MODEL ANSWER
CODE: AS-2513
B. Pharm. (Third Semester) Examination
PHARMACEUTICS-V
(Dispensing Pharmacy)

SECTION – A

1. (i) Transparent

(ii) (a) Three times s day

(b) To be taken

(iii) These consist of mixture of citric acid and tartaric acids with bicarbonate of soda and usually some medicament and occasionally sugar.

(iv) 000 – 950 mg approx.

5 – 100 mg approx.

(v) both (a) & (b)

(vi) (a) Rhubarb powder

(b) Bismuth carbonate

(vii) Tablet triturate are small, discoid masses of molded powder weighing 30 to 250 mg each. The base of consist lactose, mannitol, dextrose or other rapidly soluble materials. It is desirable in making tablet triturates to prepare a solid dosage form which is rapidly soluble. They are generally softer than compressed tablets.

(viii) Sorting of capsule

(ix) A bottle contains one dose it is called draught.

(x) (a) Sedimentation method

(b) Rheological method

(xi) O/W

(xii) (a) 30ml

(b) 4ml

SECTION – B

2. **(a)** Suspension are the biphasic liquid dosage form of medicament in which the finely divided insoluble solid material suspended in a liquid medium. The average size of suspended particles ranges from 0.5 µm to 5.0 µm in most of the pharmaceutical suspension.

Classification of suspension

A. Oral suspension

B. Parenteral suspension

C. Ophthalmic suspension

D. Suspension for external use

A. Oral suspension:

These suspensions are to be consumed by the patient by oral route. Oral suspensions generally contain flavouring agent and sweetening agent to mask the bitter taste of the drug. In the present time suspension are available in the market in dry powder form and these are reconstituted by adding a specified quantity of freshly boiled and cooled water before use example antibiotics in suspension for pediatric use.

B. Parenteral suspension:

The suspension which are administered by parenteral route are called parenteral suspensions. These suspensions are required to fulfill the following qualities.

- The particle size of drug should be such that it can be easily pass through the needle of the syringe.
- There should not be any crystal growth in the suspension during its storage.
- The concentration of solid particles in the suspension should be between 0.5 to 30%.
- The viscosity of the suspension should not interfere with its flow through the syringe needle.
- The suspension should be sterilized.

C. Ophthalmic suspension:

These are not commonly used as compared to eye drops. These are prepared only in those cases when the drug is insoluble in the desired solvent or unstable in liquid form. The suspensions must fulfill the following conditions.

- The particle size of the eye suspensions should be fine enough so that it should be non irritating to the eye.
- The suspension should be sterilized.
- The suspension should be isotonic.
- These should desired viscosity.
- The suspension should be packed in a suitable container so that it can be easily instilled into the eye.

D. <u>Suspension for external use:</u>

These suspensions are meant for external use example lotions, inhalations, ear drops etc.. These suspensions are containing very small particles.

Calamine lotions is a suspension type preparation which is applied on the skin to provide protective effect, Lotions which are meant for application on broken or inflamed skin should be free from harmful microorganisms.

2. (b)

Flocculated Suspension	**Deflocculated Suspension**
1. Particles are loose aggregates.	1. Individuals particles exists as separate entity.
2. The rate of sediment is high.	2. The rate of sediment is slow.
3. Supernatant is clear.	3. Supernatant is cloudy.
4. Particle experience attractive forces.	4. Particle experience repulsive forces.
5. Sediment is easy to redisperse.	5. Sediment is difficult to redisperse.
6. Does not form a hard cake.	6. Hard cake is formed.
7. Sediment is rapidly formed.	7. Sediment is slowly formed.
8. Sediment is loosely packed.	8. Sediment is very closely packed.
9. Suspension is not pleasing in appearance.	9. Suspension is pleasing in appearance.

3. Ideal requirement of suppository bases

- It should melt at body temp.
- It should compatible with large no. of drugs.
- It should release the medicament readily.
- It should non toxic.
- It should non irritant.
- It should dissolve or disperse in body fluid.
- It should be easily mouldable by pouring or cold compression.
- It should be stable if heated above its melting point.
- It should keep its shape when being handled.
- It should be stable on storage and transportation.

Manufacturing procedure of suppositories

A. Rolling method

B. Hot process or Fusion method

C. Cold compression

A. Rolling method :

It is an ancient method of preparing the suppositories. The suppository base is rolled and then desired shape is given with the hand. The method is not used now a day.

B. Hot process or Fusion method :

This method is commonly used in the preparation of suppositories for dispensing purposes. The suppositories based is melted , the medicament is incorporated in it and filled in lubricated mould. On cooling suppositories are formed which are removed from the suppository mould.

C. Cold compression :

Mix theobroma oil and drug the mixture is forced into a mould under pressure using a wheet operated press. Mould is removed, opened and replaced. On large scale cold compression machine are hydraulically operated by water jacketed cooling and screw fed.

Automatic mould machine :

All filling ejection and mould cleaning operation are fully automatic. The output of a typical rotary machine ranges from 3500 to 6000 suppositories per hour. The suppository mould is

lubricated by brushing or spraying and then filled to a slight excess. Excess material is removed after the mass gets solidified and collected for re use. All heating and cooling system are fully automatic.

Suppository mould :

The suppository mould of various types and sizes are available in the market for commercial use. In dispensing the suppository mould having 6 – 12 cavities, with desired shape and size may be used. These moulds are generally made up of stainless steel nickel copper alloy, brass, aluminum or plastic.

The suppository mould can be opened longitudinally by removing the screw in the centre of the plates. The mould is opened at the time of cleansing, lubrication and removal of suppositories. The mould is cleaned by removing the plates and immersed in hot water containing detergent. After washing with water the mould is dried thoroughly.

4. (a) <u>Qualities of an ideal ointment base</u>

- It should be inert.
- It should be physically and chemically stable.
- It should be compatible with skin.
- It should be odourless and smooth.
- It should not produce irritation or sensitization of the skin.
- It should be of such a consistency that it spreads and softens when applied to the skin with stress.
- It should not retard healing of the wound .
- It should non toxic.

4. (b) You take

The formula for 10 powders will be

Sodium Bicarbonate ..... 100 gr

Rhubarb Powder ..... 30 gr

Oil of Peppermint ..... 5 minims

Lactose .....to 140 gr

Make a powder. Send such nine. Label: to be taken a wine glass with water after meal
Weigh out the required amounts of first three ingredients are known but that of lactose is not. Therefore after admixture of the first three ingredients transfer the whole of the material to a scale add lactose to produce 140 grains return to the glass mortar and mix thoroughly. Weigh out the prescribed number of powders. Then proceed with double wrap because of the volatile oil.

5. Incompatibility occurs as a result of mixing of two or more antagonistic substances and an undesirable product is formed which may affect the safety, efficacy and appearance of the pharmaceutical preparation. The interection of the drug with another drug or of a drug with additives or adjunts dosage errors etc. comes under the incompatibility.

Classification of Incompatibilities

A. Physical Incompatibility

B. Chemical Incompatibility

C. Therapeutic Incompatibility

A. Physical Incompatibility :

When two or more than two substances are combined together, a physical change take place and an unacceptable product is formed. Physical incompatibility is usually due to immiscibility, insolubility, precipitate formation or liquefaction of solid materials. These changes which occurs as a result of physical incompatibility are usually visible and can be easily corrected by applying thee pharmaceutical skill to obtain a product of uniform dosage, an attractive appearance and having satisfactory therapeutic activity. The physical incompatibilities may be corrected by using any one or more of the following methods :

i. Change the order of mixing of ingredients of the prescription.

ii. Emulsification.

iii. Addition of suspending agent.

iv. Change in the form of ingredients.

v. By addition, substitution or omission of therapeutically inactive substance to help in compounding of the prescription.

Immiscibility

Oils and water are immiscible with each other. They can be made miscible with water by emulsification.

Insolubility

Insolubility means the inability of material to dissolve in a particular solvent system. Generally , polar solvents, such as water are able to dissolve ionic and polar solutes because of high dielectric constant which reduce the forces of attraction between unlike charged ions. Polar solvent has the ability to disrupt covalent bonds of compounds such as hydrochloric acid, through an acid base reaction.

The majority of physical incompatibilities are due to insolubility of the organic as well as organic as well as organic compound in a particular solvent. To prevent incompatibility it is important to study the insolubility of inorganic and organic compounds used as ingredient in compounding and dispensing of medicines.

i. Insolubility of inorganic compounds :

Inorganic compounds usually possess strong binding forces which are ionic or covalent in nature. So these compounds are soluble in polar or semipolar solvents, such as, water, alcohol and acetone. Strong solvation energies are required to distribute these binding forces. Hence measurements of any parameter related to hydration energy, such as lyotropic number, ratio of change to ionic radius or heat of hydration, reflects solubility within a group of inorganic compounds.

(a) Metal and their salts

(b) Non metals

ii. Insolubility of organic compounds :

(a) Hydrocarbons

(b) compounds solubilised through hydrogen bonding and polarization.

Precipitation

A drug in solution may be precipitated, if the solvent in which it is added to the solution eg resins are insoluble in water. When tincture containing resinous matter is added in water, resin agglomerates forming indiffusible precipitates. This can be prevented by slowly adding the undiluted tincture with vigorous stirring to the diluted suspension or by adding some suitable thickening agent.

6. Mixture containing indiffusible solids :

Indiffusible solids are those solids which are not soluble in water and do not remain uniformly distributed in the vehicle for sufficiently long time. Therefore to suspend the drug suspending agents are added. The commonly unused indiffusible drug in mixture form are acetylsalicylic acid, quinine salicylate, phenacetin, benzoic acid etc.

The suspending agents which are commonly used in mixtures containing indiffusible solids are:

(a) Compound tragacanth powder

(b) Tragacanth mucilage

Method of dispensing (Compound tragacanth powder)

Stage 1. Finely powder indiffusible solids add any soluble or diffusible solids and compound tragacanth powder. Mix them uniformly.

Stage 2. Measure about three fourth of the vehicle. Triturate the powder with a portion of it until a smooth cream is formed. Then add remainder of the vehicle.

Stage 3. Examine the contents of the preparation. If any foreign particle is visible, pass the contents throughs through the muslin cloth. Rinse the mortar with little of vehicle.

Stage 4. Add any liquid ingredients if present and transfer the mixture into a measure.

Stage 5. Add more the vehicle to produce the required volume.

Stage 6. Transfer the mixture into the bottle. Then thoroughly clean the bottle attach the label with a direction "Shake well before use". Dispense the bottle.

Method of dispensing (Tragacanth mucilage)

Stage 1. Finally powder the indiffusible solids add any soluble or diffusible solids. . Mix them uniformly. Triturate the material with tragacanth mucilage (1/4 th of the volume) to form a smooth cream. Then gradually dilute with 1/2 of the vehicle. The product will thus measure about 3/4 of the finished volume.

Stage 2. Examine the contents of the preparation. If any foreign particle is visible, pass the contents throughs through the muslin cloth. Rinse the mortar with little of vehicle.

Stage 3. Add any liquid ingredients if present and transfer the mixture into a measure.

Stage 4. Add more the vehicle to produce the required volume.

Stage 5. Transfer the mixture into the bottle. Then thoroughly clean the bottle attach the label with a direction "Shake well before use". Dispense the bottle.

7. (a) Proportions of Oil, Water and Gum required for formation of primary emulsion

Type of oil	**Example**	**Proportions of**		
		Oil	**Water**	**Gum**
Fixed	Almond oil A rachis oil Castor oil Cod-liver	4	2	1
Mineral	Liquid paraffin	3	2	1
Volatile	Turpentine oil Cinnamon oil Peppermint oil	2	2	1
Oleo-resin	Male fern extract Balsam of peru	1	2	1

<u>Dry Gum Method</u>

Pestle mortar

↓

Oil

↓

Gum acacia

↓

Dispersion by trituration only one direction

↓

Water (all at once)

↓

Stir at one side (direction) until thick paste (white colour)

↓

Stir vigorously (clicking sound are appear)

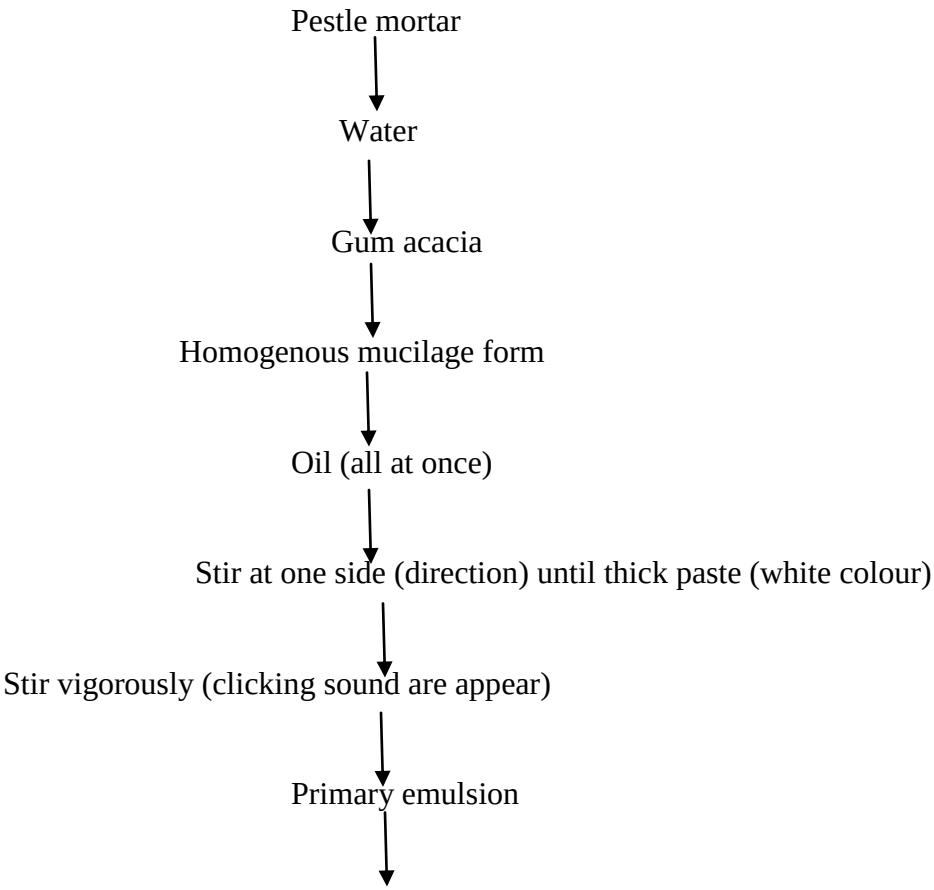
↓

Primary emulsion

↓

Add more of water to produce required volume

Wet Gum Method



7. (b) Stability of Emulsion

A. Flocculation and Creaming

B. Cracking

C. Miscellaneous Instability

D. Phase Inversion

A. Flocculation and Creaming:

Flocculation consists of the joining together of globules to form large clumps or floccules which rise or settle in the emulsion more rapidly then the individual globules to give a concentrated

layer is known as creaming. Separation of cream from milk is a good example of creaming of emulsions.

Creaming is a temporary phase and it is redistributed by mild shaking or stirring to get again homogeneous emulsion.

Creaming is does not aggregation process.

The velocity of creaming is governed by stokes law process of creaming is explained by stokes law.

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

Where

V is velocity of creaming

d_1 is density of disperse phase

d_2 is density of dispersion medium

g is gravitational consta

r is radius of globules

η is viscosity of continuous phase

Directly proportional to the density difference between the oil and water phases

Directly proportional to the square of the radius of globules

Inversely proportional to the viscosity of dispersion medium

Factor affecting the rate of creaming and sedimentation

i. Globule size:

Globule of small size have less tendency to cream

ii. Viscosity:

Higher the viscosity of continuous phase less creaming

iii. Density:

Less difference in density of two phase means more stability of emulsion

iv. Temperature:

Lower temperature is more suitable for the better stability of emulsion.

B. Cracking:

Separation of two layers of disperse and continuous phase. Due to the coalescence of dispersed phase which is difficult to redisperse by shaking a cracked emulsion cannot be corrected cracking represent permanents instability cracking of the emulsion may be due to

- addition of an emulgent of opposite nature.
- decomposition or precipitation of emulgent.
- addition of a common solvent in which both oily and aqueous phases are miscible.
- extremes of temperature.
- microorganism.

C. Miscellaneous Instability:

Emulsions may deteriorate if stored under extremely high or low temperature or in presence of light. Hence emulsions are usually packed in air tight containers and stored at moderate temperature.

D. Phase Inversion:

It is the change in the type of emulsion from oil in water to water in oil and vice versa. It is the physical process. Phase inversion may be brought about by varying the phase volume ratio, addition of electrolytes and temperature changes.