Subject Title: PHARMACEUTICS-ll Subject Cod: 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.

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Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Attempt any EIGHT of the following.**	½ mark for each
	a)	**Give English meaning for following:** 1. Utenda-to be used 2. Haustus A drought 3. Jentaculum-breakfast 4. Nebula- A spray solution	
1	**b)**	**Why white paraffin is used in eye ointment** White soft paraffin is prepared by bleaching yellow soft paraffin. Some of the bleaching agent may remain sticking to the base even after careful washing. Which when used in the eye may lead to irritation.	2marks
1	**c)**	**Definition :** Prescription is a written order from a registered medical practitioners, such as dentist, veterinarian etc. to a pharmacist to compound & dispense a specific medications for the patient. **Parts of prescription:** 1. Date:. 2. Name, age, sex & address of the patient : 4. Superscription: 5. Inscription: 6. Subscription: 7. Signature : 8. Renewal instructions :	0.5 mark for definition& 1.5Mfor naming parts
1	**d)**	1 minims=0.006ml 1 ounce=28.4gm (Avoir system) or 1 ounce=31.1gm (Apothecary) 1drachm=3.6gm Or 1drachm=4gms 1 desertful spoon =8ml	½ mark for each

1	**e)**	**Give the reason:** **i) Glycerine is used as base in throat paint.** □ Glycerine is viscous in nature and adheres to the throat □ Increases contact time and prolong the action □ It is also act as soothing agent. **ii) Oily vehicles are not used in the preparation of nasal drop.** Because oily drop inhibits the movement of cilia in the nasal mucosa and if used for longer periods, may reach to lung and cause lipoid pneumonia.	**2M** 1 mark for each reason
1	**f)**	**What are the precautions taken during storage of eye drops** 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	**2M** **(0.5x4)**
1	**g)**	**What is physical incompatibility? Give one example** When two or more than two substances are combined together, a physical change takes place and an unacceptable product is formed. Physical incompatibility is usually due to immiscibility, insolubility, precipitate formation or Liquefaction of solid material. **(Consider any one e.g)** **Immiscibility**: Rx Castor oil .....15 ml Water ..... 60 ml Make an emulsion • Oil and water are immiscible with each other. they can be made miscible with water by emulsification. • In this prescription castor oil is immiscible with water. • To overcome this incompatibility an emulsifying agent is added. **Insolubility**: Liquid preparation containing indiffusible solids such as chalk, aromatic chalk powder, aspirin etc, a suspending agent may be incorporated so as to increase the thickness 0f preparation which helps in uniform distribution of solid and solid are suspended for long time after shaking. Rx Phenacetin …….3 gm Caffeine ……1 gm Orange syrup ….12 ml Water upto ….. 90 ml Make a mixture	**2M** 1 mark definati on1mar k any one e.g

		Precipitation: A drug solution can be precipitated if solvent is added in which they are insoluble, or when tincture are present and it is diluted with aqueous solution resin tend to get precipitate out, which may get stick to the side of the bottle, therefore suspending agent like tragacanth powder or tragacanth mucilage has to be added. Rx Tincture benzoin ……5 ml Glycerine ……..15 ml Rose water ……q.s …100ml Make a mixture **Liquefaction**: 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. Rx Menthol ---------- 5g. Camphor ---------- 5g. Ammonium chloride ---------- 30g. Light magnesium carbonate ---- 60g. Send five powders The combination forms eutectic mixture.	
1	**h)**	**Define:** **i) Total parenteral 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. **ii) Dialysis:** Dialysis is a process by which the substances are separated from one another due to differences in diffusibility through membranes the fluids used in process is known as dialysis fluid. In case of renal failure transplantation of kidney or certain cases of poisoning dialysis is needed to save patents life.	**2M** 1mark for each
1	**i)**	**The qualities of Ideal suspension.** 1. It should settle slowly 2. It should be readily re-dispersed on gentle shaking of the container. 3. It should pour readily and evenly from its container. 4. It should be chemically inert. 5. The suspended particle should not form a cake. 6. It should be free from large particles which spoils its appearance& give gritty taste to oral preparation & also cause to irritation to sensitive tissues when applied externally	**2M** ½ mark for each point

1 j) Give four point of differences between paste and ointment — **2M** ½ mark for each point

Sr. No.	Paste	Ointment
1	They contain high concentration of medicament.	They contain low concentrate of insoluble medicament.
2	They are stiffer, less greasy in consistency	They are soft & greasy in consistency
3	They are more absorptive	They are less absorptive.
4	They resist to flow with increase in force of application.	They flow more easily with increase In force of application.
5	The paste adheres to the skin.	They do not adhere to the skin.
6	They are used mainly as Antiseptic, Protective.	They are mainly used as protective Emollient.
7	Zinc oxide paste BPC	Ex. Sulphur ointment

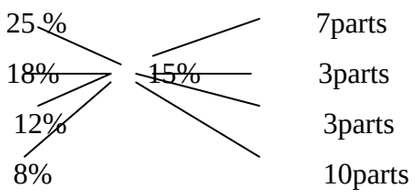
1 k) Describe two methods used to calculate the dose of drug in children depending on age. — **2M** 1mark for each

1. **Young's formula:**
   Dose of child = Age in years /Age in years +12 **X** Adult dose
2. **Dilling's formula:**
   Dose of child = Age in years/20 **X** adult dose

1 l) Write four advantages of suppositories — **2M** 1/2mark for each advantage

Advantages of suppositories

- These can be easily administered to children, old persons & to unconscious patients.
- These are inserted into body cavity to produce local effect of the medicament incorporated in the base.
- These are inserted into the rectum to exert a direct & rapid action on the rectum.
- These are inserted into the rectum to promote evacuation of the bowel
- .Suppositories are unit dosage form of drugs.
- These are convenient mode of administration of drugs which irritate gastro-intestinal tract, causes vomiting & destroyed in the acidic pH of gastric juice of stomach.
- Drugs in suppositories are slowly absorbed giving sustained action.
- They are also been used for prolongation of drug action

2		**Attempt any FOUR of the following**	**12M**
2	**a)**	**What volume of alcohol is required to prepare 500ml of15% alcohol using, 25%,18%,12%and8% alcohols**  Total =23parts 7x500/23 =152.17ml 3x500/3 =65.21ml 3x500/3 =65.21ml 10x500/23 =217.39ml Answer: 25% -152.17ml 18% -65.21ml 12% -65.21ml 8% -217.39ml	**3M**
2	**b)**	**Explain the term 'Aseptic technique'** **Definition:** The method which is used to prevent the access of microorganism during the preparation of parenteral product and their testing are called "Aseptic Technique" • The entry of the personnel into the aseptic should be through air lock. To maintain sterility • Special trained person should be selected to work in sterile area • They are required to wear sterile clothes and should be subjected to regular health check up • They should not be the carrier of infectious disease • Ceiling walls and floor of aseptic area sealed and well painted • Stainless steel counters should be fitted on the wall • Mechanical equipment should be housed in stainless steel cabinet • The air of aseptic area should be free from fibre, dust and micro organism • The work has to be carried out under HEPA filter • The air has to be supplied under positive pressure • Ultra violet lamps are fitted in the area to maintain sterility	**3M** Definati on1mar k 2 marks for techniq ue
2	**c)**	**Define the term prescription and list various errors seen in dispensing 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. **Common errors in Prescription.**	**3M (1/2 mark for definiti**

		Abbreviations: i. Problem in understanding. ii. Wrong interpretation by pharmacist. iii. May guessed by pharmacist iv. Ex. To dispense Achromycin for" Achro" may pharmacist dispense Achrostatin. 2. Name of drug. Certain drugs have sound like other. i. Ex. Digitoxin&digoxin., Prednisone & prednisolone, Indocin &Lincocin. 3. Strength of Preparation. i. There are various strength of preparations are available for same drug. ii. The strength of preparation should be mention in prescription otherwise error may occur in dispensing. iii. Ex. Paracetamol tablet is written in prescription without strength, then how pharmacist will dispense it. 4. Dosage form of drug prescribed. i. Same drug available in different dosage form so it is very essential to mention the dosage form. ii. Ex. Tablet, capsule, suppository, liquid etc. 5. Dose. i. Dose error may takes place with paediatric patients. ii. Pharmacist must discuss the dose with physician. 6. Instruction for patient. i. Incomplete or inappropriate instructions cause error in prescription. ii. Ex. Two time a day or three time a day. iii. Ex. Take with milk, take after meal etc. 7. Incompatibility. i. It is very important to check the incompatibility by pharmacist in prescription to avoid any therapeutic incompatibility. ii. Different drugs prescribed for same patients may cause synergism or antagonism. iii. Ex. Acetylcholine and Atropine produce antagonism.	**on 2.5 marks for errors**
2	**d)**	**Define dentifrices and explain formulation of it** 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 **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	**3M** ½ mark for definati on 1/2 mark for each

		damage the tooth structure. **1. Detergents:** • They contain a suitable detergent or soap. • Soap removes the debris from surface of tooth by the mechanism of emulsification **2. Humectants:** • Humectants are added to prevent the drying of preparation. • Ex. Glycerin, propylene glycol, etc. **3. 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. **4. Colours:** Colour is added to improve appearance of preparation to make it attractive. • Ex. Coal tar dyes, **5. Flavours:** • Flavours are added to improve the taste of the formulation. • Ex. Peppermint oil, cinnamon oil, etc.	ingredient
2	**e)**	**Explain 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. 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. 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.	**3M**
2	**f)**	**What is indiffusible mixture; Give composition of compound tragacanth powder, mention the example of indiffusible mixture.** Indiffusible mixture are those mixture which contain indiffusible solids, solids are not soluble in water they do not remain suspended for long time after shaking therefore to maintain their stability suspending agent are added, the suspending agent used is compound tragacanth powder or tragacanth mucilage Composition of compound tragacanth powder Tragacanth 15% Starch 20% Sucrose 45% Acacia 20%	**3M (1+1+1)**

		(Any example of formulation of indiffusible mixture can be consider) Rx Acetyl salicylic acid ……..1.5 gm Oxyphenbutazone ……..0.25 gm Simple syrup ……15 ml Water ….upto …….90 ml	
3		**Attempt any FOUR of the following.**	**12M**
	a)	**Write a short note on formulation and method of preparation of 'Effervescent granules'.**	**3M**
		Formulation : These are solid dosage form of medicament, meant for internal use. • These are composed of **citric acid, tartaric acid & sodium bicarbonate**. • In presence of water, acid reacts with alkali to release carbon dioxide. • Carbon dioxide helps to mask the bitter and saline taste of the drugs • Carbon dioxide stimulates the flow of gastric juices and therefore helps in absorption of drugs • Sometimes saccharin or sucrose may be added as **sweetening agent** • **Colour** can be imparted to enhance the appearance	**(1.5M)**
		Preparation: **Method of preparation:** **1) Heat method:** A large porcelain dish is placed on a water bath, with as much of the dish as possible exposed to the water or steam. The dish must be hot to ensure rapid liberation of water of crystallization from citric acid. If heating of the dish is delayed, the powder which is added to it, will heat up slowly and the liberated water of crystallisation will go on evaporating simultaneously. As a result sufficient water will not be available to make coherent mass. 3) Generally heating takes 1 to 5 minutes. The damp mass is then passed through sieve dried in an oven temperature not exceeding 60^0C. **2) Wet method:** i) The mixed ingredients are moistened with non-aqueous vehicle(e.g. alcohol, propylene glycol) to prepare a coherent mass. ii) It is then passed through a sieve no.8 & dried in an oven at temperature not exceeding 60^0C. iii)The dried granules then passed through the sieve to break the lumps which may be formed during drying. iv) Then packed in air tight containers.	**(any one method 1.5M)**
3	**b)**	**Define 'Incompatibility'. What is adjusted type of Incompatibility, explain with example.** **Definition:**	**3M (1+1+1)**

Incompatibility occurs as a result of two or more antagonistic substances & an undesirable product is formed which may affect the safety, efficacy & appearance of the pharmaceutical preparation.

Adjusted type of 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 acid present in caffeine citrate reacts with sodium salicylate to liberate salicylic acid which get precipitated as indiffusible solid . 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.

3 c) Differentiate between flocculated and deflocculated suspension. **3M (1/2 marks for each point)**

Sr. no.	Flocculated suspension	Deflocculated suspension
1	Particles form loose aggregates and form a network like structure.	Particles exist as separate entities.
2	The rate of sedimentation is high	The rate of sedimentation is slow
3	Sediment is rapidly formed	Sediment is slowly formed
4	Sediment is easy to redisperse	Sediment is difficult to redisperse
5	Sediment is loosely packed and does not form a hard cake	Sediment is very closely packed and a hard cake is formed
6	Supernatant liquid is clear	Supernatant liquid is not clear
7	The floccules stick to the sides of bottle.	The floccules do not stick to the sides of bottle.
8	Suspension is not pleasing in appearance	Suspension is pleasing in appearance.
9.	Ex. Bismuth carbonate mixture	Ex. Precipitated chalk mixture

3 d) Define mixture. Describe method of dispensing mixture containing diffusible solids. **3M (1+2)**

Definition:

Mixture is a liquid dosage form containing medicament or medicaments are dissolved, disperse and suspended in the given vehicle.

Method of dispensing:

- Finely powder the drug in a mortar. Add any soluble drug and mix.

		• Measure the ¾ th of the vehicle. Make a smooth cream by using a portion of the vehicle and then add the remaining portion of the measured vehicle. • Transfer the content of the mortar into a measure. Rinse the mortar with a little of vehicle and transfer it into a measure. • Add any liquid ingredient. • If any foreign particle are present strain through muslin cloth • Add more of vehicle to produce the required volume. • Transfer the mixture to the dispensing bottle, cork, label and dispense. • Apply the secondary label "Shake the bottle well before use".	
3	**e)**	**What is 'Cracking of emulsion'? Describe any four factors responsible for cracking of emulsion** **'Cracking of emulsion':** Cracking means the separation of two layers of dispersed phase and continuous phase, due to the coalescence of dispersed phase globules which are difficult to redisperse by shaking **Factors responsible for cracking of emulsion.** The following factors results in the cracking of emulsion. i) Decomposition of the emulsifying agent ii) Addition of a solvent which dissolves both the phases iii) High temperature and change in pH. iv) Addition of opposite types of emulgents v) Growth of micro – organism vi) 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 &viceversa may leads to cracking. **Growth of microorganism:** Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking. **Extensive creaming**.	**3M (Definition 1M, 2M for any four factors)**

		A creamy emulsion is more liable to crack than the homogenous emulsion. So it is necessary to take steps to retard creaming as far as possible.	
3	**f)**	**Explain the formulation of parenteral preparation.** **1) Vehicles** **2) Adjuvants** ➢ **Solubilising agent** ➢ **Stabilizers:** ➢ **Buffering agents** ➢ **Antibacterial agents:** ➢ **Chelating agents:** ➢ **Suspending,** ➢ **Emulsifying and wetting agents:** ➢ **Tonicity factors** **1) Vehicles :** There are two types of vehicle which are commonly used for preparation of parental **i) Aqueous vehicle** – Water for injection is used which is sterile water free from volatile and non volatile impurities and also from pyrogens **ii)Non aqueous vehicle** –Commonly used non aqueous vehicle are oils and alcohols Fixed oil such as arachis oil, cotton seed oil, almond oil and sesame oil are used as vehicle Dimercaprol injection where arachis oil is used as vehicle Ethyl alcohol is used as vehicle for preparation of hydrocortisone injection **2)Adjuvants:** These substances are added to increase the stability or quality of the product. The following adjuvants are commonly used in preparing stable parenteral preparations **Solubilising agents:** These are used to increase the solubility of drugs which are slightly soluble in water. The solubility of drug is increased by using surface active agent like tweens and polysorbates by using co-solvents. **Stabilizers:** The drugs in the form of solutions are more liable to deteriorate due to oxidation and hydrolysis. The stabilizers are added in the formulation to prevent this. The oxidation can be prevented by adding a suitable antioxidant such as thiourea, ascorbic acid or the product is sealed in an atmosphere of nitrogen. Hydrolysis can be prevented by using a non-aqueous vehicle or by adjusting pH. **Buffering agents**- The degradation of the preparation which is due to change in pH can be prevented by adding a suitable buffer to maintain the desired pH. For e.g.Citric acid and sodium citrate, acetic acid and sodium acetate. **Preservatives.** These substances are added in adequate quantity to prevent the growth of microorganism	**3M**

		during storage. **Chelating agents:** Chelating agents such as EDTA and its salts, sodium or potassium salts of citric acid are added in the formulation, to chelate the metallic ions present in formulation. **Suspending,Emulsifying and wetting agents:** The suspending agents are used to improve the viscosity and to suspend the particles for a long time. Methyl cellulose, carboxymethyl cellulose, gelatin and acacia are commo0nly used. Emulsifying agents are used in sterile emulsion.eg-Lecithin. The wetting agents are used to reduce the interfacial tension between the solid particles and the liquid so as to prevent formation of lumps. **Tonicity factors:** Parenteral preparation should be isotonic with blood plasma or other body fluids. The isotonicity of solution may be adjusted by adding Sodium chloride, dextrose etc.	
4		**Attempt any FOUR of the following**	**12M**
4	**a)**	**Define 'Gargles' & 'Mouth Wash'. What are the uses of douches? Discuss with example.** **Gargle:** Gargles are aqueous solutions to prevent & treat throat infections & are used to relieve soreness in mild throat infections. **Mouthwash:** Mouth washes are aqueous solutions with pleasant taste and odour used to make clean& deodorize buccal cavity. **Uses of Douches:** 1) Cleaning agent's e.g. Isotonic sodium chloride solution. 2) Antiseptics: e.g. mercuric chloride (0.001%), potassium permanganate (0.025%), lacticacid (0.5 to 2%),Chlorohexidine (0.002%) 3) Astringent e.g.alum(1%),	**3M (1+1+1)**
4	**b)**	**What are 'Syrups'? Give different methods of preparation of syrup.** **Syrup:** Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar. **Methods of preparation of syrup.** 1. Simple solution method 2. By process of extraction. 3. By Chemical interaction **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 required weight. 2) By process of **extraction** e.g tolu syrup Add boiling purified water to tolu balsam, cover	**3M (Definition1M and2 M for any 2methods)**

		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 flavouring agent than adjust the volume with purified water.	
4	**c)**	**Calculate the displacement value of zinc oxide from following data** i) Capacity of mould = 15 grain ii) Wt. of 6 unmedicated suppositories = 90 grain iii) Wt. of six suppositories containing 40% zinc oxide = 132 grain. **Note: student may use grain value as 65 mg and may calculate by converting the grain value both are agreeable)** Weight of 6 unmedicated suppositories = 90 grain x 64.8 mg = 5.832 g Weight of 6 suppositories containing 40% of zinc oxide = 132 grain = 132 x 64.8 mg = 8.553 gm Amount of base present in 6 suppositories = 60/100 x 8.553 = 5.1318 g Amount of medicament present in 6 suppositories = 40 /100 x 8.553 =3.4212g Amount of base displaced by 3.4212 g of medicament = 5.832- 5.1318 = 0.7002 g **Displacement value = Amount of Medicament / Amount of base without drug – actual amount base** 3.4212 / 0.7002 = 4.886 = Approx.5	**3M**
4	**d)**	**What is the principle behind sterility testing? Describe Membrane filtration method for sterility testing.** **Principle:** Basic principle of sterility test is that if bacteria or fungi are placed in a medium which provides the nutritive material and water and kept at favourable temperature the organism will grow and their presence can be indicated by the turbidity in the clear medium.	**3M** **1M**

Method: Selection of sample size: **1.5M**

Number of items in batch	Minimum number of items recommended to be tested
Injectable preparation not more than 100 containers	10% or 4 containers whichever is the greater
More than 500 containers	2% or 20 containers whichever is the less

Quantity in each container	Minimum quantity to be used
Less than 1ml	Total contents of a container
1ml or more but <4ml	½ content of a container
4ml or more but less than 20ml	2ml
20 ml or more but <100ml	10% of content f the container Unless otherwise specified in monograph
100ml or more	NLT ½ the content of a Container unless otherwise specified in the monograph

		Membrane filtration method This method is preferred in case of an oily preparation, an ointment that put into solution, non-bacteriostatic solid not readily soluble in culture medium, a soluble powder or a liquid that possesses bacteriostatic and fungistatic properties. The method involves the filtration of the sample under test through a membrane filter having normal porosity of 0.45µ and a diameter of approximately 47 mm. After the filtration the membrane is removed aseptically from the metallic holder and divided into two halves. The first half is transferred into 100 ml of culture media meant for fungi and incubated at 20^0 to 25^0 C for not less than seven days. The other half is transferred into 100 ml of fluid thioglycolate medium and incubated at 30^0 to 35^0 C not less than 7 days .Observe the growth of media. **Result & interpretation:** ▪ No evidence of growth – passes the test for sterility. ▪ Evidence of growth – Re-testing	**(0.5 M)**
4	**e)**	**Define 'Pyrogen'. Name the different methods of Pyrogen testing. Describe Rabbits method.** **Definition:** Pyrogens are by-product of bacterial metabolism, pyrogens are polysaccharides, thermostable, soluble in water, unaffected by bactericide and can pass through bacterial proof filters **Different methods of Pyrogen testing** • Sham Test • LAL test **Principle:** The test involves the measurement of the rise in the body temperature of rabbit following i.v. injection of a sterile solution of a substance being examined. Rabbits are used to perform this test because they are more sensitive to pyrogens **Method** **Method of testing :** **Sham Test**: Pyrogen testing done on rabbit: The test involves the measurement of rise in body temp of rabbit following intravenous injection of a sterile solution of a substance being examined. Three healthy rabbits, each weighing not less than 1.5 kg are selected. They are kept on balanced diet.& are not showing any loss in body weight .The solution under test is injected slowly through ear vein in a volume of 0.5 to 10 ml/body weight. Record the temperature of each rabbit in an interval of 30 mins for three hrs. after the injection. The difference between initial temp & the maximum recorded as response. If no rabbit shows an individual rise in temperature of 0.6 °C or more above its respective control temperature, and if the sum of the 3 temperature rises does not exceed 1.4 °C, the tested material meets the requirements for the absence of pyrogen. If 1 or 2 rabbits show a	**3M** **(1M)** **(0.5M)** **(1.5M)**

		temperature rise of 0.6 °C or more, or if the sum of the temperature rises exceeds 1.4 °C, continue the test using 5 other rabbits If not more than 3 of the 8 rabbits show individual rises in temperature of 0.6 °C or and sum of group maximum temp rises doesn't exceed 3.7°c.	
4	**f)**	**List different test for identification of an emulsion & explain any one.** **List different test for identification:** 1) Dilution Test - 2) Dye Test- 3) Conductivity Test- 4)Fluorescence Test: 5)Cobalt Chloride Test: **Explanation of any one.** **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 **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 **3) Fluorescence Test**: ➢ If an emulsion on exposure to ultra-violet radiations shows continuous fluorescence under UV light, 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.	**3M** **(1M)** **(2M any method)**
5		**Attempt any FOUR of the following.**	**12M**
5	**a**	**Define** **(i)Nasal drops** Nasal drops are aqueous solutions for instilling into nose with dropper torelieve	**3M** **(1+1+1)**

congestion ,inflammation & to combat infection

(ii)Inhalation:

These are liquid preparation consisting of volatile substances and are use to relieve congestion & inflammation of respiratory tract.

(iii)Ear Drops:

Ear drops are solution instilled into the ear with a dropper for cleaning of ear, softening of wax and for treating mild infection

5 b) Differentiate between liniment and lotion. **3M (0.5 for each points)**

Liniments	Lotion
1. They are used for counter irritant, rubefacient, soothing or stimulating purpose.	1. They are used for topical effect such as local cooling, soothing protective & emollient effect.
2.Applied with friction	2. Applied without friction.
3.Vehicle is mostly oily or alcoholic	3. Vehicle is mostly aqueous.
4. These are used for application to the unbroken skin.	4. Lotions can be applied on broken skin.
5.Applied directly	5. Applied with cotton gauze
6. alcohol is added to improve penetration power	6. Alcohol is added for cooling action.
7.These are semi-liquid preparations	7.These are liquid preparation
8.Turpentine liniment	8 .Sulphur lotion.

5 c) Define parenteral. Give essential qualities of parenteral products .give the steps involved in manufacturing of parenteral products. **3M**

Definition of parenteral products **1M**

Parenteral products are considered to be the sterile solutions, suspension or emulsions that are administrated by hypodermic injection either in the form in which they are supplied or after the addition of suitable solvent or suspending agent. **1M**

General requirements for parenteral dosage forms.

i) Free from foreign particles: It should be free from foreign particles, fibres and filaments.

ii) Sterility: It should be free from all type of microorganisms.

iii) Isotonicity: The preparation should be isotonic with blood plasma and body fluids.

iv) Free from pyrogen: It should be free from pyrogens. **1M**

v) Chemical purity: It should be free from chemical impurities or it should be within certain limit (as specified by the pharmacopeia).

vi) Stability: It should be physically and chemically stable.

vii) Specific gravity: The specific gravity of preparation if it is meant for intra spinal

		route should be same as spinal fluid. **Enlist various steps involved in processing of parenteral products.** • Cleaning of containers, closures and equipment. • Collection of materials. • Preparation of parenteral products. • Filtration. • Filling the preparation in final containers. • Sterilisation. • Evaluation of parenteral preparations. • Labelling and packaging.	
5	**d)**	**What is Dusting powder, Give classification of it mention the formulation ingredients of it.** Dusting powders are the powders meant for external application to the skin and are generally applied in a fine state of sub division to avoid local irritation. The dusting powders are used for antiseptic, astringent, absorbent, antiperspirant and antipuritic action. **Dusting powders classification:** • Medical Dusting powders: Medical dusting powders are used mainly for superficial skin conditions, whereas. Medical dusting powders must be free from pathogenic micro organisms. • Surgical Dusting powders. Surgical dusting powders are used in body cavities and also on major wounds as a result of burns and umbilical cords of infants surgical dusting powders must be sterilized before their use. **Formulation ingredients:** Dusting powders are generally prepared by mixing of two or more ingredients; such as starch, talc, kaolin as they are chemically inert	**3M** **1M** **1M** **1M**
5	**e)**	**Point out incompatibility (if any) and describe suitable method for its dispense.** **Rx** **Quinine sulphate ……1.5 gm** **Dilute sulphuric acid …..4ml** **Potassium iodide …….8gm** **Water upto ……200 ml** **Prepare mixture, send ……100 ml** 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, now free iodine, hydroiodic acid and quinine sulphate together form iodosulphide of quinine called “herapathite” It form olive green scales after three days stay. **Correction:**	**3M**

		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.	
5	**f)**	**Define 'Shampoo', and discuss the formulation of it.** Shampoos are used as a preparation containing surface active agents which are used to remove dirt ,grease from the hair without affecting natural gloss of the hair and help to keep hair fragrant ,lustrous ,soft and manageable. **Formulation of Shampoo** **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, Glycerine, Propylene Glycol **2. Thickening Agents:-** Use to increase the viscosity of shampoo & provide desired consistency. e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate **3. Solubilising 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 Paraben, Propyl Paraben	**3M** **1M** **2M**
6		**Attempt any FOUR of the following**	**16M**
6	**a)**	**What are cachets? Mention its advantages and disadvantages.** **Definition**: - Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used 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 made 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	**4M** **(1M)** **(1.5M)** **(1.5M**

6	**b)**	**Explain methods of evaluation of suspension.** **Method of evaluation:** • Sedimentation Method: • Rheological Method: • Electrokinetic's Method: • Micrometrics Method: **Sedimentation Method:** • Sedimentation volume is the most important parameter in the evaluation of the stability of suspension • It is determined by keeping a measured volume of the suspension in a graduated cylinder in an undisturbed position for a definite period of time and noted the ultimate height (Hu) of the sediment and initial height of the total suspension. • The sedimentation volume F is the ratio of the ultimate height and initial height .(Hu/Ho) • The sedimentation volume plotted against time, the graph indicates the sedimentation pattern of suspension on storage. • A stable suspension shows a horizontal or less steep curve. • The evaluation of redispersibility can also be determined by shaking the suspension and again find out the sedimentation volume (Hu/Ho). **Rheological Method:** The viscosity of the suspension is studied at different time intervals by using a good quality of viscometer. It provide useful information regarding stability of suspension. **Electrokinetic's Method:** The determination of surface electric charge or zeta potential is helpful to find out the stability of suspension. Certain zeta potentials produce more stable suspensions because of controlled flocculation. Zeta potential can be calculated from the migration velocity of the particles measured by the electrophoretic method. **Micrometrics Method:** The stability of suspension depends on the particle size of the disperse phase. The size of the particle in a suspension may grow and may ultimately leads to the formation of lumps or cracking. So any change in the particle size with reference to time will provide useful information regarding the stability of a suspension. A change in particle size distribution and crystal habit may be studied by microscopy and coulter counter method.	**4M** **(1M for each method)**
6	**c)**	**Name the various facial cosmetics. Explain different eye makeup preparation.** **Facial cosmetics:** a) Face powder	**4M** **0.5M**

b) Rouge
c) Eye makeup
d)Lipstick
e)Creams

0.5M

EYE MAKEUP

- MASCARA
- EYE SHADOW
- EYEBROW PENCIL
- EYE LINER

1 x3M

1)MASCARA : Black pigmented preparation for application to eyelashes or eyebrow to beautify the eyes .

- It darkens the eyelashes & improves brightness & expressiveness of eyes.
- Applied with brush.

It is available in 3 forms.

- Cake mascara: prepared by melting together waxy material , adding the colours . E.g. Lamp black.
- Cream mascara: prepared by mixing the pigments in vanishing cream base.
- Liquid mascara : It is alcoholic solution of resin in which carbon black is suspended

2)EYE SHADOW

- Applied to eyelids in order to produce an attractive moist looking background to the eyes.
- It is available in variety of shades like pink 'yellow , green & brown.
- Available in following forms:
- EYE SHADOW CREAM: Prepared by mixing selected colours in the wax bases or with petroleum.
- EYE SHADOW STICK: contains high proportion of waxes .eg. Carnauba wax.
- LIQUID EYE SHADOW : are liquid suspension or a liquid dispersion of pigments.

3)Eyebrow pencil-

Eyebrow pencil is used to accentuate line of eyebrow or to modify their outline after packing.

These are available in brown or black colour. The brown eyebrow pencil contains black iron oxide. The eyebrow pencil contains a high proportion of waxes to make them hard, so that they can be moulded as a thin stick sharpened to a point.

4) Eyeliner

It is used to increase expressiveness of eyes available in liquid, cake & pencil form. Brown colour is considered a good colour for daytime

6	**d)**	**Find the amount of sodium chloride required to make 50 ml of isotonic solution containing solution containing 0.5% ephedrine HCl and chlorobutol** **Note : F.P. of 1% solution of chlorobutal = 0.138^0 c & F.P.of 1% solution of ephedrine HCl = -0.165^{0}c)** (formula=0.5 marks, calculation up to 100 ml qty 1.5 mark and for 50 ml 1 mark) As the concentration of ephedrine hydrochloride in the preparation is 0.5% w/v, the depression in freezing point of ephedrine hydrochloride = 0.165 X 0.5 = 0.0825^{o}C As the concentration of chlorobutol in the preparation is 0.5% w/v, the depression in freezing point of chlorobutol = 0.138 X 0.5 = 0.069^o C Therefore, total depression in freezing point of both the substance = 0.0825 + 0.69 = 0.1515 Percentage w/v of sodium chloride required = $\frac{0.52 - 0.1515}{0.576}$ = 0.644% w/v Weight of sodium chloride required to make 100 ml of solution = 0.644 g Weight of sodium chloride required to make 50 ml of solution = 0.322 g	**4M**
6	**e**	**Classify emulsifying agents with one example of each class. Describe dry gum method for preparation of emulsion.** **Classification of Emulsifying Agent:** Emulsifying Agents can be divides as follows: 1. Natural: a. Vegetable source: eg. Gum acacia, Tragacanth, agar, pectin, starch, iris moss (chondrus) b. Animal Source: wool fat, egg yolk, gelatine. 2. Semi-Synthetic; Methyl cellulose, Sodium carboxy methyl cellulose 3. Synthetic: a. Anionic: sodium luryl sulphate, b. Cationic: cetrimide, Benzalkoniumchloride, etc. c. Non ionic: glyceryl esters etc. 4. Inorganic: Milk of magnesia, magnesium oxide ,Magnesiumtrisilicate, Magnesium aluminum silicate, Bentonite . 5. Alcoholes -CarbowaxesLecithins Cholesterols **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 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.	**4M (Classification 2M, Method 2M)**

		4. Add more of water to produce required volume.	
6	**f**	**Define 'Jellies. Give its type. Write disadvantages of jellies.**	**4M**
		Jellies are translucent or translucent non-greasy, semisolid preparations meant for external application to the skin or mucous membrane.	**1M** **2M**
		Types of Jellies 1) Medicated jellies 2) Lubricating jellies 3) Miscellaneous jellies; a)Patch testing b)Electro-cardiography	
		Medicated jellies used on mucous membrane and skin for their spermicidal, local anaesthetics, and antiseptic properties. These jellies contain sufficient water which evaporates & provide a local cooling effect. For example, ephedrine sulphate jelly as a vasoconstrictor &Proxamine hydrochloride as local anaesthetic	
		• **Lubricating jellies** • These jellies are used for lubrication of diagnostic equipment such as, surgical gloves, cystoscopes, fingerstalls, catheters, rectal thermometers etc. • These jellies should be sterile	
		Miscellaneous jellies **Patch testing** : These jellies are used as a vehicle for allergens which are applied on the skin to check the sensitivity. On drying, the residual film is formed which helps to keep the patches separate and avoid confusing results. **Electro-cardiography**:: The jelly is applied on the electrode to reduce the electrical resistance between the patient's skin and the electrode. The jelly contains sodium chloride, pumice powder and glycerine.	
		Disadvantages of jellies • Due to hygroscopic nature it will loose its consistency. • Preservation problem due to gelling agent. • Fluctuation in temperature will effect its consistency.	**1M**