Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate’s answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate’s understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.
<table>
<thead>
<tr>
<th>Q. No.</th>
<th>Sub Q. N.</th>
<th>Answer</th>
<th>Marking Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>a)</td>
<td>Attempt ant EIGHT of the following. Define: (i) 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. (ii) Paste- Paste are semisolid preparation intended for external application to the skin as protective, antiseptic, or soothing dressing.</td>
<td>16M 2M (1+1)</td>
</tr>
</tbody>
</table>
| 1      | b)       | Calculate dose of Paracetamol for 4 yr child and whose Adult dose is 500mg. **Young's formula** 
Dose for child = \( \frac{\text{Age in years}}{\text{Age} + 12} \times \text{Adult dose} \)
\[ = \frac{4}{4+12} \times 500 \text{ mg} \]
\[ = 125 \text{ mg} \] | 2M |
| 1      | c)       | Differentiate between suppositories and pessaries. | 2M (0.5x4) |
| | **Suppositories** | **Pessaries** | |
| | They are solid dosage form meant for insertion into body cavities other than mouth | They are solid dosage form meant for insertion into the vagina | |
| | They are available in different shapes sizes and weight | They are available in conical, wedge shape or rod shape | |
| | The weight differs depending on purpose for which it is use | The weight ranges from 4 to 8gms | |
| | Base used mostly cocoa butter | Base used glycerol-gelatine | |
| | Suppositories used for systemic and local action | Pessaries are used only for local action. | |
| | Ex. Dulcolax suppositories | Ex. Fluconazole pessaries. | |
| 1      | d)       | Mention four qualities of an ideal lipstick. 
1. It should be non toxic and non irritating 
2. It should be free from gritty particles 
3. It should be easily applicable and removable 
4. It should give shiny and smooth appearance 
5. It should not dry on storage 
6. It should be long lasting after application 
7. The stick should not break during application | 2M (0.5x4) |
### Model Answer

**Subject Title:** PHARMACEUTICS-II

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>8.</td>
<td>It should be stable both physically &amp; chemically.</td>
</tr>
<tr>
<td>9.</td>
<td>It should be free from sweating</td>
</tr>
<tr>
<td>10.</td>
<td>It should maintain its firmness till it is fully used up.</td>
</tr>
</tbody>
</table>
| **1 e)** | **Give reason:** Why oily vehicle is not used in the preparation of nasal drops.  
Because oily drop inhibits the movement of cilia in the nasal mucosa and if used for longer periods, may reach to lung and cause lipoid pneumonia. |
| **1 f)** | **Write advantages of parenteral preparations.**  
**Advantages of parenteral products**  
i. Rapid onset of action.  
ii. Immediate therapeutic action is possible.  
iii. Each dose can be administered accurately.  
iv. When oral route is not possible in unconscious and non-co-operative patient.  
v. When drugs get inactivated in GIT tract  
vi. Prolong action can be possible by this route.  
vii. Absorption of the drug faster compare to other route. |
| **1 g)** | **Translate following Latin terms in English.**  
(i) **Jentaculum**- Breakfast  
(ii) **Cochleare maxium**- one tablespoonful  
(iii) **omni quarta hora** – Every 4 hrs.  
(iv) **Dolare urgente**- When pain is severe. |
| **1 h)** | **Differentiate between Ointment and paste.**  
| **Ointments** | **Paste** |
| Contains less amount of solid. | Contain large amount of solid. |
| Soft preparation. | These are thick and stiff. |
| More greasy. | Less greasy. |
| Protective, emollient. | Form protective coating. |
| More macerating. | Less maceration. |
| Ex. Sulphur ointment | Zinc oxide paste BPC. |
| **1 i)** | **Describe adjusted incompatibility with example.**  
**Adjusted incompatibility** - In adjusted incompatibility the chemical interaction can be prevented by addition or substitution of one of the reactant.  
e.g. caffeine citrate substituted with caffeine in sodium salicylate & caffeine mixture.  
or any other example of adjusted incompatibility |

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**Page 3/24**
1. j) Prepare 1 lit. solution 1 in 4000 using 0.1% w/v solution.

**Calculation**
- Strength of concentrate = 0.1%
- Strength of dilute solution 1 in 4000 = \( \frac{100}{4000} = 0.025\% \)

**Applying formula:**
- Degree of dilution = \( \frac{\text{Strength of concentrate}}{\text{Strength of dilute solution}} \)
- Degree of dilution = \( \frac{0.1}{0.025} = 4 \) times
- Volume of solution to be prepared = 1000 ml
- Therefore, dilute solution is obtained by diluting \( \frac{1000}{4} = 250 \) ml of 0.1% solution to get 1 l

**Solution:** 250 ml of 0.1% solution to get 1 l of 1 in 4000 soln.

2. Attempt any FOUR of the followings

2 a) Define and classify Jellies

**Jellies:** Jellies are transparent or translucent non-greasy, semisolid preparation for external application to the skin or mucous membrane.

**Types 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 as a lubricating agent for catheters, rubber gloves, thermometers. These jellies should be sterile.
- (iii) **Miscellaneous jellies:** these are used as vehicle for allergens during sensitivity testing or as electro-cardiography jelly applied on electrode to reduce electrical resistance between patients skin and the electrode.

2 b) Give advantages of suppositories. Discuss any two new trends of suppositories.

**Advantages of suppositories**
1. The main use of a suppository is to partially overcomes the first pass effect and prevents gastric irritation,
2. When the oral route is not possible for some reason.
3. In old people, post operative people, bed ridden people, or in infants.
4. It may also be used if there is severe nausea or vomiting or there is a paralytic ileum
5. Suppositories are mainly used to treat constipation or hemorrhoids
6. Suppositories can exert local or systemic action

**New trends of suppositories:**
1. Tablet suppositories:
   - Now a days the rectal suppositories and pessaries are prepared by compression like compressed tablets.
   - Are almond shaped for ease in insertion and to provide large surface area for
disintegration and absorption.

- Are coated with polyethylene glycol for protection and its easy insertion into rectum.

2) Layered suppositories:

- These suppositories contain different drugs in different layers to avoid incompatibility between them.
- Release is controlled by adding drugs having different melting point or dissolution rate.
- Theses are prepared by partially filling the mould one type of material
- When it gets solidified, then other materials are added one after other as separate layer.

3) Capsule suppositories:

- Soft gelatin capsules of different shapes and sizes are used for insertion into rectum or the vagina.
- The liquids, semisolids and solids are filled in soft gelatin capsules.

4) Coated suppositories:

- Suppositories are coated by dipping in the solution of the coated material such as polyethylene glycol and cetyl alcohol until coats of desired thickness have been obtained.
- These suppositories impart lubricant properties or to provide lubricant during storage.
- Also helps to control release of medicament.

5) Disposable mould:

- The suppositories are directly moulded into the disposable moulds made up of plastic material or tin foils and then sealed.
- Useful when suppositories mass melts during storage, it will remain in mould itself and can be converted into suppository after cooling.
- Cheaper and elegant.
c) Enlist tests for identification of Emulsion type. Explain any one with neat diagram.

Tests for identification
1) Dilution Test
2) Dye Test
3) Conductivity Test
4) Fluorescence Test
5) Cobalt Chloride Test

1) Dilution Test -
- Emulsion diluted with water  
  i) Emulsion remains stable then it is o/w emulsion  
  ii) Emulsion break it is w/o emulsion
- Emulsion diluted with oil  
  i) Emulsion remains stable then it is w/o emulsion  
  ii) Emulsion break it is o/w emulsion

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

3) Conductivity Test-
This type of emulsion show bulb glowing on passing electric current.
- If bulb glow the emulsion is o/w type
- If bulb does not glow the emulsion is w/o type
4) Fluorescence Test:
   - If an emulsion on exposure to ultra-violet radiations shows continuous fluorescence under microscope, then it is w/o type
   - If it shows only spotty fluorescence, then it is o/w type.

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

2 d) Explain any three Therapeutic incompatibilities.

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.

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. 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 contra-indicated 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.

2 e) **Define Powder. How will you dispense powder containing**

   i) **Potent drugs (ii)Hygroscopic and Deliquescent drugs.**

**Definition of Powder:**

Powder is a mixture of finely divided drug or chemical in dry form which are meant for internal or external use.

(i) **Potent drugs**
- The substances having a maximum dose of less than one grain (60 mg) and poisonous substances are regarded as the potent substances
- The potent drugs are triturated with some diluent such as lactose in definite proportion in definite proportion to make a weighable quantity for each powder.

(ii) **Hygroscopic and Deliquescent drugs.**
- 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.
2  f) What are Pyrogens? Write a note on BET.
   Pyrogens are metabolic products of microorganisms and produced by all microorganisms. **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 ameboiyes 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.

3  Attempt any FOUR of the followings

3  a) List the factor that influence dose of drug. Explain any two.
List of factors:
1. Age.
2. Sex.
4. Body surface area
5. Frequency of administration.
6. Dosage form.
7. Physiological condition.
8. Environmental factor.
9. Disease condition.
10. Tolerance.
11. Iodiosyncrasy.
12. Tachyphylaxis.
15. Antagonism.

Explanation:
1. **Age**: The pharmacokinetics of many drugs changes with age. So while determining the dose of a drug, the age of an individual is of great significance. Children and old people need lesser amount of drug than the normal adult dose, because they are unable to exercise drugs to the extent as adults. Children can tolerate relatively larger amounts of belladonna, digitalis and ethanol; whereas, elderly patients are more sensitive to some drug e.g. hypnotics and tranquilizers which may produce confusion states in them.
2. **Sex**: Women require less doses that the male. Morphine and barbiturates may produce more excitement before sedation in woman. The strong purgatives such as aloe should be avoided during menstruation and pregnancy. During lactation drug like antihistamine, morphine and tetracycline should be avoided.
3. **Body weight**: Dose of the drug can be calculating according to body weight. Obese patients, children and malnourished patients require less doses.
4. **Route of Administration**: Intravenous doses of drugs are usually smaller than oral doses, because the drug administered intravenously enters the blood stream directly.
5. **Time of administration**: Presence of food in the stomach delays the absorption of drug. The drug more rapidly absorbed from empty stomach. So the amount of drug
is very effective when taken before meal.

6. **Environmental Factor:** Daylight is stimulant enhance the effect of stimulating drugs and diminish the effect of hypnotics. Darkness is sedative. Hypnotics are more effective at night. The amount of barbiturates required to produce sleep during day time is much higher than the dose require in the night.

7. **Emotional factors:** The personality and behaviour of a physician may influence the effect of drugs especially the drug which are intended for use in a psychosomatic disorder. The female are more emotional than male require less doses.

8. **Presence of disease:** Drug like barbiturates chlorpromazine may produce prolongs effect in patients having liver cirrhosis. Streptomycin is excreted mainly by kidney may prove toxic if kidney is not functioning properly.

9. **Accumulation:** Drug excreted slowly may get accumulated in the body and produce toxic effects. Repeated administration of drug like digitalis, emetine and heavy metal may produce toxic effects.

10. **Additive effect:** When the total pharmacological action of two or more drugs administered together is equivalent to sum of their individual pharmacological action, the phenomena is called as an additive effect. For example, combination of ephedrine and aminophylline in the treatment of bronchial asthma.

11. **Synergism:** When two or more drugs are used in the combination form, their action is increased. The phenomena is called synergism. Synergism is very useful when desired therapeutic result needed is difficult to achieve with a single drug e.g. procaine and adrenaline combination, increases the duration of action of procaine.

12. **Antagonism:** When the action of one drug is opposed by the other drug on the same physiological system is known as drug antagonism. When adrenaline and acetylcholine are given together, they neutralise the effect of each other.

13. **Idiosyncrasy:** An extraordinary response to a drug which is different from its characteristic pharmacological action is called idiosyncrasy. The word idiosyncrasy has now been replaced by the term drug allergy. Penicillin & sulphonamide.

14. **Tolerance:** When an unusually large dose of drug is required to elicit an affect ordinarily produce by normal therapeutic dose of the drug, the phenomenon is termed as tolerance. e.g. smokers can tolerate Nicotine.

15. **Tachyphylaxis:** When certain drugs are administered repeatedly at short intervals, the cell receptors get blocked up (depletion of NT takes place) & pharmacological response to that particular drug is decreased. The decreased response cannot be reversed by increasing the dose. This phenomenon is known as tachyphylaxis. E.g. ephedrine in bronchial asthma.

16. **Metabolic disturbances:** Changes in water electrolyte balance and acid base balance, body temperature and other physiological factor may modify the effect of drugs. The absorption of iron from GIT is maximum if the individual has iron deficiency anemia.

<table>
<thead>
<tr>
<th>3</th>
<th>b) Classify different facial cosmetics. Mention four qualities of a good face powder.</th>
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<tbody>
<tr>
<td>Facial cosmetics:</td>
<td></td>
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<tr>
<td>a) Face powder</td>
<td></td>
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<tr>
<td>b) Rouge</td>
<td></td>
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<tr>
<td>c) Eye makeup</td>
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</table>
### Ideal properties of face powder

1. It should be very fine and should not have any gritty particles.
2. It should be non-toxic.
3. It should be non-irritant to the skin.
4. It should look natural.
5. It should not remove from the skin immediately after its application.
6. It should be stable both physically and chemically.
7. It should have good absorbing property.
8. Its ingredients should be evenly distributed.
9. It should remove shine from the face.
10. It should stick to the face and should not dust off in a few minutes.

### What are the effervescent granules? Why they are prepared? Explain any one method of preparation.

**Definition:** (0.5M)

Effervescent granules are the specially prepared solid dosage form of medicament, meant for internal use.

**Why prepared:** (1M)

- To mask the test of drug.
- When large doses has to be administered.
- Increase rate of absorption.
- Change the pH.

**Method of preparation:** (1.5M)

1. **Heat method:**
   - A large porcelain dish is placed on a water bath, with as much of the dish as possible exposed to the water or steam. The dish must be hot to ensure rapid liberation of water of crystallization from citric acid. If heating of the dish is delayed, the powder which is added to it, will heat up slowly and the liberated water of crystallisation will go on evaporating simultaneously. As a result sufficient water will not be available to make coherent mass.
   - Generally heating takes 1 to 5 minutes. The damp mass is then passed through sieve dried in an oven temperature not exceeding 60°C.

2. **Wet method:**
   - i) The mixed ingredients are moistened with non aqueous liquids (e.g. alcohol) to prepare a coherent mass.
   - ii) It is then passed through a sieve no.8 & dried in an oven at temperature not exceeding 60°C.
   - iii) The dried granules then passed through the sieve to break the lumps which may be formed during drying.
   - iv) Then packed in air tight containers.

### Define mixture. How will you dispense mixture containing precipitate forming liquid?

**Definition:** (1M)

A mixture is a liquid preparation meant for oral administration in which medicament or medicaments are dissolved, suspended or dispersed in a suitable vehicle.

**Dispense:**

1M for definition and 1M
### Method of dispensing:

#### Method of dispensing using compound tragacanth powder:
1. Mix tragacanth mucilage with equal volume of vehicle.
2. Triturate the powder with a portion from ⅔ of vehicle to form smooth cream.
3. Add precipitate forming liquid in the centre of cream and triturate.
4. Add remaining portion of vehicle from 3/4th.
5. Examine for presence of foreign particles, if present pass through muslin cloth
6. Add other liquid ingredient + soluble ingredients.
7. Make up the volume with remaining vehicle

#### Method of dispensing using tragacanth mucilage:
1. Mix Tragacanth Mucilage with equal volume of vehicle.
2. Pour Precipitate forming liquid in center of Tragacanth Mucilage(1/4th) triturate to form sooth cream.
3. Dissolve solid substance if any, in about 1/4th of the vehicle and mix with above mixture.
4. Examine for presence of foreign particles, if present pass through muslin cloth
5. Add other liquid ingredient + soluble ingredients if any.
6. Make up the volume with remaining vehicle

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<table>
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<tr>
<th>3</th>
<th>e) Write in brief about different parts of prescription. Parts of prescription: (0.5 x 6 = 3M)</th>
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<tbody>
<tr>
<td></td>
<td>1. <strong>Date</strong>: It is important to avoid misuse of prescription if it is presented by the patient, a number of times for dispensing.</td>
</tr>
<tr>
<td></td>
<td>2. <strong>Name, age, sex &amp; address of the patient</strong>: The Name, age, sex &amp; address of the patient is important for proper handling of prescription &amp; also identification of patient. Age &amp; sex is important especially for children to check prescribed dose of medication.</td>
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<td>3. <strong>Superscription</strong>: 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.</td>
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<td>4. <strong>Inscription</strong>: This is main part of prescription contains Base, Adjuvant and vehicle or name &amp; quantities of the prescribed ingredients.</td>
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<td></td>
<td>5. <strong>Subscription</strong>: Direction to the pharmacist for preparing dosage form as instructed with quantity. Ex. ‘Mix’, ‘Send tablets’, or ‘capsules’ etc.</td>
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<td></td>
<td>6. <strong>Signature</strong>: It consist of the direction to be given to the patient regarding administration of the drug.</td>
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<tr>
<td></td>
<td>7. <strong>Renewal instructions</strong>: The prescriber indicate on every prescription order whether it may be renewed &amp; if so, how many times. It is important particularly in the prescription containing the narcotic &amp; other habit forming drugs to prevent misuse.</td>
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<td></td>
<td>8. <strong>Signature, address &amp; registration number of the prescriber</strong>: The prescription bears signature, address &amp; registration number of the prescriber. It is important particularly in the prescription containing the narcotic &amp; other habit forming drugs to prevent misuse.</td>
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<table>
<thead>
<tr>
<th>3</th>
<th>f) Comment on the following prescription. Rx</th>
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<tbody>
<tr>
<td></td>
<td>Quinine sulphate………….. 1.5g. (2+1=3 M)</td>
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<tr>
<td>Identification of incompatibility: (2M)</td>
<td></td>
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<tr>
<td>----------------------------------------</td>
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<tr>
<td>Dil. sulphuric acid is added to dissolve the quinine sulphate, but potassium iodide present in formulation react with dil. sulphuric acid to form hydroiodic acid further it gets oxide to form free iodine, now free iodine, hydroiodic acid and quinine sulphate together form iodosulphide of quinine called “herapathite” It form olive green scales after three days stay.</td>
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</table>

**Correction:** (1M)
1. Dispense it for three days.
2. Otherwise dispense in two different bottles ,one bottle containing dil. sulphuric acid with quinine sulphate and in another bottle potassium iodide and water. Instruct the patient to mix them before the dose actually taken.

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### 4 Attempt any FOUR of the followings 12M

#### 4 a) Define shampoo. Describe the formulation of shampoo.

**Definition:** (1M)
Shampoos are used as a preparation containing surface active agents which are used to remove dirt ,grease from the hair without affecting natural gloss of the hair and help to keep hair fragrant,lustrous ,soft and manageable.

**Formulation of Shampoo:** (0.5 X 4 =2M)
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, Propylene Glycol
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 Paraben, Propyl Paraben

#### 4 b) Define cachets, explain its types and write the disadvantages of it.

**Definition:** - (0.5M)
Cachets are the solid Unit dosage form of drugs. These are moulded from rice paper, used to enclose nauseous or disagreeable Powders and are available in different sizes to hold drugs from 0.2 to 1.5 gm of powders.

**Types:**
- **Wet sealed:**
  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 sealed:**
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.

**Disadvantages:**
1) They have to be soften before swallowing
2) They are easily damaged
3) They cannot protect drug from light and moisture
4) The shell is very fragile
5) They cannot be manufactured on large scale

**4 c) Mention essential characteristics of different ophthalmic products. Explain any two in brief.**

**Characteristic:**
- It should be Free from foreign particle.
- It should be Isotonic with lachrymal secretion.
- Viscosity.
- pH.
- Sterility.
- Surface activity: wetting

1. Foreign particle: all the ophthalmic product should be clear and free from foreign particles, fibers and filaments. Ophthalmic solution should be clarified very carefully by passing through bacteria proof filters, such as, membrane filters and sintered glass filters.

2. Viscosity: In order to prolong the contact time of the drug in the eye, various thickening agents are added in the ophthalmic preparations. Polyvinyl alcohol (1-4%), polyethylene glycol, methylcellulose, carboxy methylcellulose are some of the commonly used thickening agents.

3. Ophthalmic products must be isotonic with lachrymal secretions to avoid discomfort and irritation. It has been observed that eye can tolerate a range of tonicity from 0.5 to 2% sodium chloride. There are certain isotonic vehicles which are used to prepare ophthalmic products like 1.9% boric acid, sodium acid phosphate buffer.
4. **pH of the preparation:** pH plays an important role in therapeutic activity, solubility, stability and comfort to the patient. Tears have a pH of about 7.5. Eye can tolerate solution having wide range of pH provided they are not strongly buffered, since the tears will rapidly restore the normal pH value of the eye. Alkaloidal salt solutions are stable at pH 2 to 3 but this pH is irritant to the eye. The alkaloids get precipitated at pH above 7 and creates a number of formulation problem.

5. **Sterility:** Ophthalmic preparation must be sterile when prepared. Pseudomonas aeruginosa is very common gram negative bacteria which is generally found to be present in ophthalmic products. It may cause serious infection of cornea. It can cause complete loss of eye sight in 24-48 hours.

6. **Surface activity:** Vehicles used in ophthalmic preparation must have good wetting ability to penetrate cornea and other tissues. Certain surfactants or wetting agents are added which are found suitable for ophthalmic products. E.g. Benzalkonium chloride, polysorbate 20, polysorbate 80.

4 d) **Find the quantity of sodium chloride required to yield a solution iso-osmotic with blood plasma of procaine hydriehloride 1.5% w/v.** (given F.P. of 1% w/v procaine HCl = -0.122°C)

Percentage w/v of adjusting substance needed = \(0.52 - \frac{a}{b}\)

Where \(a =\) freezing point of the unadjusted solution
\(b =\) Freezing point of a 1% w/v solution of the adjusting substance.

As the concentration of **procaine hydriehloride** in the preparation is 1.5% w/v, the depression in freezing point of **procaine hydriehloride** = 0.122 X 1.5 = 0.183°C

Percentage w/v of sodium chloride required = \(\frac{0.52 - 0.183}{0.576}\) = 0.585% w/v

Weight of sodium chloride required = 0.585 g

4 e) **Discuss in brief processing of parental preparations.**

**Steps Involved:**

1. **Cleaning** of containers, closures and equipments: All the containers, closures and equipments which are required for the preparation are cleaned thoroughly with detergent and washing is done with tap water followed by distilled water and finally rinsed with water for injection. Rubber closures are washed with hot solution of 0.5% sodium pyrophosphate in water, than washed with water and rinsed with water for injection.

2. **Collection of materials:** Ingredients of parental preparation are weighed and collected in preparation room all the ingredients has to be of pharmacopial standards Water for injection which is free from pyrogen has to be used for preparation.

3. **Preparation of parenteral product:** The pharmacist should decide the order of mixing and exact method of preparation to be followed before preparing the parenteral product, the parental preparations must be prepared under strict aseptic conditions.
4. **Filtration:** The parental solution so formed is passed through bacteria proof filter, the primary objective is to clarify the solution by removing foreign particles, if the preparation has to be sterilized by filtration than it has to be done in strict aseptic conditions before it is transferred into final container and sealed.

5. **Filling the preparation in final containers:** The filtered product is filled into final container, which are cleaned dried and sterilized on small scale hypodermic syringe and needle are used and on large scale automatic filling machine are used. The sterile powders are filled into the container by individual weighing or by using automatic or semi automatic devices. The filling operation is carried under strict aseptic precautions.

6. **Sealing the container:** Sealing should be done immediately after filling. Ampoules are sealed manually on a small scale, but on a large scale ampoule sealing machine is used. Vials and transfusion bottles are sealed by closing its opening with rubber closures, and then crimping of aluminum cap is done manually or mechanical means.

7. **Sterilization:** The parental preparation should be immediately sterilized after sealing any method of sterilization can be used depending on nature of medicaments present in the preparation.

8. **Evaluation of parentral preparations:** The finished products are subjected to following tests in order to maintain quality control a) sterility test b) clarity test c) leakage test d) pyrogen test e) essay.

4 f) In what proportion 12%, 10% and 6% ointment be mixed in order to obtain 20 gm of a 8% ointment.

12  2 parts of 12%
10  8  2 parts of 10%
6  4 + 2 = 6 parts of 6%
Total parts = 10 parts

For 12%:
10 pars; 02 parts
20 gm; ?
20 X 2/10 = 4gm

For 10%:
10 pars; 02 parts
20 gm; ?
20 X 2/10 = 4gm

For 6%:
10 pars; 06 parts
20 gm; ?
20 X 6/10 = 12gm

5 Attempt any FOUR of the following.
5 a Define i) Epilation  ii)Depilation .Mention any four qualities of ideal depilatory agents

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.

Qualities of Ideal depilatory agents:
1. It should be non-toxic and non irritant to the skin.
2. It should be odourless but pleasantly perfumed.
3. It should be elegant.
4. It should not leave any stains on the cloth.
5. It should be capable of removing the hair within 2-5 mins
6. It should be easy to apply.
7. It should be economical.
8. It should be stable during storage.

5 b) Differentiate between flocculated and deflocculated suspension.

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Flocculated suspension</th>
<th>Deflocculated suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Particles form loose aggregates and form a network like structure.</td>
<td>Particles exist as separate entities.</td>
</tr>
<tr>
<td>2</td>
<td>The rate of sedimentation is high</td>
<td>The rate of sedimentation is slow</td>
</tr>
<tr>
<td>3</td>
<td>Sediment is rapidly formed</td>
<td>Sediment is slowly formed</td>
</tr>
<tr>
<td>4</td>
<td>Sediment is easy to redisperse</td>
<td>Sediment is difficult to redisperse</td>
</tr>
<tr>
<td>5</td>
<td>Sediment is loosely packed and does not form a hard cake</td>
<td>Sediment is very closely packed and a hard cake is formed</td>
</tr>
</tbody>
</table>

3M (Definition 1M each, qualities 1M)
5 c) **Define Dentifrices and explain the formulation additives used in dentifrices with examples.**

**Definition:**
Dentifrices are the preparations meant to be applied to the teeth with the help of a toothbrush for the purpose of cleaning the accessible surface of the teeth.

**Additives:**
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 be used as it may damage the tooth structure.

2) **Detergents:**
They contain a suitable detergent or soap. Soap removes the debris from the surface of the tooth by the mechanism of emulsification.

3) **Binders:**
Binders are used to keep the solids and liquids in the united form and to maintain the consistency.
Ex. gum tragacanth, sodium alginate, methyl cellulose, etc.

4) **Humectants:**
Humectants are added to prevent the drying of the preparation.
Ex. Glycerin, propylene glycol, etc.

5) **Preservatives:**
Preservatives are used to prevent growth of bacteria in the preparations.
Ex. Methyl paraben, propyl paraben.

6) **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.

7) **Colours:**
Colour is added to improve appearance of preparation to make it attractive.
Ex. Coal tar dyes,

8) **Flavours:**
Flavours are added to improve the taste of the formulation.
Ex. Peppermint oil, cinnamon oil, etc.

5 d) **Give significance of particulate matter monitoring and explain any two methods for particulate matter monitoring.**

**Significance:** Presence of particulate matter in IV solutions may lead to septicemia,
fever and blockage of small blood vessels. The presence of undissolved particles create doubt about the quality of product

Methods:
1) Visual method
2) Coulter counter method
3) Filtration method
4) Light blockage

**Visual Method:**
It is an old but reliable method. The filled containers are examined against strong illuminated screen by holding the neck and rotating it slowly or inverted it to exclude the possibility of foreign particles. If any particulate matter is visible, that container is rejected.

**Coulter Counter Method:**
The method is based on the principle that increase in resistance is observed between two electrodes, as the particle approaches and passes through the orifice. An electrolyte is required to be included in the preparation before its evaluation. The particles with diameter below 0.1 /um can be detected by this method.

**Filtration method:**
The liquid sample is passed through a filter and the material collected on the surface of the filter. It is examined under microscope.

**Light blockage method:**
It allows a stream of the fluid under test to pass between a bright white light source and photodiode sensor. It is possible to detect cross sectional area in this instrument because it blocks the path of light and size of the particle is considered as a diameter of a circle of equivalent area.

5 e) **Classify ointment base with one example each. Give disadvantage of paraffin base.**

**Classification of Ointment bases:**
2) Absorption base:
   i) Non-emulsified base: eg wool fat, wool alcohol
   ii) Water in oil emulsions: eg. hydrous wool fat(lanolin)
3) Emulsion bases (Water miscible base): eg Emulsifying ointment
4) Water soluble base: eg. Propylene glycols, carbowaxes

**Disadvantages of Paraffin bases:**
- They are greasy
- They are sticky & difficult to remove both from skin & clothing
- They retain body heat which may produce an uncomfortable feeling of warmth.
- They do not help in the absorption of medicaments
- They prevent drainage from oozing areas of also prevent evaporation of cutaneous secretions along with perspiration.

5 f) **Prepare and dispense the Iodoform suppository**

Rx

| Iodoform | .......... 0.9 gm |
| Cocoa butter | sufficient quantity |

Make the suppositories.
Send 8 suppositories of 2 g each.
Note- Displacement value of iodoform is 4.0

Calculation: Calculate for 2 extra suppositories
Weight of cocoa butter for one suppository= 2 gm
Weight of cocoa butter for 10 suppositories = 2x 10=20g
Weight of iodoform for one suppository=0.9 g
Weight of cocoa butter for 10 suppositories= 0.9x 10=9 g
Displacement value of iodoform=4.0

The quantity of cocoa butter required = Total amount of base - Displacement Value

\[
\text{Total amount of drug} = 20 - 9.0/4.0
\]
\[
= 20 - 2.25
\]
\[
=17.75 g
\]

Formula for 10 suppositories is as under
Iodoform .................9.0 g
Cocoa butter ----------17.75 g

6   Attempt any FOUR of the following.  16M

6 a) Define Emulsion and classify polysaccharide emulsifying agents with one example each and list disadvantages of it.
Definition:
An emulsion is a biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other.
Classification of polysaccharide emulsifying agent.
  a) Methyl cellulose They are used as suspending, thickening and emulsifying agents they are used in concentration of 2%
  b) Sodium carboxy methyl cellulose :They are used in concentration of 0.5-1.0%
Some people may have allergic reaction or sensivity to cellulose gum although this is extremely rare.

6 b) Mention the qualities of ideal suspension. Explain any two methods used for evaluation of physical stability of suspension
The qualities of Ideal suspension.
1. It should settle slowly
2. It should be readily re-dispersed on gentle shaking of the container.
3. It should pour readily and evenly from its container.
4. It should be chemically inert.
5. The suspended particle should not form a cake.
6. It should be free from large particles which spoils its appearance & give gritty taste to oral preparation & also cause to irritation to sensitive tissues when applied externally.

Methods of evaluation of suspension.
Method of evaluation:
  • Sedimentation Method:
  • Rheological Method:
  • Electrokinetic's Method:
Micromeritic Method:

- **Sedimentation Method:**
  - Sedimentation volume is the most important parameter in the evaluation of the stability of suspension.
  - It is determined by keeping a measured volume of the suspension in a graduated cylinder in an undisturbed position for a definite period of time and noting the ultimate height \( (H_u) \) of the sediment and initial height of the total suspension.
  - The sedimentation volume \( F \) is the ratio of the ultimate height and initial height \( (H_u/H_o) \).
  - The sedimentation volume plotted against time, the graph indicates the sedimentation pattern of suspension on storage.
  - A stable suspension shows a horizontal or less steep curve.
  - The evaluation of redispersibility can also be determined by shaking the suspension and again finding out the sedimentation volume \( (H_u/H_o) \).

- **Rheological Method:**
  - The viscosity of the suspension is studied at different time intervals by using a good quality of viscometer.
  - It provides useful information regarding the stability of suspension.

- **Electrokinetic's Method:**
  - The determination of surface electric charge or zeta potential is helpful to find out the stability of suspension.
  - Certain zeta potentials produce more stable suspensions because of controlled flocculation.
  - Zeta potential can be calculated from the migration velocity of the particles measured by the electrophoretic method.

Micromeritic Method:

- The stability of suspension depends on the particle size of the disperse phase.
- The size of the particle in a suspension may grow and may ultimately lead to the formation of lumps or cracking.
- So any change in the particle size with reference to time will provide useful information regarding the stability of a suspension.
- A change in particle size distribution and crystal habit may be studied by microscopy and coulter counter method.

### 6c) Define Suppository. Explain cold compression method of preparation of suppositories.

**Definition:**

Suppositories are solid dosage form of medicament for insertion into body cavities other than mouth.

**Method:**

- Compression moulding is a method of preparing suppositories from a mixed mass of grated suppository base and medicaments which is forced into a special compression mould using suppository making machines.
- The suppository base and the other ingredients are combined by thorough mixing.
- The friction of the process causing the base to soften into a past-like consistency.
- In the compression machine, the suppository mass is placed into a cylinder which is
then closed.

- Pressure is applied from one end to release the mass from the other end into the suppository mould or die.
- When the die is filled with the mass, a movable end plate at the back of the die is removed and when additional pressure is applied to the mass in the cylinder, the formed suppositories are ejected.
- The end plate is returned, and the process is repeated until all of the suppository mass has been used.

### EYE MAKEUP

- **MASCARA**
- **EYE SHADOW**
- **EYEBROW PENCIL**
- **EYE LINER**

#### 1) MASCARA

- Black pigmented preparation for application to eyelashes or eyebrow to beautify the eyes.
- It darkens the eyelashes & improves brightness & expressiveness of eyes.
- Applied with brush.

It is available in 3 forms:

- **Cake mascara**: prepared by melting together waxy material, adding the colours. E.g. Lamp black.
- **Cream mascara**: prepared by mixing the pigments in vanishing cream base.
- **Liquid mascara**: it is alcoholic solution of resin in which carbon black is
2) EYE SHADOW
- Applied to eyelids in order to produce an attractive moist looking background to the eyes.
- It is available in variety of shades like pink, yellow, green & brown.
- Available in following forms:
  - EYE SHADOW CREAM: Prepared by mixing selected colours in the wax bases or with petroleum.
  - EYE SHADOW STICK: contains high proportion of waxes, e.g., Carnauba wax.
- LIQUID EYE SHADOW: are liquid suspension or a liquid dispersion of pigments.

3) Eyebrow pencil-
Eyebrow pencil is used to accentuate line of eyebrow or to modify their outline after packing.
These are available in brown or black colour. The brown eyebrow pencil contains black iron oxide. The eyebrow pencil contains a high proportion of waxes to make them hard, so that they can be moulded as a thin stick sharpened to a point.

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

Ideal qualities of eye make up preparations.
- It should not cause irritation to the eyes.
- It should be non-toxic
- It should be applied easily, evenly, and smoothly.
- Mascara should not cause eye lashes to stick together.

6 e) Classify monophasic liquid dosage forms. Mention any three advantages of syrups and give reason why glycerine is used as vehicle in preparation of Throat paint.

Classification:

<table>
<thead>
<tr>
<th>Monophasic Liquid Dosage Form</th>
<th>Internal</th>
<th>External</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Syrup</td>
<td>Elixir</td>
</tr>
<tr>
<td>Application</td>
<td>Used in</td>
<td>Instilled into body cavities</td>
</tr>
<tr>
<td>On the skin</td>
<td>Mouth</td>
<td></td>
</tr>
</tbody>
</table>

(Classification 2M, advantages of syrups 1M, give reason 1 M)
Advantages of syrups
- It retards oxidation as it is partly hydrolysed into reducing sugars such as levulose and dextrose.
- It prevents decomposition of many vegetables substances.
- They are palatable.

Glycerine is used as vehicle in throat paint.
- Glycerine is viscous in nature and adheres to the throat
- Increases contact time and prolong the action
- It is also act as soothing agent.

6 f) Define cracking. Explain any six factors responsible for cracking.

Definition:
Cracking means the separation of two layers of disperse and continuous phase due to coalescence of disperse phase globules which are difficult to redisperse by shaking.

factor responsible for cracking of emulsion.
The following factors results in the cracking of emulsion.

1. 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

2. Decomposition of emulsifying agent:
When acid is added to alkali soap emulsion it causes decomposition of emulsifying agent & thus leading to cracking of emulsion.

3. 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.

4. Growth of microorganism:
Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking.

5. Change in Temperature:
Increase in temperature leads to reduction in viscosity; encourage creaming thus leads to cracking. Low temperature causes freezing of water content.

6. By creaming:
A creamy emulsion is more liable to crack than a homogenous emulsion.