevation of SGPT and SGOT levels 6. Urine darkens due to rise in bilirubin (jaundice) serum level to about 2mg /100ml(Normal 0.3 TO 1.1mg /100ml)	
2	**e)**	**Define Adverse Drug Reaction. Classify ADR with examples. (definition - 1 mark, 2 marks for classification with any 1 example each)** **Adverse drug reactions (ADR)** – "Any response to a drug which is noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy".	**3M**

Classification of ADRs:

A) Predictable ADRs:

1. Excessive Pharmacological Effect.
2. Secondary Pharmacological Effects.
3. Rebound response on discontinuation.

B)Unpredictable ADRs:

1. Allergic drug reaction and Anaphylaxis.
2. Idiosyncrasy.
3. Genetically determined Toxicities.

Examples:

1. Excessive Pharmacological effect :

It is common experience of patient receiving CNS depressants, cardioactive, hypotensive and hypoglycemic agents. If excessive dose is given, all patients are at risk of developing this reaction. Certain patients are more susceptible to this reaction even when average dose is prescribed.

a) Patient with Kidney disease who have lost more than 70% of their kidney function

b) Patients with hypoalbuminemia due to failure of albumin production by liver or excessive loss of albumin as in nephrotic syndrome.

c) Patients age – Neonates, infants and elderly patient.

2. Secondary Pharmacological Effects

It is mainly observed in patients, who consumes OTC drugs or go for self-medication .e.g. Drugs like Antihistamine used mainly as anti-allergic particularly for common cold and cough , but it may produce drowsiness in large repeated doses for repeated doses on self-medication.

3. Rebound response on discontinuation

- Rebound hypertension on sudden discontinuation of hypotensive agents like clonidine.
- Sudden withdrawal of corticosteroids causes acute adrenal crisis (Addison's disease).
- Confusion, delirium, tachycardia, convulsions and extreme agitation after the discontinuation of long-term CNS depressants like benzodiazepines, barbiturates and alcohol.

Unpredictable ADRs

1.Allergic drug reaction and anaphylaxis

Allergic reaction	**Causative drugs**
Anaphylaxis	Penicillin, Dextran, Iodine containing compound.
Skin rashes	Sulphonamide, penicillin, Barbiturates
Hemolytic anemia	Sulphonamide, penicillin, Quinidine and methyl dopa.
Hepatitis	Phenothiazines, methyldopa
Leucopenia	Sulphonamide, Thiouracil, Phenylbutazone
Nephritis	Methicillin, oxacillin ,nafcillin

2.Idiosyncrasy

It includes the drug induced foetal abnormalities, such as phocomelia developing in offspring of mothers exposed to thalidomide.

Cancer of Organ	Causative drug
Vaginal adenocarcinoma	High doses of stilbesterol during pregnancy
Kidney pelvis	Analgesic induced nephropathy
Uterus	Oestrogens (long term)
Lymphoid tissue	Azathioprine, cyclophosphamide

3.Genetically determined Toxicities

Hereditary condition	Drug causing toxicity.
Pseudocholinesterase deficiency	Succinylcholine
Porphyria	Barbiturates, sulphonamides
Glucose -6-phosphate dehydrogenase deficiency.	Antimalarials, quinidine, sulphas, nitrofurantine.
Glaucoma	Corticosteroids
Methaemoglobinemia	Phenacetin, salicylates.

2	f)	**Define Bioavailability. Enlist factors affecting bioavailability of drugs.** **(definition - 1 mark, 2 marks for list of factors)** **Bioavailability** defined as the rate and extent at which the drug reaches the systemic circulation in the active form. **Factors Affecting Bioavailability:-** **1) Physical properties of drug:-** a) pKa of the drug b) Partition coefficient c) Particle size **2) Pharmaceutical factors:-** a) Dosage forms b) Manufacturing variables c) Dissolution rate **3) Physiological factors:-** a) Effect of GIT fluids b) G.I transit time c) First Pass effect d) Diseased state	**3M**
3		**Solve any FOUR questions (3 marks each)**	**12M**
3	**a)**	**Give any six functions of hospital. (½ mark each)** **Functions of Hospital**: The main functions of the hospital are: **1. Patient care:** It includes services for diagnosis, prophylaxis and treatment of diseases to the sick or injured patients. It is a centre of community health and contributes a great deal to preventive and social medicine. 2. **Public health:** The hospitals are required to support all the activities carried out by various public health and voluntary agencies such as immunization programme, blood	**3 M**

		donation camps, social and economics rehabilitation, health education etc. by providing facilities and advice. **3. Medical research**: Research is an important activity in the hospital that helps in developing the new methods of treatment and improving the hospital services. Some of the common areas of research in the hospital are development of new techniques in surgery, laboratory diagnostic procedures, evaluation of investigational drugs in diseases. **4. Educational training**: - This facility, particularly for medical students, pharmacist, nursing, medical technologist and allied health professional helps to fulfil their curriculum requirement. Hospital also educates the general public through lectures and demonstrations on the preventive aspects of common and serious diseases. Hospital provides the methods by which the persons can work together in groups with the object of care of patient and community. **5. Patient Counselling**: It is a modern concept adopted in big hospitals for the well-being of the patients. During these counselling sessions pharmacist educate people on communicable diseases, epidemics and family welfare etc. **6. Co-ordination**: It is a link between general public and policy makers.	
3	**b)**	**Enlist different abilities a hospital pharmacist should possess and explain any one ability. (1 ½ marks – enlist, 1 ½ marks -explanation)** The hospital pharmacist should possess following abilities: 1. Administrative ability 2. Technical ability 3. Manufacturing ability 4. Research ability 5. Teaching/Training ability 6. Ability to Control	**3 M**

1. Administrative ability-Hospital pharmacist should be thoroughly familiar with organization of hospital, with staff and with appropriate channel of communication. Hospital pharmacist should be capable of planning and integrating services, budgeting, inventory control, cost-review, cost-effectiveness, audit, maintenance of records and preparation of reports.

2. Technical ability- Hospital pharmacist must have ability to use his basic knowledge of effect of drug on biological systems, in assessing drug absorption, distribution, metabolism and pathophysiology, therapeutics and patient care techniques.

3. Manufacturing ability-Hospital pharmacist must be able to develop formulations not available commercially. Hospital pharmacist should possess an adequate understanding of the principals involved in formulations and p[reparation of dosage forms.

4. Research ability-Hospital pharmacist must be prepared to participate in clinical research initiated by medical staff and to conduct pharmaceutical research himself. Hospital pharmacist must be able to establish database for drugs being used and patients participating in studies. Hospital pharmacist must have ability to collect appropriate data interpret them and make conclusion from data.

5. Teaching/Training ability- Hospital pharmacist is responsible for training of new personnel and for carrying out continuous educational programme for pharmacist and pharmacy supportive personnel. Hospital pharmacist must be able to develop well planned and co-ordinate training programme and able to deliver lectures.

6. Ability to Control-Hospital pharmacist must be able to develop quality assurance programme for quality services of pharmacy department and products dispensed. Hospital pharmacist must be able to develop control programme for distribution of drugs throughout the hospital.

3	c)	**Discuss the role of PTC in drug safety.** **Role of PTC in Drug safety** – The PTC plays an effective role in ensuring drug safety on a continuous basis by creating safety awareness in all departments of the hospital. The PTC provides following guidelines to hospital administration. 1. Employment of qualified registered pharmacist with at least B. Pharm degree holder as the chief pharmacist & rest are diploma holders. 2. Takes care that dispensing is done only by the pharmacist. 3. Sufficient number of pharmacists are employed. 4. Proper & adequate storage facilities are provided in pharmacy. 5. Poisonous material & non-poisonous material are stored separately. 6. Pharmacy should have adequate equipments. 7. External preparations are kept separately from internally used preparations. 8. Follow of GMP effectively in the in-house manufacturing unit. 9. Stock & issue of narcotic & psychotropic substances shall conform to the legal requirements. 10. Hospital shall have a drug formulary which is periodically revised & kept up to date. 11. Expired & deteriorated drugs are physically separated. 12. Providing a library & documentation facility.	**3 M**
3	d)	**What is unit dose dispensing? Write benefits of UDD.(1 mark - definition, 2 marks for any 4 benefits)** **Unit dose dispensing-** Unit dose dispensing is an in-patient drug distribution system in which medications which are ordered, packed, handled, administered and charged in the form of multiples of single dose unit containing a predetermined amount of drug for one regular use or application. **Benefits of unit dose dispensing-** 1. The patients are charged for those doses which are administered to them. 2. It reduces the medication errors since the pharmacist checks the copy of physician's	**3 M**

		original order. 3. It avoids drug losses, no pilferage of drug. 4. Less space is required at nursing stations as compared to floor stock. 5. Patients receive the nursing service 24 hrs a day. 6. It avoids duplication of orders and extra paper work. 7. It enhances more efficient utilization of personnel 8. It eliminates labelling error. 9. Drug accounting become easier. 10. Better financial control means credits are eliminated.	
3	**e)**	**Explain the role of pharmacist in patient counselling. (½ mark each-6 roles)** **Role of Pharmacist in patient counselling-** **1) Name of the drug and its action**- The pharmacist should inform the patient about the name of drug and its common name, if any. He must explain the use of that drug and action on the body. **2) Route of administration-** It is important for the pharmacist to inform the patient about the route of administration of drug. Whether the drug is to be taken orally or it is to applied locally or to be used into eye, ear or nose or inserted rectally or vaginally. The pharmacist should ensure that the patient understands how to use ophthalmic preparations, and suppositories. **3) Time of administration-** The pharmacist should instruct the patient when to take the medication e.g. some drugs should be taken on empty stomach i.e. about 1 hour before meal or 2-3 hours after meal to ensure adequate absorption of drug. The patient should be provided for the medication calendar. **4) Duration of therapy-** The pharmacist should encourage the patient to continue taking the medicine for the prescribed duration of the treatment. He should explain that the	**3 M**

		course of treatment must be completed to achieve best results. **5) Storage of drugs**- The pharmacist should inform the patient regarding storage of drugs; those are labelled on the container. The patient should be advised to store the drugs in a separate cabinet where children will not reach. **6) Side effects of drugs-** The patient should be informed about the known side effects of the drugs. This knowledge will help the patient to follow treatment without any fear and thereby improve the compliance of patient. e.g. change in colour of urine, stool; drowsiness, **7) Contraindications (Restrictions) -** The patient should be informed well that he should avoid certain drugs and foods during the therapy. E.g. Restriction of Tyramine containing food in patients on MAO inhibitor therapy **8) Allergic reactions**- Before dispensing the drugs like penicillin or sulphonamide, the pharmacist should ask the patient about his allergic reactions in the past. It helps in avoid in further complications of treatment. **9) Removal of drug from package**- The patient is not familiar with the packing of the product, as the pharmacist. Hence, the pharmacist should demonstrate the method of removal of drug from the package to the patient so that he can handle it properly. **10) Refill information-** The pharmacist should inform the patient verbally, whether the prescription is refillable, or not. If it is, then for how many times it should be refilled and length of time during which it may be refilled. If it is not refillable, he should be instructed such, so that he may contact the physician after completion of treatment.	
3	**f)**	**Explain how purchase order is prepared?** **Purchase order is prepared in 2 steps-** **Step 1- Purchase requisition:** Once the specifications are drawn, a purchase requisition is prepared. The requisition carries the description of items needed, their packaging, their price, their quantity. It may also mention the quantity right now in hand and the quantity required for future period. The original requisition is sent to the administrative head of the concerned department. Once approved by administrative head, it is sent to the purchasing officer. One copy is	**3 M**

		retained by the pharmacist. Several copies of purchase order can be prepared. **Step2- Purchase order:** After the receipt of purchase requisition, the purchase officer/pharmacist prepares a detailed purchase order in a printed form. The items are systematically order by spelling out the specifications, prices and quantities of ordered. Then 7 copies of purchase order are prepared. 1st copy—Sent to supplier by post or hand delivery for supply. 2nd copy--Sent to accounts department where it will be retained for accounting. 3rdcopy—Retained by purchasing officer for his departments file. 4th copy—sent to the department from where 'request form' is received. 5th & 6th copy—Completion of 5th copy is done if articles are received and sent to account departments and 6th copy is utilized only when goods are back ordered. 7th copy---Is history copy is kept by purchase officer to ascertain rates and for other things in future use. When the supplies are obtained they are carefully checked with purchase order. If it is according to the given order, the supplies are retained; if not even in part that part or whole lot is returned to supplier immediately with goods. Returned note and a credit note are obtained from the supplier. The supplies received are entered on the Purchase Record Register and complete inventory is prepared. This supply is then ready for dispensing to inpatients or outpatients.	
4		**Solve any FOUR questions (3 marks each)**	**12M**
4	**a)**	**Define clinical pharmacy. Give different roles of clinical pharmacist.(1 mark-definition, 2 marks – any 4 roles of clinical pharmacist)** **Definition of Clinical pharmacy** – Clinical pharmacy is a new-born discipline that carries traditional hospital pharmacist from his product oriented approach to more healthier patient oriented approach, so as to ensure maximum well-being of the patient while on drug therapy. **OR** It is the branch of pharmacy which is concerned with various aspects of patient care & deals not only with dispensing of drug but also advising the patients on safe & rational	**3M**

		use of drugs. **Role of clinical pharmacist—** **1. Medication history**-It includes past and present of prescription and non – prescription drug, dietary supplements, dietary habits, drug and estimate of patient compliance with the drug therapy. **2. Monitoring drug therapy**- It includes evaluation of patient pharmacokinetics and pharmacodynamics parameters, lab findings, medical problems and communicating relevant findings to physician. **3. Participation in ward rounds**- The clinical pharmacist with physicians participates in ward rounds, observe individual patient and decide the drug therapy. **4. Drug information**- The clinical pharmacist establish drug information centre. The drug info is available at this centre and utilized suitably. This data is sent to physician as per their requirements. **5. Patient counselling**- it involves providing information to the patient about drug therapy and illness. The pharmacist acts as resource for information about health promotion and disease prevention. **6. Participation in new drug investigation**- Clinical pharmacist along with physician participates in investigation of new drugs. Data of this investigation is compiled, analyzed and maintained at drug information centre. **7. ADR management**- Along with physicians, clinical pharmacist is actively involved in reporting and management of ADR. **8. Educational Programme-** Clinical pharmacist organizes educational programs for Nursing and education related to safe and effective use of drugs. **9. Tailoring drug therapy**- Clinical pharmacist after the diagnosis of physician formulates drug therapy to clinical need of patient.	
4	**b)**	**Write three administrative patterns of central sterile service department.** **(1 mark each)** **1- Department as a part of Nursing services-** The majority of items to be dispensed are used by the nurses for the patients care. She should therefore be work as head of this department.	**3 M**

		2- Department under a pharmacist- Pharmacist by taking training is competent to handle the functions of this department.i.e-purchase, storage and distribution of supplies and also the preparation of sterile solution. **3- Department under dual control of pharmacist as well as nurse-** Some functions of the department like cleaning, packaging and distribution of medical supplies and equipments should be placed in charge of nurse whereas manufacturing of sterile solutions should be placed in charge of pharmacist.	
4	**c)**	**Comment on various sources of drug information.(1 mark for each source)** **Sources of drug information-** **1.Primary sources –** Information obtained from basic researches and developments which are published for first time .e.g. Peer reviewed journals-International Journal of Pharmaceutics, Indian Journal of Pharmacology, Journal of Pharmacy and Pharmacology. **2.Secondary sources –** Information in the form of abstracts, journals, periodicals, references and official books is called secondary sources. i) Abstract Services: Chemical Abstract Service, Pharmaceutical Abstract Service. ii) Text books –Text book of Hospital Pharmacy, Clinical Toxicology. iii) Reference books- Remington's Pharmaceutical Sciences, Merck Index iv) Pharmacopoeias – The Indian Pharmacopoeia, British Pharmacopoeia v) Formularies – National Formulary of India, British National Formulary. **3) Tertiary Sources -** It includes dictionaries, encyclopaedias, and desk references. The Chemist and Druggist directory Indian Pharmaceutical Guide- which gives the manufacturers or suppliers catalogues and price list. Medical register and Directory of Pharmaceutical Chemists. Statistical Table and Mathematical table to provide scientific data Websites: Drugscontrol.org, who.int, usfda.org	**3 M**

4	**d)**	**Enlist methods of drug distribution in hospital. Give advantages and disadvantages of floor stock system. (1 mark enlist, 1 mark for any 2 advantages & 1 mark for any 2 disadvantages.)** **Methods of drug distribution in hospital-** **I) Outpatient services** II) **Inpatient services-** It includes i) Floor Stock System ii) Unit Dose Dispensing System iii) Individual Prescription Order System iv) Combination of Floor Stock and Individual Prescription Order System **Advantages of floor stock system-** 1. The drugs are easily available at the wards and nursing units. 2. Elimination of drug returns. 3. Reduction in number of drug transcription orders at pharmacy. 4. Reduction in the number of pharmacists required. **Disadvantages of floor stock system-** 1. Chances of medication error may increase. 2. Increased drug inventory at wards and nursing units. 3. Greater opportunity for spoilage of the drug as they are stored in large quantity. 4. Increased hazards associated with drug deterioration.	**3 M**
4	**e)**	**Explain food drug interactions with examples. (any 6 examples)** Food affects the absorption of the drug. It may be attributed to 1) Dilution of the drug 2) Adsorption or complexation of drug 3) The alteration of gastric emptying. Examples: 1) Food reduces the absorption of aspirin, isoniazid, tetracycline, benzylpenicillin, amoxicillin, Ampicillin, levodopa and Rifampicin 2) Food increases the absorption of hydralazine, Nitrofurantoin, lithium citrate, riboflavin, carbamazepine, metoprolol, propanolol, and spironolactone.	**3 M**

		3) Iron absorption is reduced if food has been taken within the previous two hours. On the other hand, nausea is more likely if iron is taken on empty stomach so iron tablets are often given with food. 4) Nitrofurantoin is given with food to avoid GIT irritation. 5) Meals containing high fat increase the absorption of fat soluble drug Griseofulvin. Fat containing drug increases degree of ionization of Griseofulvin, so increases its absorption. 6) The diuretic effect of tea takes place rapidly if given before meals but diuresis is delayed if it is given after food. 7) The absorption of nitrazepam, glibenclamide, metronidazole, oxazepam, theopylline is unchanged by food. 8) Monoamine oxidase (MAO) is an enzyme which breaks down catecholamines such as or epinephrine. When the enzyme is inhibited, there are increased levels of nor epinephrine in adrenergic neurons. Thus, MAO inhibitors are used as antihypertensive. Certain food like cheese, chocolate, alcoholic beverages, liver, yeast extract contain tyramine. Tyramine is metabolized by MAO. When the patients being treated by MAO inhibitors also take tyramine containing food, tyramine reaches the systemic circulation causing severe hypertension. 9) Milk reduces absorption of tetracycline by forming an insoluble complex	
4	**f)**	**Write pathophysiology & signs &symptoms of diabetes.(1 ½ marks each)** **Pathophysiology-** Lower levels of insulin results in over-production of hepatic glucose and its underutilization. This results in hyperglycemia. In presence of insulin, glucose enters into cells of adipose tissue and muscles and ise used up. Due to lack of glucose, muscle cells carries out glycogenolysis and gluconeogenesis. Lack of glucose and insulin in adipose tissue causes impaired triglyceride synthesis and release of free fatty acids which are metabolised in the liver to form ketones. Hyperglycemia results in glycosuria which leads to polyuria, polydipsia and dehydration. As glucose level rises, glucoprotein is deposited in the capillaries. Glucose is metabolised to sorbitol which is responsible for development of cataracts and neuropathy.	**3 M**

		Signs & symptoms- • Hyperglycemia • polyuria • polydipsia • polyphagia • Weight loss • Decreased muscle strength • Irritability • Slow wound healing process • Itching • Ketonuria • Nocturia • Blurred vision	
5		**Solve any FOUR questions (3 marks each)**	**12M**
5	**a)**	**Define and classify surgical dressings with one example each. (1 mark- definition , 2 marks – classification)** **Surgical dressings** - Surgical dressings are the materials which are used for the dressing of wounds as coverings, absorbents, protective or supports for injured or diseased tissues. **Classification of surgical dressings (2 marks)** **1.Fibers/Absorbents:** Absorbent cotton (medicated/non-medicated), Non- Absorbent cotton, eye pad, cotton ball, sanitary napkins. **2. Fabrics/Primary wound dressing:** Absorbent gauze, Absorbent lint, Gauze pad (gauze sponge). **3. Bandages:** Elastic bandages, Muslin bandage roll, Triangular bandage, Common gauze roller bandage. **4. Adhesive tapes/Self-adhesive plaster (Rubber /Acrylated based):** Zinc oxide adhesive plaster, capsicum plaster, Belladona plaster.	**3M**

5	b)	**Define patient compliance? Discuss factors that influence patient compliance. (1 mark for definition and 2 marks for any 4 factors)** **Patient compliance**- A faithful adherence by a patient to prescriber's instructions is called as patient compliance. **Factors that influence patient compliance- (Any 4 factors)** **1. Inappropriate packaging:** Sometimes design or size of container makes it difficult to remove the medicament. Many elderly patients, arthritis patients have difficulty with unit dose pack or foil wrapping while removing medicament. **2. Poor understanding**: Poorly handwritten labels are difficult to read or follow for the patient/pharmacist. Many prescriptions contain directions which are inadequate like take when required or use as directed that may produce confusion. **3. Multiple drug therapy**: Greater the number of drugs patient is taking, the higher is the risk of non-compliance. **4. Asymptomatic nature of patient**: In case of asymptomatic patient, it is difficult to convince a patient by explaining the value of drug therapy and this results in non-compliance. **5. Measurement of medication**: Many times there is confusion to the patient in measuring liquid preparations or number of tablets. **6. Cost of medication**: Because of high cost of drug, poor patients are unable to purchase such drugs. **7. Frequency of medication**: Higher the frequency of the medicines, the greater is risk of non-compliance. Many times regular schedule of dosage form cannot be followed due to work routine. **8. Duration of therapy**: Usually long duration treatment leads to patient non-compliance. **9. Illness**: The nature of patient's illness may contribute to non-compliance like chronic hypertension, mental illness. **10. Age**: Paediatric and geriatric patients contribute to non-compliance.	**3M**

5	c)	**Explain the role of computers in purchase and inventory control in hospitals.** **Purchasing & inventory control in Hospitals –** By using computers it is done by- **1. Periodic inventory control method**- In this method, quantities of drugs available in stock are manually checked. These are then compared with the minimum stock level & maximum stock level maintained on the computer. When the drug level reaches the minimum stock level purchase orders are placed by using computer. **2. Perpetual inventory control method** - In this method computer maintains running balance of all the drugs in stock. All the drugs are entered in database when new stock is received by pharmacy. Computer adds this to the initial stock & reflects current available stock. The quantities of drugs leaving the pharmacy are entered in the computer. Computer subtracts this from the initial stock & reflects current available stock. Whenever the drug level reaches the minimum stock level purchase orders are placed by using computer. Thus, the computer can list out minimum order quantity of each drug. In this way computer can help in inventory control- - To detect the items those have reached minimum order level. - To prepare the list of drugs to be ordered and their quantities. - To prepare the purchase order and avoid duplicate orders. - Keeping the inventory records for accounting aspects, audit inspections and legal requirements. - For automatic updating of price - For evaluation of demand. - To detect infrequently purchased items for possible return of elimination from pharmacy's drug supply.	**3M**

5	d)	**Classify pharmacodynamics drug interactions with examples.** **Classification:** **1) Interaction enhancing effect:**-e.g. Synergistic effect of Trimethoprim and sulphamethoxazole. MAOI and sympathomimetic drugs which increases activity. **2) Interaction inhibiting the effect:-** E.g Acetylcholine and atropine by competitive antagonism oppose the action of each other. Alcohol and amphetamines have opposite effects on CNS. **3) Alteration of electrolyte levels:** Drugs which cause alterations in fluid and electrolyte balance may modify the responses of tissues to drugs. e.g. Diuretics losing potassium, may cause hypokalaemia, in turn making the heart more sensitive to digitalis. **4) Drug interactions at same receptors:** Drugs that act at the same receptor site, if prescribed together, may produce additive effect or antagonize one another; e.g. respiratory depression and other central effects of morphine are antagonized by nalorphine. **5) Drug interactions at different receptors:** Drugs may interact on the same target organ, but at different receptor sites. E.g. Adrenaline activates adenylcyclase system and causes an increase in cyclic 3-5 AMP (Adenosine MonoPhosphate) which then acts as the mediator in a number of beta effects of adrenaline for relaxation of bronchial smooth muscles. Theophylline produces the same effect, an increase in cyclic 3-5 AMP, by inhibiting phosphodiesterase, and also causes bronchial smooth muscle relaxation. Thus, drugs that inhibit different enzymes may show synergistic effect.	**3M**
5	e)	**Define non-sterile manufacturing .Give list of equipments required in manufacturing of tablets. (definition – 1 mark, 2 marks – equipments)** **Non-sterile manufacturing:** The manufacturing of products that does not require sterilisation is called non sterile manufacturing. **Requirements for Tablets:** For effective operations, the tablet production department shall be divided into four distinct and separate sections as follows: -	**3M**

(a) Mixing, Granulation and Drying section

(1) Disintegrator and sifter

(2) Powder mixer

(3) Mass mixer/Planetary mixer/Rapid mixer granulator.

(4) Granulator

(5) Thermostatically controlled hot air oven with trays (preferably mounted on a trolley)/Fluid bed dryer.

(6) Weighing machines.

(b) Tablet compression section.

(1) Tablet compression machine, single/multi punch/rotatory.

(2) Punch and dies storage cabinets.

(3) Tablet de-duster

(4) Tablet Inspection unit/belt.

(5) Dissolution test apparatus

(6) In-process testing equipment like single pan electronic balance, hardness tester, friability and disintegration test apparatus.

(7) Air-conditioning and dehumidification arrangement (wherever necessary)

(c) Packaging section (strip/blister machine wherever required).

(1) Strip/blister packaging machine.

(2) Leak test apparatus (vacuum system)

(3) Tablet counters (wherever applicable)

(4) Air-conditioning and dehumidification arrangement (where ever applicable).

(d) Coating section (wherever required).

(1) Jacketed kettle (steam, gas or electrically heated for preparing coating suspension).

(2) Coating pan (stainless steel)

(3) Polishing pan (where applicable)

(4) Exhaust system (including vacuum dust collector)

(5) Air-conditioning and dehumidification arrangement.

(6) Weighing balance.

OR

Equipment	Examples
1.Mixer/Blender	Sigma blade mixer, tumbling mixers, Ribbon blenders.
2. Grinder /Sifter	Cutter mill, Hammer mill.
3. Dryers	Tray dryers, Fluidized bed dryers.
4. Compression machine	Single punch, double punch , rotary etc
5. Coating machine	Pan coating, spray coating pans, film coating machine and polishing pan. etc
6. Miscellaneous	S.S utensils like scoop , vessels and buckets etc
7. Packaging machine	Blister/ strip packaging machine
8. Disintegrator	
9. Sifter	
10. Granulator / Granulating machine.	

5 f) How is absorbent cotton wool evaluated as per IP? (3 marks for any 6 tests) **3M**

Evaluation of Absorbent Cotton Wool I.P.

1. Identification test:

(a) When treated with iodinated Zinc Chloride solution, the fibres become violet.

(b) Microscopic examination shows the length of each fibre to be up to 4 cm and the width up to 40 μm, the shape being flattened tube with thick rounded matter, and twisted. Only occasionally one foreign fibre is observed.

2. Alkalinity or Acidity: Thoroughly saturated about 10 g with 100 ml of recently boiled and cooled water, then with the aid of glass rod press out two 25 ml portions of water into

		white porcelain dishes. To one portion add 3 drops of phenolphthalein and to the other portion add 1 drop of methyl orange. No pink colour develops in either portion. **3.Surface active substances:** Shake 10 ml of the solution 30 times vigorously in 10 seconds; allow it to stand for 1 min after 5 minutes. The height of froth should not exceed 2 mm above the surface of liquid. **4. Sinking time:** Pack 5 gm of Absorbent cotton loosely in the basket and drop it at the height of 10 mm on the surface of water, contained in a beaker. Should not be more than 10 seconds. **5. Water holding capacity:** Not less than 23 per gram. **6. Neps:** Spread thin layer 5 g of Absorbent cotton for an area of 450 sq cm .uniformly between two glass plate and view by naked eye under transmitted light. Should not be more than 500 neps/gm of absorbent cotton. **7. Water soluble substances:** Not more than 0. 5 % **8. Ether soluble substances:** Not more than 0. 5 % **9. Sulphated ash**: Not more than 0. 5 % **10. Loss on drying:** To check % w/w of volatile & moisture substances. Not more than 8.0 % w/w **11. Fluorescence Test-** A 5 mm thickness layer examine under 365 nm UV. lamp. It shows only a slight brownish violet fluorescence & few yellow particles. Not more than few fibers show an intense blue fluorescence.	
6		**Solve any FOUR questions (4 marks each)**	**16M**
6	**a)**	**What are the steps involved in general treatment of poisoning? Explain.** **The general steps involved in treatment of poisoning are:** 1. Removal of unabsorbed poison 2. Use of antidote 3. To remove absorbed poison 4. Supportive care	**4M**

5. Treatment of general symptoms

1.Removal of unabsorbed poison:

A)Ingested Poison

Gastrointestinal Decontamination

a) Activated Charcoal b) Gastric Lavage c) Syrup of Ipecac d) Diuretics e) Purgative

B) Contact Poison

- Poison spilt or spread on skin is immediately washed with large quantity of water, saline. Saline is preferred for eye irrigation.
- A triple wash (water, soap, water) is best for dermal decontamination.

C)Injected Poison:It is removed by making incisions at certain place causing bleeding

2.Use of Antidote:

a) Non systemic antidote e.g Kaolin and activated charcoal, Sodium thiosulfate and sodium nitrite.

b) Systemic antidote e.g. Dimercaprol (BAL), Penicillamine, Disodium EDTA and Desferrioxamine.

c) Universal antidote: It is a mixture that contains activated charcoal, magnesium oxide and tannic acid. All three components neutralize the actions of many poisons. It is intended to be administered to patients who consumed poison that is unknown.

3.To excrete absorbed poison

After 6 hrs. of ingestion of poison ,emesis and gastric lavage is useless .The poison has entered the intestine and hence the following measures should be taken

Forced diuresis : use I.V Chlorthiazide / mannitol

Use of cathartics

		Use of hot packs :-For increased sweating Peritoneal dialysis : for salicylate poisoning in children Hemodialysis:-For excretion of barbiturates, salicylates, thiocyanates, bromides. **4. Supportive care**: In poisoning there is possibility of upper respiratory tract infection, to avoid this prophylactic administration of antibiotics is given. Stabilisation of vital centres like cardiac, vasomotor and respiratory centre. Good nursing care is required to maintain general condition of victim. **5.Treatment of general symptoms**: When poison is unknown the treatment is given according to symptoms. **Symptoms** — **Treatment** Pain — Morphine Dehydration — ORS saline Respiratory Failure — Oxygen therapy Cardiac depression — Cardiotonics	
6	**b)**	**Explain teratogenicity and Idiosyncrasy. (2 marks for each explanation)** **Idiosyncrasy-** The term idiosyncrasy is used to denote abnormal drug response. Idiosyncrasy covers unusual, bizarre or unexpected drug effects which cannot be explained or predicted in individual recipients. It also includes drug induced foetal abnormalities, e.g. phocomelia which developed in the offsprings of mothers exposed to thalidomide.	**4M**

Cancer of Organ	Causative drug
Vaginal adenocarcinoma	High doses of stilbestrol during pregnancy
Kidney pelvis	Analgesic induced nephropathy
Uterus	Oestrogens (long term)
Lymphoid tissue	Azathioprine ,cyclophosphamide

Teratogenicity: Certain chemical agents can affect the somatic cells of a developing embryo in such a way that defects are produced in one or another organ system. Thus, drugs or other factors producing deviations or abnormalities in the development of embryo that are compatible with pre-natal life and are observable post-natally are called teratogens and this phenomenon is called teratogenicity.

Examples of certain drugs that affect foetal development adversely are shown are-

Drug	Teratogenic effects
Thalidomide	Phocomelia, heart defects, gut atresia
Penicillamine	Loose skin
Corticosteroids	Cleft palate and congenital cataract-rare
Estrogens, diethylstilbesterol	Vaginal adenosis /cervical cancer in female foetus or structural abnormalities in the genitourinary tract in male offspring etc.

6	**c)**	**Define DIB. Give qualifications and abilities required for running DIC.** **(definition- 1 mark, any 6 qualifications and abilities, 3 marks)** **Drug Information Bulletin**: The Drug Information Centre may publish a journal or periodical or any booklet about current or amendment information on drugs, Various technical aspects and modernization of hospital practices for all the health professional which is referred as "Drug information Bulletin"	**4M**

		Qualifications and Abilities: 1. He must be able to critically evaluate drug literature. 2. He has an ability to edit the information. 3. He should be aware of sources of information for drug literature. 4. He must have good communication skills. 5. Familiarity with electronic data processing for information retrieval. 6. He should be a member of PTC. 7. Participation directly and indirectly in patient care by monitoring drug regimen. 8. He should have knowledge of research methodology. 9. Contributing to clinical pharmacy practices and education of its practitioners.	
6	**d)**	**Explain the factors influencing make or buy decision in hospital. What are the different methods of estimation of demand? (2 marks for factors influencing make or buy decision, 2 marks for methods of estimation of demand)** Following factors affect make or buy decision in hospital manufacturing: 1. Quality 2.Quantity 3.Cost and 4.Service. **1) QUALITY-** The quality of outside purchases & the quality that could be possibly achieved when manufactured within the hospital are compared. If there are no wide variations between these two, it is not an important consideration. If there is a wide variation, it becomes a crucial factor. If a better quality results from in-house manufacturing, the matter should be probed further. **2) QUANTITY-** Generally, those items whose orders are too small to purchase it from an outside supplier are manufactured within the hospital. Similarly, items which are required every day for use in hospitals, in large quantities, are generally decided to be manufacture. Break-even analysis and EOQ give the hospital the quantity of production.	**4M**

3) COST-

Here we compare the costs of buying from outside with the cost of in-house manufacturing. The cost of manufacturing the items within the hospital is estimated by drawing up a cost-sheet. Cost and quantity together considered for making the decision.

4) SERVICE:

Generally, a supply is more assured when a hospital makes an item then when it buys it. Assured supply is often a valid reason for manufacturing. Interruption in supplies may affect the major clinical services of the hospital. Unfair practices of outsider make a hospital opt for making rather than buying.

There are three methods of estimation of demand-

1) **Judgmental Method-**

This is a method which depends upon the judgment of clinical and pharmacy staff where they express an opinion based on experiences about name and quantity of product that will be required majorly in the hospital.

2) **Experience of Past -**

The experience and reviewing records of consumption of drugs in the past helps in deciding the requirement of drugs in future.

3) **Causal Method-**

In this method by assessing medical record of the hospital one can estimate the demand for specific drug based on specific criteria.

e.g. - i) Antibiotic drugs –No of patients admitted every month for whom the specific antibiotic is used.

ii) Insulin- No of diabetic patients admitted in the hospital.

iii) Demand of whole blood- Is estimated on the basis of no of patients admitted in emergency wards.

6	e)	**Define Hospital formulary? Write the guiding principles while using Hospital Formulary.** **(1 mark for Definition, 3 marks for guiding principles- any 6 points)** **Hospital formulary-** Hospital formulary is revised compilation of pharmaceutical preparations and ancillary drugs which reflects current clinical judgment of medical staff of the hospital. **Guiding principles for preparation of Hospital Formulary: (any 6 points)** The following principles will serve as guide to all those utilizing the formulary system: 1. The medical staff of the hospital shall appoint P and T Committee and outline its scope, purpose, organization and function. 2. The formulary system will be sponsored by medical staff based upon recommendations of P and T Committee. 3. The medical staff shall adopt the written policies and procedures of the formulary system. 4. Drugs should be included in the formulary by their nonproprietary names and should be prescribed by the same name. 5. Limiting the number of drugs available from pharmacy can produce substantial patient care and financial benefits. These benefits can be greatly increased by using generic equivalents. Generic equivalent- The drugs containing identical active compounds. .E.g Two brands of tetracycline. Therapeutic equivalent- The drugs differing in composition but having very similar pharmacological or therapeutic effects. E.g: two different antacid products. 6. The management of the hospital shall inform all the medical and nursing staff about the existence of the formulary system, procedures of the operation of the system and any	**4M**

		changes in those preparations. Copies of formulary must be readily available at all times. 7. Provision shall be made for the use of drugs not included in the formulary, by the medical staff. 8. The pharmacist shall be responsible for specification as to quality, quantity, and source of supply of all the drugs used in the diagnosis and treatment of patients	
6	**f)**	**What are the objectives of hospital pharmacy?(any 8 objectives – ½ mark each)** 1. To professionalize the functioning of pharmaceutical services in a hospital. 2. To ensure the availability of the right medication at the right time, in the right dose, at the minimum possible cost. 3. To teach the hospital pharmacist about the philosophy and ethics of hospital pharmacy and guide them to take responsibility of professional practice. 4. To strengthen the management skills of hospital pharmacist working as the head of the department 5. To strengthen the scientific and professional aspects of practice of hospital pharmacy such as his consulting, teaching role and research activities. 6. To utilize the resources of hospital pharmacy for the development of profession. 7. To attract the greater number of pharmacist to work in the hospital. 8. To promote the payment of good salaries to pharmacist. 9. To establish drug information services 10. To participate in research projects carried out in hospital. 11. To implement decisions of Pharmacy and Therapeutics Committee.	**4M**