SUMMER-16 EXAMINATION

Subject Code: **0811** **Model Answer** Page No: 01/23

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.

1. Attempt any EIGHT of the following: 16

a. Define the term- posology and official doses.(1 X 2 = 2M)

Posology: it is the branch of medical science which deals with dosage or quantity of drug.

Official Dose: it is the quantity of drug/doses to be taken which is mentioned in the official pharmacopiea, like IP, BP, USP etc.

b. List reasons causing therapeutic incompatibilities. (0.5 X 4 = 2M)

1. Error in dosage.
2. Wrong dose or dosage form.
3. Synergism and Antagonism drug.
4. Contraindication.
5. Drug interactions.

c. How much 5% solution is required to prepare 600 ml of a 1 in 800 solution?

Data given:

Strength of concentrated solution: 5%

Strength of dilute solution: 1 in 800 = 0.125%

$$\text{Strength of dilute solution} = \frac{\text{Strength of conc.}}{\text{Degree of dilution}}$$

$$\text{Degree of dilution} = \frac{\text{Strength of conc.}}{\text{Strength of dilute solution}}$$

$$\text{Degree of dilution} = \frac{5}{0.125}$$

$$= 40 \text{ times}$$

Volume of the solution to be prepared = 600 ml

Therefore,

Dilute solution obtained by diluting 600/40 = **15 ml** of 5% solution to 600 ml.

d. Give minimum weighable quantity of powder on dispensing balance.

Ans: 2 grain in imperial system & 100mg in metric system.

e. Enlist monophasic dosage form for internal use and define any one.

monophasic dosage form for internal use (0.5 X 2 = 1M)

1. Syrup.
2. Elixir.
3. Mixture.
4. Linctus.

Definition: (1 x 1 =1M)

Syrup: Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar (USP contains 64.74 w/v of sugar) having specific gravity 1.31g.

Elixir: Elixirs are clear, sweetened and flavored hydro alcoholic liquid preparation intended for oral use.

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

Linctuses: Linctuses are viscous, monophasic liquid preparation containing a high concentration of syrup intended to be sipped and swallowed slowly for treatment of cough.

f. Name four methods of preparation of syrup.(0.5 X 4 = 2M)

1. Simple solution with heat
2. Simple solution without heat (cold Method)
3. Chemical reaction.
4. Extraction.

g. Define with example (any one) (Def. 1M and any one example 1M = 2M)

i. Elixirs: Elixirs are clear, sweetened and flavored hydro alcoholic liquid preparation intended for oral use. Ex. Chloral Hydrates elixir, Piperazine citrate elixir, etc.

ii. Emulsions: it is a biphasic liquid preparation containing two immiscible liquids which are made miscible by adding emulsifying agent. Ex. castor oil emulsion, liquid paraffin emulsion, olive oil emulsion, etc.

iii. Throat Paint: Throat paint is viscous preparation of medicament used for application in throat for its local action. Ex. Mandl's Paint B.P.C.

h. Explain the term Vanishing cream and cold cream. (1 X 2 = 2M)

Vanishing cream :(Marks can be given for any two points)

- These are oil in water type emulsion which when applied to the skin leave an almost invisible layer on it. Hence, they are called vanishing cream.
- These creams can quickly washed off with water due to a presence of o/w emulsifier.
- Vanishing creams are prepared by emulsification of stearic acid and water by means of alkalies such as sodium hydroxide, potassium hydroxide, borax, triethanolamine etc.
- The main ingredient in vanishing cream is stearic acid which gives a pearly white shinning appearance to the cream, which on application gives a thin white film of free stearic acid.

Cold cream :(Marks can be given for any two points)

- Cold cream is an emulsion, which when applied on the skin; a cooling effect is produce due to slow evaporation of water present in the emulsion.
- They are generally prepared by emulsifying of oils and water.
- Vegetable oils have the tendency to become rancid; they are replaced by mineral oil which gives a more stable product.
- Cold cream are o/w type emulsion but after application on the skin, sufficient water evaporates to permit phase inversion to w/o type.

i. Define poultice or list bases used for paste. (Any one 2M)

Poultice: these are soft, viscous, wet masses of solid substance applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as counter –irritant.

Bases used in paste :(2 Marks can be given for any 3 examples)

- **Hydrocarbon bases:** ex. Hard and soft paraffin and liquid paraffin.
- **Water miscible bases:** ex**.** emulsifying ointments.
- **Water soluble base:** ex. Carbopole, PEG.etc.

- Paste with gelatin base -A hot 2% gelatin solution is used which becomes jelly on 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
- Paste with starch base (gelatinized or ungelatinised) In case of gelatinized paste 10% starch solution is prepared and gelatinized by heating and than 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.
- 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.
- Paste with cellulose derivatives-cellulose ether are dissolve in cold water and allowed to stand overnight it forms jelly and in this solid substances are incorporated
- Paste with pectin base-

j. Name different types of jellies with example.

(Any two type with example 1 +1 =2M)

i) **Medicated jellies** are used on mucous membrane and skin for their spermicidal, local anesthetics and antiseptic properties.

ii) **Lubricating jellies** are used for lubrication of diagnostic equipment such as, surgical gloves, stethoscopes, fingerstalls, catheters, rectal thermometers.

iii) **Cosmetic jellies:** set wet gel.

iv) Miscellaneous jellies:

a) Patch testing: these jellies are used as a vehicle for allergens which are applied on the skin to check the sensitivity.

b) Electrocardiography: The jelly is applied on the electrode to reduce the electrical resistance between the patient's skin and the electrode.

k. Explain basic principal of test for pyrogen on rabbits.

Principle: (2Mark)

- The test involves the measurement of the **rise in the body temperature** of rabbit following i.v. injection of a sterile solution of a substance being examined.
- Rabbits are used to perform this test because they are more sensitive to pyrogen.

l. Define eye drop and eye lotion. (1 X2 = 2M)

Eye drop: Eye drop are sterile aqueous or oily solution or suspension of drugs that are instilled into the eye with the dropper

Eye lotion: These are the sterile aqueous solutions used for washing of the eyes.

2. Attempt any FOUR of the following: 12

a. Define the term prescription, and list various errors seen in dispensing prescription.

Definition: (1M)

Prescription is a written order from a registered medical practitioners, such as dentist, veterinarian etc. to a pharmacist to compound & dispense a specific medications for the patient.

List various errors: (0.5 X 4 =2M)

1. Abbreviation.
2. Name of drug.
3. Strength of the preparation.
4. Dosage form of the drug prescribed.
5. Dose.
6. Instruction to patient.
7. Incompatibility.

b. Point out the incompatibility and suggest suitable remedy.

Rx

Sodium salicylate ……..5gm.

Syrup of lemon ……. 20 ml.

Water to make …….. 75 ml.

Ans: (1.5 for incompatibility and 1.5 for remedy =3M)

In above prescription syrup of lemon contain citric acid which react with sodium salicylate and form salicylic acid which is a indiffusible solid, therefore substitution should be done with syrup and lemon tincture which will serve the purpose of lemon syrup because lemon syrup is added for sweetening & flavouring purpose and it will form a clear mixture and not affect the therapeutic property of the mixture.

c. Define the term, synergism and additive effect with example.

Synergism and additive effect: (1mark for definition and 0.5 marks for example each)

Synergism: When two drugs are prescribed together, they tend to increase the effect of each other, this is known as synergism. **Ex.** Combination of aspirin and paracetamol increase analgesic effect, combination of penicillin and streptomycin increase antibacterial effect of antibiotics.

Additive effect: when the pharmacological action of two or more drugs administered together is equivalent to sum of their individual pharmacological action, the phenomena is called additive effect. **Ex**. ephedrine and aminophylline in treatment of bronchial asthma.

d. Calculate quantities of 20%, 15%, and 10% of alcohol to make 1.5 liters of 12%alcohol. (3M)

20		2 parts for 20%
15	12	2 parts for 15%
10		8 + 3 = 11 parts for 10%
	Total = 15 parts.	

1. For 20%

15 parts; 2parts

1500 ml; ?

1500 X 2/15 = 200 ml

2. For 15%

15 parts; 2parts

1500 ml; ?

1500 X 2/15 = 200 ml

3. For 10%:

15 parts; 11parts

1500 ml;?

1500 X11/15 =1100 ml

e. Translate the term in English and convert as directed. (0.5 X 6 = 3M)

1. Mitte tales: send such.
2. More dictodanda: as directed, or in the manner prescribed.
3. Si opus sit: when required or when necessary.
4. Tussi urgent: when cough is troublesome.
5. One desert-spoonful: 8ml.
6. One fluid drachm: 3.6 ml or 4 ml approx.
7. 60 mg = 1 grain or 0.92 grain approx.

f. Define mixture and draught. Give steps in preparing mixture containing diffusible solid.

Definition: (1 X2 =2M)

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

Draught: These are the liquid preparation to swallow once whole.

Method of preparation: (1M)

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

Smooth cream

Add remaining vehicle from 3/4th

Add to measure

Add other liquid ingredient

↓

Strain through muslin cloth for removal of foreign particles

↓

Make up the volume with remaining vehicle

3. Attempt any four of the following: **12**

a) Define the term Suspension and explain storage and labelling of various suspensions.

(1 marks for definition and 1 marks for storage and1 marks for labelling.)

Ans: Pharmaceutical suspensions are the biphasic liquid dosage form of medicament in which the finely divided solid particles ranging from 0.5 to 5.0 micron are dispersed in a liquid or semisolid vehicle.

Storage and labelling of various suspensions.

"Shake well before use".

In case of dry suspension powders, the specified amount of vehicle to be mixed may be indicated clearly on the label.

labelling of various suspensions

Suspensions should be "**store in a cool place**". **"Do not refrigerate"** because it may lead to aggregation of the suspended particles

Q3b) What is primary emulsion? Explain the preparation of emulsion by 'wet gum method.

(1 marks for definition 2 marks for method.)

Primary emulsion is biphasic liquid preparation having two immiscible liquid with emulsifying agent with nearly white appearance, due to internal reflection of light.

Wet gum method:

1) Calculate the quantity of oil, water and gum required for preparing primary emulsion

2) Powder the gum acacia in a mortar. Add required quantity of water and triturate it with gum so as to form mucilage

3) Add required quantity of oil in small portions with rapid trituration until a clicking sound is produced and the product becomes white. At this stage emulsion is known as primary emulsion.

4) Add more of water in small proportion to the primary emulsion with trituration to produce the required volume. Stir thoroughly so as to form a uniform emulsion

5) Transfer the emulsion to a bottle, cork, label and dispense.

3c) Explain physical incompatibility due to Liquefaction of solids and give methods of dispensing such substances.

(1 mark Liquefaction and 2marks for methods of dispensing)

Liquefaction: When certain low melting point solids are mixed together they form a new chemical compound which has melting point lower than room temperature, therefore they become liquid at room temperature.

Rx

Menthol ---------- 5g.

Camphor ---------- 5g.

Ammonium chloride ---------- 30g.

Light magnesium carbonate ---- 60g.

Send five powders

The combination forms eutectic mixture.

The substance can be dispensed by any one of the following methods;

i) Triturate together to form liquid and mixed with an absorbent like light kaolin or light magnesium carbonate to produce free flowing powder.

II) The individual medicaments are powdered separately and mixed with absorbent and then combined together lightly and filled in suitable container.

3d) Write the qualities of Ideal suspension.

The qualities of Ideal suspension. (0.5 X 6=3marks)

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.

Q.3 e) Define the term 'Creaming of Emulsion' and explain Stoke's law is applies to minimize decrease the rate of creaming in emulsions? (1mark for definition, 2 mark for equation, consider 4 factors for each 0.5 mark)

Ans:

Creaming: (1M)

- When large globules or aggregate of globules rises to the top of an emulsion or fall to the bottom and form concentrated thick layer.
- Temporary phase.
- Creaming should be avoided because it leads to cracking.
- Stock equation:

$$V = \frac{2r^2 (d_1 - d_2) g}{9\mu}$$

Where; V= rate of creaming

r = Radius of globules

d_1-d_2= Difference between the Density of dispersed phase and continuous phase

μ = Viscosity

g = gravitational constant

Factors (0.5 X4 = 2M)

i)Radius of the globules:

The rate of creaming is directly proportional to the radius of the globules. The small globules will rise less quickly than larger globules. Hence, creaming can be reduced by reducing the size of the globules by passing the emulsion through a homogenizer.

ii)Difference in densities of the disperse phase and continuous phase:

Greater the difference more will be the creaming. The difference can be reduced but it is not desired because it is not required therapeutically.

iii)Viscosity of the dispersion medium:

It is inversely proportional to rate of creaming, if viscosity of the dispersion medium is increased rate of creaming decreases

iv)Storage condition:

The emulsion should be stored in cool place because the rise in temperature reduces the viscosity may lead to creaming. Freezing should be avoided because it may lead to cracking of emulsion.

3f) Define the term' Emulsifying agents.' Write the qualities of ideal emulsifying agents.

(Definition (1 mark, Ideal properties 2 marks)

Ans: The emulsifying agent are defined as agent reduce the interfacial tension between two phases i.e. oily & aqueous phase & thus make them miscible with each other & form a stable emulsion.

Ideal properties:

1) It should be capable of reducing the interfacial tension between the two immiscible liquids.
2) It should be compatible with other ingredients of the preparation.
3) It should be non toxic.
4) It should be capable to produce and maintain the required consistency.
5) It should be chemically stable.
6) It should be capable of keeping the globules of dispersion liquid distributed indefinitely throughout the dispersion medium.

Q.4a) Name the ingredients in Kaolin Poultices BPC with their role in the formula (3M)

Name of the ingredients(1.5mark) and role in formula(1.5 marks).

Ans : Name of the ingredients role in formula

Heavy Kaolin dried at 100^0C and finely sifted. -----absorbent

Boric acid, finely sifted------antimicrobial agent

Thymol---- a Bactericide

Peppermint oil-----for Odour

Methyl salicylate -----–anti-rheumatic drug

Glycerin-------Hygroscopic in nature, draws infected material

Direction: Spread the warm poultice on a dressing material and applied on the affected part.

4b) **Differentiate between Pastes and Ointments Difference: (any six points 0.5 X 6 = 3).**

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

4**c) What are creams? Explain their method of preparation.**

(1mark for definition, 2 marks for method).

Ans::

Creams are viscous semi-solid emulsions which are meant for external application to the skin or mucous membrane for protective, therapeutic or prophylactic purposes.

General method of preparation of creams(Emulsification)

- The fats, oils, and waxes are melted together on water bath at temperature of 70^0 C.
- The aqueous solution of all the heat stable water soluble components are also heated at the same temperature as that of melted bases.

- Add aqueous phase to oily phase with continuous stirring until the product cools down and semi-solid mass is formed.
- Rapid stirring is avoided to prevent air entrapment.
- Transferred it into suitable container, cork it and label.

4d) Classify ointment bases and give disadvantages of Oleaginous Bases.

(1 mark Classification of Ointment bases)

Ans: Classification of Ointment bases:

1) Oleaginous bases: eg. Hard paraffin., Soft paraffin, Liquid paraffin.

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 Oleaginous bases: - (0.5 X 4 = 2M)

1. They are greasy
2. They are sticky & difficult to remove both from skin & clothing
3. They retain body heat which may produce an uncomfortable feeling of warmth.
4. They do not help in the absorption of medicaments
5. They prevent drainage from oozing areas of also prevent evaporation of cutaneous secretions along with perspiration.

4e) Explain the term Gel and Jelly. Give formulation of Jellies.

(1/2mark each for definition Gel and Jelly , 2 marks for formulation).

Gel is a colloid in which the disperse phase has combined with the dispersion medium to produce a semi solid material, such as a jelly

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

Formulation ofjellies:

1. Gelling agent: These are usually organic hydrocolloids but occasionally, a hydrophilic inorganic substance is more appropriate.

a. Tragacanth

b. Sodium alginate

c. Pectin

d. Starch

e. Gelatin

f. Cellulose derivatives

2. Preservatives: The jellies contains large amount of water so they are prone to bacterial and fungal growth.the jellies are preserved by adding preservatives like

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 (0.02 %)

3. Other ingredients.-Loss of water can quickly lead to skin formation on jellies .To prevent this a hygroscopic substance such as glycerine, propylene glycol can be added. Bases and Medicaments are sensitive to heavy metals are sometimes protected by a chelating agents such as E.D.T.A.

4(f) Prepare calcium gluconate injection 5%, isotonic with adjusting substance NaCl (0.5 M for formula, 2.0 M for calculation and 0.5M for unit)

Ans: Data Given:

F.P.of 1%w/v solution of cocaine hydrochloride = - 0.091^0C

& F.P.of 1%w/v solution of sodium chloride = -$.58^0$C

Formula:

Qty of sodium chloride required= 0.52-a/b

Where, a = F.P.of 1%w/v solution of unadjusted substance

And b = F.P.of 1%w/v solution of adjusting substance

= 0.52- (5 X 0.091)/0.58

= 0.52-0.455/0.58

= 0.112 % w/v

Q.5 Attempt any FOUR of the following:

a) Define the term suppository and classify various types of suppositories.

Definition (1 mark)

Suppositories are solid dosage form of medicament for insertion into body cavities other than mouth. They may be inserted into rectum, vagina or nasal cavity.

Types: (0.5 X 4 =2M)

1) Rectal suppositories
2) Vaginal suppositories
3) Nasal suppositories
4) Urethral suppositories
5) Ear cones suppositories
6) Tablet suppositories
7) Layered suppositories
8) Capsule suppositories
9) Coated suppositories
10) Disposable mould suppositories

b) How will you find displacement value of a medicament?

Example – (0.5 marks for each step)

1. Prepare & weigh 6 suppositories containing theobroma oil = a g.

2. Prepare & weigh 6 suppositories containing, 40% medicament = b g.

3. Calculate the amount of theobroma oil present in medicated suppositories

= 60/100 X b = c g.

4. Calculate the amount of medicament present in medicated suppositories

= 40/100 X b = d g.

5. Calculate the amount of theobroma oil displaced by d g of Medicament = (a-c) g.

6. Displacement value of the medicament = d/ (a-c)

c) Define displacement value with examples and explain its importance in preparation of suppositories.

Definition: (1mark)

Displacement value of a medicament is defined as "The quantity of the drug which displaces one part of the base."

Example:(1mark) (any two examples)

Sr.no	Name of the Medicament	Displacement value
1	Boric acid	1.5
2	Castor oil	1.0
3	Iodoform	4.0
4	Resorcinol	1.0
5	Zinc oxide	5.0
6	Tannic acid	1.0

Importance :(1mark)

For preparation of uniform suppositories, accurate weight, allowance must be made for the change in density of the mass due to added medicament. For this purpose displacement value is consider.

d) List the various dentifrice products and give qualities of good dentifrice.

Dentifrice products :(1mark)

- Liquid dentifrices
- Tooth powders
- Tooth pastes.

Qualities of good dentifrice.(0.5 x 4=2 mark)

- It should be economical.
- It should be non-toxic.
- It should be properly sweetened & flavoured.
- It should give fresh & clean sensation.

- It should be efficient in removing food substances, plaques & other foreign particles.
- It should clean the teeth.

e) Define 'Shampoo'. Write the qualities of an ideal shampoo.

Definition: (1mark)

Shampoos may be define as preparation containing surface active agents which are used to remove dirt grease and debris from the hair scalp and other part of body without affecting the natural gloss of hair

Qualities of an ideal shampoo. (0.5 x 4=2 mark)

- It should be capable of removing grease, dirt, and skin debris from the hair and scalp.
- It should be non-toxic.
- It should be non-irritant.
- It should provide sufficient fragrance to the hair after its use.
- It should be effective in small amounts
- It should get easily removed by washing with water.
- It should produce sufficient foam, both in hard soft water.
- It reduces the fluffiness and smoothens the hair shafts.
- It makes the hair soft and shiny.

f) Describe 'Depilation and Electrolysis' methods for removal of hair.

Depilation :(1.5 marks)

When the hairs are removed by chemical methods without injury to the skin is known as depilation. The chemicals most commonly used are Sulphides of barium, calcium & strontium. Calcium thioglycerol & calcium thioglycolate are also used. Calcium sulphide is popular depilating agent without serious effect. Depilatories are available in the market as powder, lotion, cream and paste.

Electrolysis: **(1.5 marks)**

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.

Q.6 Attempt any four of the following.

a) Define parentral products. Give general requirements for parentral dosage forms.

Definition of parenteral products (1 mark for definition)

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

General requirements for parentral dosage forms. (0.5 X 6 = 3)

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

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

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

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

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

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

vii) Specific gravity: The specific gravity of preparation if it is meant for intra spinal route should be same as spinal fluid.

b) Enlist various steps involved in processing of parentral products. (0.5 X 8 = 4)

- Cleaning of containers, closures and equipment.
- Collection of materials.
- Preparation of parentral products.
- Filtration.
- Filling the preparation in final containers.
- Sterilisation.
- Evaluation of parenteral preparations.
- Labelling and packaging.

c) Name two methods for 'Test for sterility' and explain basic principle of any one. (Name of the two methods = 0.5 mark, Basic principle 1 mark, Explanation of any one method = 2.5 marks.)

Two methods for sterility testing are

- **Membrane filtration method**
- **Direct inoculation method**

Basic principle:

Basic principle of sterility test is that if bacteria or fungi are placed in a medium which provides the nutritive material and water and kept at favourable temperature the organism will grow and their presence can be indicated by the turbidity in the clear medium.

1. Membrane filtration method

This method is preferred in case of an oily preparation, an ointment that put into solution, non-bacteriostatic solid not readily soluble in culture medium, a soluble powder or a liquid that possesses bacteriostatic and fungistatic properties.

The method involves the filtration of the sample under test through a membrane filter having normal porosity of 0.45µ and a diameter of approximately 47 mm. After the filtration the membrane is removed aseptically from the metallic holder and divided into two halves. The first half is transferred into 100 ml of culture media meant for fungi and incubated at 20^0 to 25^0 C for not less than seven days. The other half is transferred into 100 ml of fluid thioglycolate medium and incubated at 30^0 to 35^0 C not less than 7 days .Observe the growth of media.

2. Direct inoculation method

In this method the specified quantity of sample under test is drawn aseptically from the container (The quantity of the substance or preparation to be used for the inoculation varies) and transferred into a vessel of culture medium. Mix the liquid with the medium and incubate for not less 14 days. Observe the growth of microorganisms in the medium.

d) Enlist ophthalmic products and give formulation of eye drops.

(Enlist 1 mark, formulation of eye drops 3 marks)

- Eye-drops
- Eye-lotions
- Eye-ointments
- Eye-suspensions
- Contact lens solutions.

Formulations of Eye drops

1. **Vehicle**: The aqueous or oily vehicle is used. In preparation of eye drops. The aqueous vehicle may support bacterial growth or fungal growth, so one of the following bactericide may be used to preserve the eye drops: Benzalkonium chloride 0.002% and Phenylmercuric nitrate/acetate 0.01%.
2. **Adjuvants**:
    1. **Thickening agent:** It helps to prolong the contact time. Ex. Methyl cellulose, carboxymethyl cellulose.PVA etc.
    2. **Buffers**: to maintain the pH ex. Boric acid, sodium acid phosphate, etc.
    3. **Antioxidants**: to prevent oxidation ex. Sodium metabisulphite.
    4. **Wetting agents**: used for proper penetration of the eye drop in to the cornea of the eye.
    5. **Iso-tonicity adjusting agents**: they are made isotonic with lachrymal secretion with the help of various buffers and other solutions ex. Sodium chloride.

e) Define compound powder with example and give disadvantages of powder dosage forms.

Definition of Compound powder: (1mark)

Compound powders contain two or more than two substances which are mixed together and then divided into desired number of individual doses which are dispensed into each powder paper.

Example of compound powder: (1 mark)

Rx

Aspirin----------300mg

Paracetamol--------150mg

Caffine----------50mg

Make a Powder

Disadvantages (0.5 x 4 = 2 marks)

- Drugs having bitter, nauseous, unpleasant taste cannot be dispensed in powder form.
- Deliquescent & Hygroscopic drug cannot be given in powder form.
- Drugs affected by atmospheric condition cannot be given in powder form.
- Dispensing is time consuming
- Weighing difficulty (qty. Less than 100mg.)

f) Explain 'Heating method of preparation of effervescent granules'.

Method of preparation: (Method of preparation 2 marks and Reaction 2 marks)

Method of preparation:

1) A large porcelain dish is placed on a water bath.

2) 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 crystallization from the citric acid will go on evaporating simultaneously. As a result sufficient water will not be available to make coherent mass.

3) Generally heating takes 1 to 5 minutes. The damp mass is then passed through sieve dried in an oven temperature not exceeding 60^0C.

(**Reaction**)

The water needed for granulation is provided from two sources

i) From water of crystallization of citric acid.

The citric acid contains one molecule of water of crystallization which is liberated during heating.

$3NaHCO_3 + C_6H_8O_7.H_2O \rightarrow C_6H_5Na_3O_7 + 3CO_2 + 3H_2O$

Sodium Bicarbonate — Citric acid — Sodium citrate

ii)The water produced from the reactions of citric acid & tartaric acid with sodium bicarbonate.

$2NaHCO_3 + C_4H_6O_6 \rightarrow C_4H_4Na_2O_6 + 2CO_2 + 2H_2O$

Sodium bicarbonate — Tartaric acid — Sodium tartarate