WINTER– 19 EXAMINATION

Subject Title: PHARMACEUTICS-ll Subject Code: 0811

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for anyequivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.

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

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

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

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

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

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

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

3. Polyethylene glycol.

C. Emulsifying/Synthetic bases:

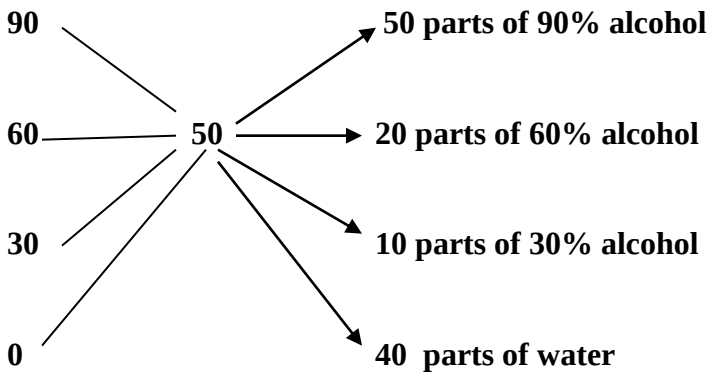
1. Witepsol
2. Massa estarinum
3. Massuppol.

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

Cocoa butter:

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

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

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

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

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

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

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

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

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

b) Semisynthetic :

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

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

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

2) Inorganic agents –

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

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

3) Synthetic compounds :

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

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

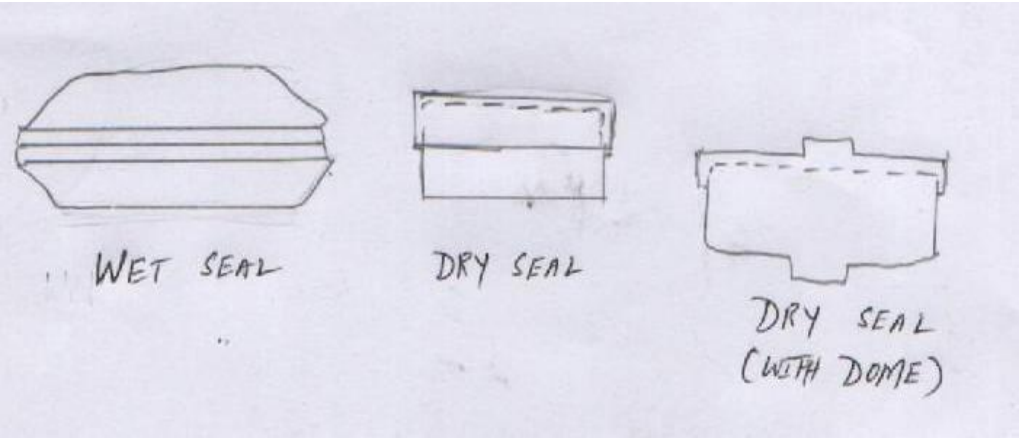
2. Flocculating agents

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

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

3. Wetting agents.

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

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

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

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

Rx

Atropine sulphate -------0.006gm

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

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

Prepare 10 capsule

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

2. Wrong drug or dosage form:-

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

3. Contra-indicated drugs:

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

4. Synergistic & antagonistic drugs:-

Many drugs exhibit synergism & antagonism when administered in combination.

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

5. Drug interaction:-

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

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

3. Humectants:

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

4. Sweeteners:

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

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

Ex. Coal tar dyes,

6. Flavours:

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

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

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

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

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

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

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

Therapeutic uses

1. Antibiotic ointments :

Used to kill micro organism.

Eg. Bacitracin , neomycin , Chlorotetracycline

2. Antifungal ointments:

inhibit or kill fungi

eg.Benzoic acid, salicylic acid , & nystatin

3. Anti-inflammatory ointments:

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

Eg. Betamethasone valerate, hydrocortisone.

4. Antipruritic ointments

Used to relieve itching

Eg. Benzocain & coal tar.

5. Astringent ointments

Causes contraction of skin & decreases discharge.

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

6. Anti-eczematous ointments

Used to prevent oozing & excrection from vesicles on the skin

Eg Hydro cortisone, coal tar &

7. Keratolytic ointments

Used to remove & soften horny layer of skin

Eg. Resorcinol ,salicylic acid , & sulphur.

8. Counter irritant ointments

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

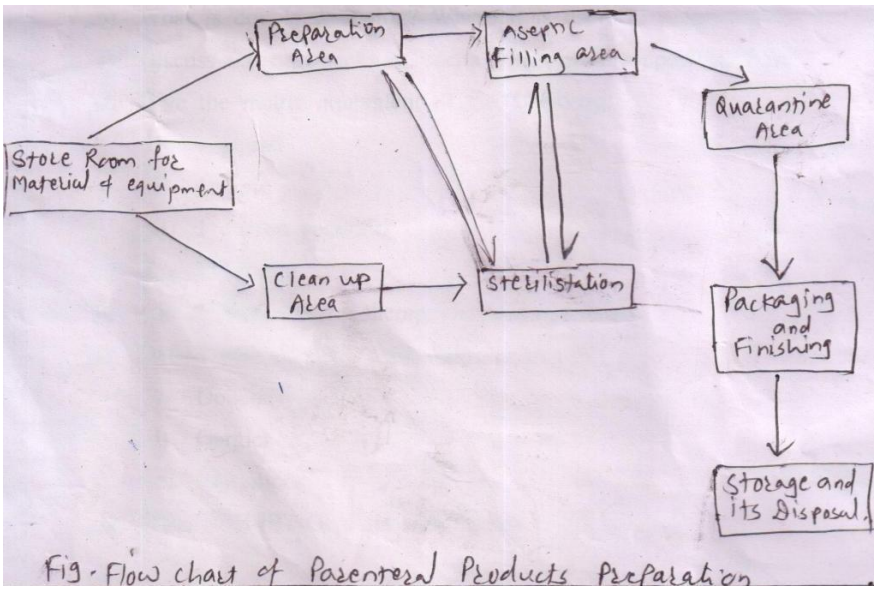
9. For Dandruff treatments

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

10. For Psoriasis

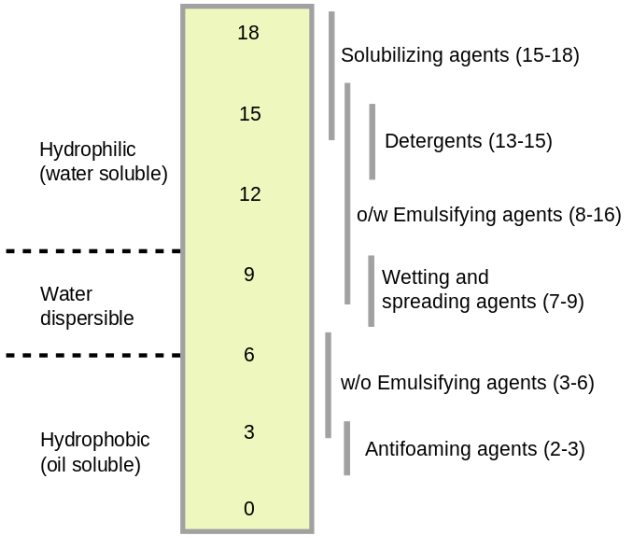
Coal tar ,corticosteroids, dithranol ,& salicylic acid .

11. Parasiticide ointments

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

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

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



Role of HLB in formulation of Emulsion:

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

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

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

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

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

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

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