WINTER– 16 EXAMINATION

Model Answer 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 themodel answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may tryto assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given moreImportance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in thefigure. 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 constantvalues 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
01		**Attempt any FIVE of the following.**	**10**
	a)	**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.	**(1M)** **(1M)**
	b)	**What is phase inversion? How it is prevented?** **Phase inversion:** Phase inversion means change in the type of emulsion i.e. o/w to w/o or vice versa. **It is prevented by** • Keeping the concentration of disperse phase between 30 % to 60% • Storing the emulsion in a cool place • By using a proper emulsifying agent in adequate concentration.	**(1M)** **(1M)**
	c)	**What are labelling conditions for eye drop and emulsion** **Eye drop** : 'For External Use Only', 'If irritation persists discontinue the use', 'Never use eye drops that have changed colour', 'Never touch the dropper surface'. **Emulsion** : 'Shake well before use',Do not Freeze	**(1M for each)**
	d)	**Translate the Latin term in English:** i) Omni nocte : Every night ii) Jentaculum : Breakfast iii) Doloreurgente : When the pain is severe iv) Mitte : Send	**(0.5M for each)**

Q. No.	Sub Q. N.	Answer	Marking Scheme
	e)	**Define :** **i) Depilatories :** It is preparation designed for removal hair from face, legs & hands by chemical method without causing any injury to skin. **ii) Cachets :** Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used to enclose nauseous or disagreeable Powders. Cachets are also known as wafer capsules.	**(1M for each)**
	f)	**What does symbol Rx signify?** Rx is a symbol represented "Superscription" which is written before writing the prescription. This symbol was considered to be originated from the sign of Jupiter, God of healing .It is an abbreviation of the Latin word recipe, meaning" You take"	**(2marks)**
	g)	**Explain the displacement value.** Displacement value is defined as " The quantity of the drug which displaces one part of the base" **Significance**–The volume of a suppository from a particular mould is uniform but its weight will vary because the densities of the medicaments usually differ from the density of the base with which the mould was 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 is consider.	**(1M)** **(1M)**
2		**Attempt any FOUR of the following**	**14**
	a)	**Describe modern methods of prescribing**. • 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.	**(1.5M)**

		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 prescribingthe 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 available in the stock.	**(1M)** **(1M)**
	b)	**Classify powders. Write a short note on dusting powders**. **Classifications:-** 1) Bulk powder for internal use. 2) Bulk powder for external use a) Dusting powder b) Insufflations c) Snuffs d) Dentifrices. 3) Simple powder & compound powder for internal use 4) Powder enclosed in cachets and capsules a)Dry seal cachets b)Wet seal cachets 5) Compressed powder	**(0.5 X 3 = 1.5M)**
		Dusting powder 1) These are meant for external application to skin and are generally applied in very fine state of subdivision to avoid local irritation, hence pass through sieve no.80 They are two types: i) Medical ii) Surgical i) Medical : These are used for superficial skin conditions .These powders must be free from	**(2M)**

		pathogenic microorganisms. ii) Surgical : These are used in body cavities and also on major wounds as result of burns and umbilical cords of infants. These powders must be sterilised before use. 2) Dusting powders generally prepared by mixing two or more ingredients one of which must be starch, talc, or kaolin. Talc and kaolin commonly used as they are chemically inert. 3)These must be sterilised by dry heat method (160^0 for 2 hours) 4) Dusting powders are dispensed in sifter-top containers or aerosol containers. 5) Dusting powders mainly used for their antiseptic, astringent, absorbent, antiperspirant and antipruritic action.	
	c)	**What are nasal drops? Explain formulation of nasal drops.** These are aqueous solutions of drops that are instilled into the nose with dropper. **Formulation of nasal drops.** • **Isotonicity contriuter:** 0.9% sodium chloride. • **Buffer**: It should have neutral pH, phosphate buffer, etc • **Viscosity Builder/Thicking agents:** use of 0.5% methyl cellulose • **Vehicle**: Use phosphate buffer of pH 6.5 as vehicle. **OR**	**(1M)** **(2.5 M)**
	c)	**Write a short note on throat paints.** Throat paints are viscous liquid preparations used for mouth and throat infections. Glycerin is commonly used as a base because being viscous; it adheres to mucous membrane for long period. Commonly used throat paints are boroglycerin, phenol glycerin, tannic acid glycerin, compound iodine paint (Mandl's paint) **Containers**-It should be dispensed in airtight, coloured fluted bottle .Glass stoppers are generally used inn such bottles. **Labelling**-"For External use only" **Storage**-It should be stored in airtight containers in cool place. **Example Prepare** and dispense 50 ml of iodine paint compound (Mandl's paint) B.P.C. Iodine paint compound(Mandl's paint) B.P.C. Potassium iodide ……25.0 g	**(1.5M)** **(02M)**

		Iodine ……12.5 g Alcohol 90% ……40.0 ml Water ……..25.0 ml Peppermint oil ……..……4.0 ml Glycerine to produce ……..……1000 ml **Method:** Dissolve the potassium iodide in water. Add the iodine and stir until completely dissolved. Dissolve peppermint oil in alcohol 90% in a small container and transfer it into iodine solution. Mix well. Add glycerine and mix thoroughly. Transfer the paint into a measure. Add more of glycerine to make the required volume. Transfer the preparation into a well closed container, label and dispense.	
	d)	**Give various additives in formulation of suspensions**. Following additives used in formulation of suspensions**.** **1. Flocculating agents**: In suspensions, the solid particles are well dispersed in dispersion medium.The dispersion can be improved by adding a surfactant or protective colloid which acts as a flocculating agent.The flocculating agent act by reducing the surface tension and thereby improving dispersion of solids and minimise flocculation. eg.SLS, tweens, spans and carbowaxes. **2. Thickening agents:**These are hydrophilic colloids which increases the viscosity of the continuous phase,so that solid particles remain suspended in it for long time to measure a uniform accurate dose. Thickening agents are classified as • Polysaccharides • Inorganic agents • Synthetic compounds. **I)Polysaccharides-** a) Natural Polysaccharides 1. Gum acacia-It is a good protective colloid and suspending agent.It is useful in mixture containing resinous tincture. 2. Tragacanth-It is used as compound tragacanth powder or tragacanth mucilage to suspend heavy indiffusible substances. 3. Starch-Starch is used with other suspending agents because of high viscosity of its mucilage.	**(3.5M)**

		4. Sodium alginate-It forms a viscous solution when dissolved in water.Its 1% solution has same suspending power as that of tragacanth mucilage. b) Semisynthetic: 1. Methyl cellulose-It is generally used in the concentration of 0.5 to 2 % as thickening agent both in external and internal preparations. 2. Sodiumcarboxymethyl cellulose-It is used in the concentration of 0.25 to 1 % as thickening agent in oral, external and Parenteral preparations. 3.Microcrystalline cellulose-It is prepared from wood cellulose by acid hydrolysis II) Inorganic agents 1. Clay-Bentonite and aluminium magnesium silicate is very commonly used as thickening agents. 2. Aluminium hydroxide-It is used as a suspending agent in suspension containing barium sulphate, calamine, sulphonamide and sulphur. III)Synthetic compounds- 1. Carbomer-It is used as a thickening agent in the concentration of 0.1 to 0.4 % for internal and external preparations. 2. Colloidal silicon dioxide-it acts as a suspending agent in 1.5 to 4% concentration. **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. Forexamples, alcohol in tragacanthmucilage, glycerin in sodium alginate or bentonite dispersion and polysorbate in oral and parenteral suspensions. **4. Preservatives**-A suitable preservative is needed to preserve suspensions against bacterial growth. Benzoic acid, sodiumbenzoate, methyl paraben and propyl paraben are commonly used. **5. Organoleptic additives**-Colouringagents, sweetening agents and flavouring agents are generally incorporated in oral suspensions.A suitable perfume and colour is incorporated in suspensions which are meant for external use.	
	e)	**Name the various bases used for ointment. Give characteristics of watersoluble bases.** **Bases used for ointment:** • Oleaginous bases • Absorption bases • Emulsion bases	**(1M)**

		• Water soluble bases **Characteristics of watersoluble bases:** i) These are commonly known as "greaseless ointment bases" ii) They consist of water soluble ingredients such as PEG polymers which are known as "Carbowaxes". iii) Depending upon the molecular weight, carbowaxes are available in different consistencies i.e. liquid, semisolid or solid. iv) Theirmol.wt varies from 200 to 8000. By mixing different carbowaxes, ointments of varying consistencies can be obtained. E.g. tregacanth, Gelatin, pectin, cellulose derivatives, bentonite, sodium alginate.	**(2.5M)**
	f)	**Name method of preparation of suppository. Describe any one of them.** **Method of preparation of suppository** 1) Handrolling and shaping 2) Hot process or Fusion method 3) Cold Compression method	**(1.5M)**
		1) Handrolling and shaping It is an ancient method of preparing suppositories. The suppository base are rolled &then desired shape is given with hand **2) Hot process or Fusion method** Hot process or Fusion method is commonly used method for Preparation of suppositories. i) Thoroughly Clean & lubricate the mould with suitable lubricant. Keep it on ice in inverted position to cool & drain excess lubricant. ii) Heat the china dish over water bath. To this add required quantityof suppository base after taking into account the displacement value of medicament. & calculating for two extra suppositories for unavoidable wastage. iii) Remove the dish from water bath, when $2/3^{rd}$ of base melts & stir thoroughly until whole mass melts. To avoid overheating. iv) Place the weighed quantity of medicament on an ointment tile. Pour about half of melted base over it. Mix it thoroughly with spatula. v) Transfer the mixed mass again to china dish, mix it thoroughly& warm china dish over water bath for few seconds with constant stirring.	**(Any 1method 2 marks**)

vi) Pour the melted mass into the cavities of suppository mould. Kept over ice. Fill each cavity to over flowing, to prevent the formation of holes in suppositories.

vii) Remove excess of mass with the help of sharp knife.

viii) Open the mould& remove suppositories.

ix) Wipe off the suppository lightly with a clean cloth or filter paper.

x) Wrap the individual suppository in a wax paper.

3)Cold Compression method

Compression is especially useful for **thermolabile**&**insoluble drugs**. This is not suitable for suppositories in which glycerogelatin base or any other base in which melting is essential for its preparation.

1. Cocoa butter is grated the ingredients are mixed with an equal quantity of grated cocoa butter.

2. In preparing suppositories with the compression machine, the suppository mass is placed in a cylinder, the cylinder is closed, pressure is applied from one end, mechanically or by turning a wheel, Suppositories are ejected are packed in shallow partitioned card board boxes.

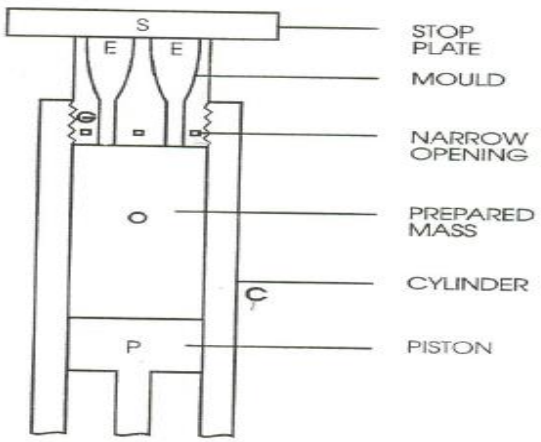

Fig. 9.2 Cold compression machine for suppositories

Q. No.	Sub Q. N.	Answer	Marking Scheme
3.		**Attempt any FOUR of followings:**	**14**
	a.	**What is cracking of emulsion? Describe factor responsible for cracking in 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 re-disperse by shaking The following factors results in the cracking of emulsion. 1. Decomposition of the emulsifying agent. 2. Addition of a solvent which dissolves both the phases. 3. High temperature and change in pH. 4. Addition of opposite types of emulgents. 5. Growth of micro – organism 6. 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.	**(1M)** **(0.5X5=2.5M)**

		Extensive creaming:cause cracking.	
	b.	**Define suspension. Give qualities of suspension. Comment on container used in suspension.**	
		Suspension: Suspension is a biphasic liquid preparation containing insoluble solid which are dispersed by addition of suspending agent.	**(1M)**
		Ideal Qualities of suspension:	
		1. It should settle slowly and should be readily re-dispersed on gentle shaking of the container. 2. It should pour readily and evenly from its container. 3. It should be chemically inert. 4. The suspended particle should not form a cake. 5. It should be free from large particles which spoils its appearance.	**(0.5X3 =1.5M)**
		Container: • Suspensions should be packed in containers which are having adequate air space above the liquid to permit adequate shaking. • The oral suspensions should be packed in wide mouth bottle to permit prompt removal of the suspension.	**(1M)**
	c.	**Explain herapath reaction for quinine.**	
		Oxidation of iodides with quinine sulphate: Quinine sulphate is not freely soluble in water.it is made soluble in presence of sulphuric acid. The sulphuric acid librateshydroiodic acid from the potassium iodide and the hydroiodic acid is partly oxidized by the sulphuric acid, yielding iodine. The iodine, hydroiodic acid and quinine sulphate then combine to form a compound called 'herapathite or iodosulphite of quinine'.	**(2M)**
		Example: Rx Quinine sulphate……1.5 g Dil. Sulphuric acid ……4.0 ml Potassium iodied ……8.0 ml Water ……..200ml	**(1.5M)**
		Dilute the sulphuric acid with 100ml of water and dissolve the quinine sulphate in it,The potassium iodide is dissolved in the remaining quantity of water and mixed with the first portion, the mixture formed is quite clear first, but after about three days it may deposit bronze	

or olive green scales which is due to "Herpath reaction" for quinine.

d. **Differentiate between syrup and elixir. Give any two uses of mixture.** **(0.5X5 =2.5M)**

Syrup	Elixir
1. Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar.	1. Elixirs are clear, sweetened and flavouredhydroalcoholic liquid preparation intended for oral use.
2. They contain little or no alcohol 3. They contain little or no preservative	2. They contain alcohol in concentration of4to 40% 3. They contain no preservative
4.They are less stable than elixir	4. They are more stable than syrup
5. Most suitable for pediatric patients	5.Not suitable for pediatric patientsas it contains alcohol

Uses of mixture: **(1M)**

1. Cough.
2. Indigestion.
3. Diarrhea.
4. Constipation.

e. **What are cleansing cream? How cleansing cream formulated.** **(02M)**

- Cleansing creams are used to remove facial makeup.
- They are also used to improve the healthy and good appearance of skin which requires frequent cleansing to remove grime, sebum and other secretions, dead cells and applied makeup.
- They are basically cold creams containing a detergent for cleaning action they also contain other ingredients which help to soften , lubricate and protect the skin.
- In case of o/w type of cleansing creams tweens are used along with detergent to remove dirt. Pepsin is added to make the facial skin smooth.

Formulation: These consist of simple mixtures of mineral oils or synthetic fatty materials, with the hydrocarbon waxes, paraffin wax etc. **(1.5M)**

Ex.

		Isopropyl myristate……25.0 g Liquid paraffin…….. 25.0 g White soft paraffin…… 30.0 g Paraffin wax……. 20.0 g Melt and mix all ingredients at about 65^0C, cool with constant stirring until the mixture is a little over solidifying point. Pour into the final container and packed.	
	f.	**What are intravenous fluids? Write there 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 to correct, for example, dehydration. 5. Used for chemotherapy. 6. To deliver Blood substitute.	**(1M)** **(0.5X5 =2.5M)**
4		**Attempt any FOUR of the following.**	**14**
	a.	**How will you dispense the powder containing:** **i. Hygroscopic and deliquescent.** The powders which absorb the moisture from the atmosphere are called as hygroscopic. But certain powder absorbs moisture to such extent that they go into solution and are called as deliquescent powders. Ex. Ammonium chloride, iron& ammonium citrate, etc Such substance should be supplied in granular form in order to expose less surface area to atmosphere. These powders should not be finely powdered. Such powder should be double wrapped. **ii. Efflorescent powder.** Some crystalline substances liberate water of crystallization wholly or partly on exposure to humid atmosphere or during triturating and thus become wet or liquefy. Ex. caffeine, citric acid, ferrous sulphate etc. This difficulty may be overcome by using either corresponding anhydrous salt or an	**(2M)** **(1.5M)**

		inert substance may be mixed with efflorescent substance before incorporating with other ingredients.	
	b.	**What is physical incompatibility? Explain any one with suitable example.** **Physical Incompatibility:**When two or more substance mixed together, a physical change takes place and an undesirable product is formed. **Types of Physical Incompatibility:** 1. Immiscibility. 2. Insolubility. 3. Precipitation. 4. Liquefaction. **1. Immiscibility:** Castor oil is immiscible in water therefore emulsifying agent is added to form emulsion. Rx Castor oil .....15 ml Water ..... 6.0 ml In this prescription castor oil is immiscible with water. To overcome this incompatibility an emulsifying agent is used to make a good emulsion. Make an emulsion **2. Insolubility:** Phenacetin is indiffusible solid which is insoluble in water therefore suspending agent is added to form suspension of phenacetin. Rx Phenacetin ..... 3 g Caffeine ..... 1 g Orange syrup ... 12 ml Water ..... 90 ml In this prescription phenacetin is an indiffusible substance. Compound powder of tragacanth or mucilage of tragacanth is used as a suspending agent to make a stable suspension **3. Precipitation:** Tincture containing resins when added into the water for precipitate, therefore to disperse it uniformly a suspending agent is added. Rx Tincture of benzoin ..... 5.0 ml	**(1M)** **(any one example for 2.5M)**

Glycerin ..... 15 ml

Rose water ..... 100 ml

Tincture benzoin compound contains resins. The change in solvent system results in an unavoidable precipitate. Addition of tincture with rapid stirring yields a fine colloidal dispersion. So there is no need of any suspending agent

4. Liquification:

Eutectic mixture: when two or more substance are mixed together they are going to form new chemical compound which has melting point lower than the room temperature, therefore they are liquid at room temperature.

To correct this incompatibility a inert solid substance is added to form free flowing powder.

Rx

Menthol ..... 5 g

Camphor ..... 5 g

Ammonium Chloride ..... 30 g

Light Mg carbonate ..... 60 g

Prepare a powder

In this prescription menthol, camphor and ammonium chloride get liquefied on mixing with each other. To dispense this prescription, menthol, camphor and ammonium chloride are triturated together to form liquid. Add light magnesium carbonate and mix it thoroughly to make free flowing powder.

c. **Classify shampoo on the basis of physical properties. Name various ingredients in formulation of shampoo with their uses.** **(0.5X4 =02 M)**

Classification of Shampoo:

1. Clear shampoo.
2. Medicated shampoo.
3. Soap shampoo.
4. Cream shampoo.
5. Gel shampoo.
6. Baby shampoo.
7. Aerosol shampoo.
8. Powder shampoo.
9. Liquid cream or lotion 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. Glycerin, PG, etc. 2) **Thickening Agents: -** Use to increase the viscosity of shampoo & provide desired consistency.e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate 3) **SolubilizigAgent :-** 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.	**(1.5M)**
	d.	**What do you understand by diffusible and indiffusible mixture? How they are dispensed.** **Diffusible Mixture:** • Diffusible solids are those which are insoluble in water but uniformly dispersed in the vehicle on gentle shaking. • No need of suspending agent. • Ex. Bismuth carbonate, bismuth subnitrate etc. **Indiffusible mixture:** • Indiffusible solids are insoluble in vehicle. • Not evenly distribute throughout the vehicle on shaking. • Ex. Acetyl salicylic acid, Quinine salicylate, calomel, phenacetin, chalk powder. • Suspending is required.	**(1.5M)**

Method of preparation of diffusible mixture: **(1M)**

Drug+ soluble material + Vehicle a part from 3/4th

↓ Smooth cream

Add remaining vehicle from 3/4th

↓ Add to measure

Add other liquid ingredient

↓

Strain through muslin cloth for removal of foreign particles

↓

Make up the volume with remaining vehicle

Method of preparation of indiffusible mixture: **(1M)**

1. **Using tragacanth powder.**

Solid's + Tragacanth powder (2%)

↓

Triturate the powder with a portion from ¾ of vehicle

↓

Smooth cream is formed

↓

Add remaining portion of vehicle from 3/4th.

↓

Examination

↓

Add other liquid ingredient + soluble ingredients

↓

Make up the volume with remaining vehicle

		2. Using tragacanth mucillage: Solid's +Tragacanth Mucilage($1/4^{th}$)Triturate ↓ Smooth cream is formed ↓ Add 1/2 of the vehicle. ↓ Examination ↓ Add other liquid ingredient + soluble ingredients ↓ Make up the volume with remaining vehicle	**(0.5M)**
	e.	**Classify the various methods and give formula for the calculation of pediatric dose.** **Method of calculation of doses:** • Dose proportionate to age • Dose proportionate to body weight. • Dose proportionate to body surface area: **formula for the calculation of pediatric dose** **1.Depending on age:** Dillings formula: Child Dose = Age in years / 20 X Adult dose Young's formula: Child dose = Age in years / Age in years +12 X Adult dose Frieds Formula: Child Dose = Age in month / 150 X Adult dose. **2.Depending weight.** Clarks formula: Child Dose = weight in pound/150 X Adult dose **3.Depending body surface area:** Body surface area formula: Child Dose = body surface area of child M^2/ avg body surface area of adult 1.73 M^2 X Adult Dose.	**(3.5M)**

	f.	**In what proportion 10%, 8% and 2% sulphur ointment be mixed to get 4% sulphur ointment.** **10 4-2 = 2 parts of 10 %** **8 4 4-2 = 2 parts of 8%** **2 10-4 = 6 and 8-4 = 4 total 10 parts of 2%** **OR** **10 8-4 = 4 parts of 10 %** **8 4 6+2=8 parts of 8%** **2 8-4= 4 parts of 2%**	**(3.5M)**

QNo.	Sub Q. N.	Answer	Marking Scheme
5	a	**Attempt any FOUR of followings:** **Define hair dyes How are they classified Give their qualities** **Definition:** Hair dyes are used to change the natural colour of the hair. The grey or white hair which has changed with age are converted into black colour with the help of hair dyes in order to restore a youthful appearance .Sometimes hair dyes are used to alter the colour of the hair temporarily for particular occasion. **Classification:** **i) Vegetable dyes :** e.g. henna & chamomile **ii) Metallic dyes:** e.g. lead acetate with precipitated sulphur, bismuth citrate, silver nitrate, copper chloride, nickel nitrate, cobalt nitrate. **iii) Synthetic organic dyes:** e.g. para toluylene -diamine, paraaminodiphenylamine, sulpho-ortho- aminophenol, paraphenylenediamine. **Qualities:** i) It should possess no systemic toxic effect when applied to the hair or skin. ii) It should be none irritating to the hair & skin. iii) It should be non injurious to the hair shaft, but should be able to colour the hair shaft. iv) It should be stable and should not change its colour when exposed to air, sunlight, water, shampoo or hair conditioning agents etc.	**14** **0.5marks** **1.5marks** **1.5marks**
5	b	**Write in brief about suspension containing precipitate forming liquid.** Suspension containing precipitate forming liquid: Certain liquid contains resinous matter when mixed with water the resin is precipitated which may adhere to the sides of bottle or form a clotted ppt which will not re-diffuse upon shaking to prevent this compound tragacanth powder or tragacanth mucilage are used. Method of dispensing: • Finely powder the indiffusible solid and diffusible solid in the mortar, mix them with compound tragacanth powder in a mortar • Measure 3/4th of the vehicle and add apportion of it and titurate to form smooth cream ,add remaining of vehicle • Measure ppt forming liquid in the dry measure and add in slow stream in the center of the cream with constant tituration	**1mark** **2.5marks for any method**

- If soluble ingredients are present dissolve in remaining amount of vehicle and add slowly with constant stirring
- Add more vehicle to make required volume

The preparation can also be prepared by using tragacanth mucilage.

c **Discuss the types of vehicles used for parental preparations** **0.5mark**

There are two types of vehicle which are commonly used for preparation of parental Aqueous vehicle –Water is used as vehicle for majority of injection as it is safest and well tolerated by body. The aqueous vehicle used are

Water for injection

Water for injection free from CO2

Water for injection free from dissolved air **1.5marks for each description**

Water for injection is sterile water free from volatile and non volatile impurities and also from pyrogens

2.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

Propylene glycol is used in preparation of digoxin injection.

d **Describe the method of preparation of ointment by chemical reaction** **1mark**

Certain chemical reactions are involved in preparing certain ointments for e.g non staining Iodine ointment

Fixed oils contains unsaturated fatty acids whish reacts with iodine and iodine gets attached to either side of double bond, therefore free iodine is not available in the preparation **1mark**

$CH_3.(CH_2)_7.CH{:}CH.(CH_2)_7.COOH + I_2 = CH_3.(CH_2)_7.CHI.CHI.(CH_2)_7,COOH$

Oleic acid di-iodo stearic acid

Rx **1.5marks**

Iodine 50gms

Arachis oil 150ml

Yellow soft paraffin 1000gms

Powder iodine and shake it with arachis oil at room temperature and then place it on the water bath where temperature is maintained to 50^o C until the colour of the preparation changes to green colour, and brown colour disappears it means reaction is complete, remove

		the preparation from water bath add sufficient of yellow soft paraffin till the reacted mass is uniformly dispersed.	
	e	**Comment on the following prescription:** Sodium benzoate……5 grams Caffeine Citrate……3 grams Liquid extract of glycerrhiza----------12ml Water upto…… 90.0 ml. Prepare a Mixture	**1marks**
		Ans: Chemical incompatibility may be a result of chemical interactions between the ingredients of a prescription and a toxic or inactive product may be formed. In above formulation there is a chemical incompatibility due to the chemical interaction among the ingredients. Caffeine citrate is a mixture of equal weight of caffeine and citric acid. The citric acid present in caffeine citrate react with sodium benzoate to liberate benzoic acid which gets precipitated. If caffeine is used instead of caffeine citrate it forms a soluble complex with sodium benzoate. Hence substitute caffeine citrate with half as much caffeine as that of caffeine citrate to form a clear mixture. Sodium benzoate is an indiffusible substance. It requires compound tragacanth powder or tragacanth mucilage as suspending agent to make a stable suspension. Here the vehicle is water hence tragacanth mucilage in the proportion of $1/4^{th}$ of the volume of the mixture will be used.	**2.5marks**
		OR	
	e	**Define particulate matter in parenteral. What is its significance .Explain any one method of detection of particulate matter.**	**0.5marks**
		Definition: Particulate matter is unwanted mobile insoluble matter other than gas bubbles present in the given product. Permitted particulate matters as prescribed in I.P:	**1marks**

Particle size in micro meter (equal to or large than)	Maximum no of particles per ml
10	50
25	O5
50	Nil

		Significance: Presence of particulate matter in IV solutions may lead to septicemia, fever and blockage of small blood vessels. The presence of undissolve particles create doubt about the quality of product Testing: (description of any one test 2 Marks) 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 neckband 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	**1mark for listing** **1mark for method**
	f	**Define suppository. State the character of glycerogelatine base used in suppository** Suppositories are semi solid dosage form of medicament for insertion into body cavities other than	**0.5mark**

		mouth.They may be inserted into rectum, vagina or nasal cavity. Glycero-gelatine base is a mixture of glycerin and water which is made stiff by the addition of gelatin the base may be used for preparing all type of suppositories but it is particularly used in making pessaries. The suppositories are translucent which tend to dissolve or disperse slowly in the body cavity and release the medicament To avoid incompatibility reactions any one of the two types of gelatin used as suppository base Pharmagel A which is acidic in nature and used for acidic drugs having iso-electric point(7-9) Pharmagel B which is alkaline in nature and used for alkaline drugs having iso-electric point (4.7to5) Glycero-gelatine base is a mixture of glycerin and water which is made stiff by the addition of gelatin the base may be used for preparing all type of suppositories but it is particularly used in making pessaries. The suppositories are translucent which tend to dissolve or disperse slowly in the body cavity and release the medicament To avoid incompatibility reactions any one of the two types of gelatin used as suppository base Pharmagel A which is acidic in nature and used for acidic drugs having iso-electric point(7-9) Pharmagel B which is alkaline in nature and used for alkaline drugs having iso-electric point (4.7to5) **Disadnvantages: (any two disadv)** The solution time depends on the content and quality of glycerin i. Gelatine is incompatible with many drugs such as tannic acid ferric chloride gallic acid ect ii. There are chances of bacterial and mould growth therefore preservative has to be added iii. The base is hydroscopic and hence special storage condition is required. iv. They have laxative action v. They are more difficult to prepare and handle. vi. difficult to prepare and handle.	**1mark for each type** **1M**
6	**a**	**Attempt any FOUR of followings:** **What is the principle behind sterility testing, Describe membrane filteration method for sterility testing**	**14**

The test for sterility is done by detecting the presence of viable forms of bacteria, fungi & yeast in parental preparations.

Principle: The test s based on the principle that if bacteria or fungi are placed in a medium which provides nutritive material & water & kept a favorable temperature the organism will grow & their presence can be indicated by turbidity in the clear medium.

0.5marks

Selection of sample size: (any one table)

1mark

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

Method of testing: Membrane filtration method:-The membrane filtration method is performed in following cases :

2 marks

- An oil or oily preparation.
- An ointment that can be put into solution.
- A soluble powder or a liquid that posses 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 & dia. 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 NLT 7 days. • The other half part is transferred into 100ml of fluid thioglycollate medium & incubated at 30 to 35^{o}C for NLT 7 days. • Observe the growth in media.	
	b	**Discuss the various factors governing the selection of ointments base.** **Factors for selection of ointments base:** **Dermatological factors: (any Four)** • Absorption & penetration • Effect on skin function • Miscibility with skin secretion • Compatibility with skin secretions • Freedom from irritant effect • Emollient properties • Ease of application and removal **Absorption &penetration**:Absorption indicates entry of medicament into the blood stream, systemic absorption.Penetration indicates passage of vehicle along with medicament through the skin, cutaneous absorption.The substances soluble both in 0il & water are readily absorbed. **Effect on skin function:**Greasy bases may interfere with skin functions like heat radiation& sweat excretions, hence are skin irritant.Water soluble bases & o/w emulsion bases provides cooling effect rather than healing effect. This bases readily mix with skin secretions. **Miscibility with skin secretion:**Water miscible & emulsion bases are miscible with skin secretions readily thereby releasing medicament rapidly & completely as compared to greasy bases.	**2 marks**

		Compatibility with skin secretions: The ointment bases should have a pH around 5.5 which is the average pH of the skin secretions.Neutral ointment bases are preferable since it does not cause irritation **Freedom from irritant effect:** The ointment bases used should be non-irritant. Greasy bases cause irritation and may cause edema. **Emollient properties:**Ointment bases used should possess emollient properties that should be able to keep the skin moist. Humectants like glycerin and propylene glycol keep the skin surface moist and soft.Wool fat, lard and paraffin keep the skin soft by preventing rapid loss of moisture from the skin. **Ease of application and removal:** Ointment bases used should be easily applicable and easy to remove from the skin. Stiff and sticky ointment bases are not suitable because they may cause damage to the newly formed tissues of the skin. o/w type emulsion bases are preferable as they are easy to apply & remove from skin. **A. Pharmaceutical factor: (any three)** 1. Stability 2. Solvent properties 3. Emulsifying properties 4. Consistency **Stability:** The fats and oils are liable to undergo oxidation. This can be prevented by adding antioxidant ointments containing liquid paraffin may get oxidized on prolong storage. O/w type emulsion bases are liable to microbial growth and needs a proper preservative. Emulsified bases are liable to phase separation due to improper formulation or under the influence of temperature **Solvent properties;** Medicaments insoluble in the ointment bases are mixed in finely powdered form for uniform distribution, Phenol in solid form is quite caustic and cause blisters in a finely divided form in an ointment base. Hence, a base consisting of a mixture of hard and soft paraffins, beeswax and lard is recommended for phenol, which keeps phenol in solution form. **Emulsifying properties:** Hydrocarbon bases can absorb only a small amount of water in comparison to animal fats which can absorb large	**1.5marks**

		quantities of water. Wool fat is included for the preparation of base meant for eye ointments. Similarly cetrimide emulsifying ointment is capable of absorbing considerable amount of water forming o/w creams **Consistency:** It should be of suitable consistency. It should neither be too hard nor too soft. Consistency is such that it withstands wide variation in temperature conditions. The consistency of an ointment can be adjusted by using of high melting point substances like hard paraffin, beeswax in soft ointments and low melting point substances like liquid paraffin in hard ointments respectively.	
	c	**What are the functional ingredients used in the formulation of Dentrifices.Give their functions and examples.** Following are the functional ingredients in Dentrifices **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 **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 attractive. • Ex. Coal tar dyes, **6. Flavours:** • Flavours are added to improve the taste of the formulation. • Ex. Peppermint oil, cinnamon oil, etc.	**1mark for each functional ingredient 0.5 mark for example**

	d	**Name the monophasic liquid dosage form for internal use. Discuss organoleptic additives of any two dosage forms.** **monophasic dosage form for internal use** 1. Syrup. 2. Elixir. 3. Mixture. 4. Linctus. **Syrup:** Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar (USP contains 64.74 w/v of sugar) having specific gravity 1.31g. **Additives are** Vehicle: purified water is used Chemical stabilizer: glycerin,sorbitol and propylene glycol is added to prevent crystallization of sucrose Colouring agent: coal tar dyes,such as amaranth, compdtartrazineect Flovouring agents: Tinctures, fruit juices or essence are added Preservative:Benzoicacid,sodium benzoate or methyl paraben are commonly used. **Elixir**: Elixirs are clear, sweetened and flavored hydro alcoholic liquid preparation intended for oral use. **Additives are** Vehicle: purified water is used to dissolve soluble ingredient other vehicle used are alcohol,syrup, glycerine, sorbitol, propylene glycol etc. Chemical stabilizer: Citric acid is used in neomycin elixirto maintain PH-5 TO prevent darking Disodium EDTA is also added to squeeze heavy metals Colouring agent: coal tar dyes,such as amaranth, compdtartrazineect Flovouring agents: such as black current syrup,lemon syrup Preservative:Benzoicacid,sodium benzoate or methyl paraben are commonly used. **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. **Additives are**	**1.5 marks for listing** **1.marks for organoleptic additives of any one**

		Vehicle: purified water is used, Aromatic waters like camphor water, chloroform water, peppermint water etcs Medicated vehicle: vehicles having therapeutic value such as compd gentian infusion,orange peel infusion etcs Chemical stabilizer: Ascorbic acid is used on ferrous sulphate mixture to prevent oxidation of ferrous ions,Sodiummetabisulphite is used in sodium salicylate mixture to prevent darking Colouring agent: No particular colouring agent is used Flovouring agents: Aromatic waters, syrups lemon spirit, orange syrup ect are addedTinctures, fruit juices or essence are added Preservative:Benzoic acid, chloroform 0.25% is used **Linctuses**: Linctuses are viscous, monophasic liquid preparation containing a high concentration of syrup intended to be sipped and swallowed slowly for treatment of cough. Vehicle: Syrup like Tolu syrup, Invert syrup,glycerin sorbitol ets is used Chemical stabilizer: Majority of lictus are stable Colouring agent: coal tar dyes,such as amaranth, compdtartrazineect Flovouring agents: such as black current syrup,lemon syrup, Oxymel and benzalehyde spirit are also used. Preservative: Benzoic acid,sodium benzoate or methyl paraben are commonly used.	
e	**Comment : Contact lens solutions** Contact lens solutions :Are usually made from polymethylmethaacrylate which is ahard hydrophobic plastic, nowadays some softer hydrophilic lenses are also used **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).	**0.5mark** **1.5marks for each type**

		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 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.	
	f	**Calculate the displacement value of zinc oxide from following data** **i) Capacity of mould = 15 grain** **ii) Wt. of unmedicated suppositories = 90 grain** **iii) Wt. of six suppositories containing 40% zinc oxide = 132 grain.** Weight of 6 suppositories containing base = 15 grain= (15 x 64.8 mg) x 6 = 5.832 g (1 grain = 64.8 mg) 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 = $\frac{60}{100}$ x 8.553 = 5.1318 g Amount of medicament present in 6 suppositories = 40 /100 x 8.553 = 3.4212 g Amount of base displaced by 3.4212 g of medicament = 5.832- 5.1318 = 0.7002 g Displacement value = 3.4212 / 0.7002 = 4.886 = Approx.5.	**(3.5Marks)**