PHARMACEUTICS

UNIT 3 NOTES

MONOPHASIC LDF

- SYRUP, ELIXERS, LINIMENTS, LOTIONS
- GARGLES, THROAT PAINTS, MOUTHWASH
- EYE DROPS, EAR DROPS, NASAL DROPS

BIPHASIC LDF

- EMULSION
- SUSPENSION

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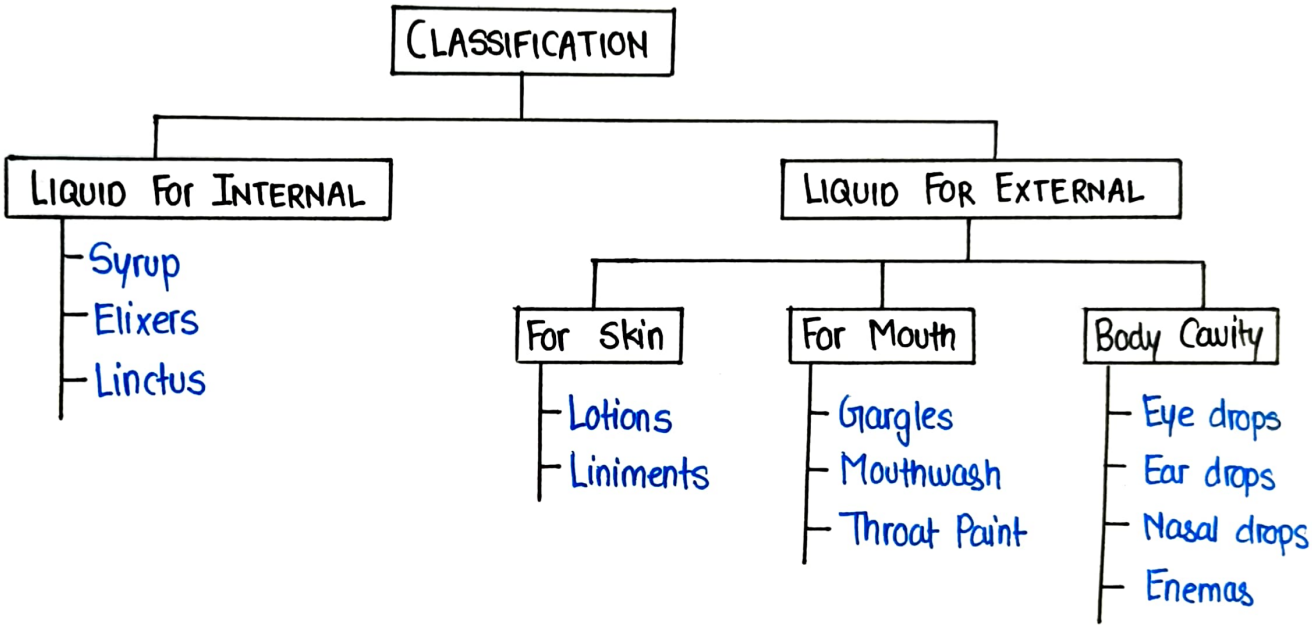
MONOPHASIC LIQUIDS

Monophasic liquid dosage form is a liquid preparation containing two or more components in one phase system. It is also known as true solution.



LIQUID FOR INTERNAL USE

Syrups :

Syrups are sweet viscous concentrated aqueous solution of sucrose in purified water

- Concentration of Syrup IP : 66.7 % w/w (sucrose in water)
- Concentration of Syrup USP : 85 % w/v (")

Types

① Simple Syrup : Contain only sucrose in water
② Flavoured Syrup : Contain flavouring agent but no medicament (cherry syrup)
③ Medicated Syrup : Contain Medicinal agent (Cough Syrup)

Method of Preparation

① Hot Press / Agitation with heat
② Percolation
③ Agitation without heat

Hot Press / Agitation with heat :-

Method is used when active constituent is not heat labile / heat sensitive

Procedure

- Weighed sucrose is taken in beaker
- Purified water is added
- Heated on water bath
- Product is filtered
- Final volume is prepared

Percolation :-

- Sucrose is placed in percolator
- Water is passed through sucrose slowly
- Final volume is prepared by adding purified water.

Agitation without heat :-

- Used for heat sensitive / heat labile substances
- Sucrose and other ingredients weighed properly.
- Purified water is added
- Final volume is prepared.

Additives Used in formulation of Syrup

Vehicle : Syrup are prepared by using purified water

Chemical Stabilizer : Glycerin, Sorbitol etc. added to maintain the stability of syrup

Colouring Agent : Dyes such as Amarnath, Tartarazine used as colouring agent.

Flavouring Agent : Lemon, Ginger, Orange etc. added as colouring agent

Preservatives : Generally most of the syrup are self preservative.

Packing : Packed in a well closed glass bottle

Storage : Store in a cool dark place

ELIXERS

- Elixers are defined as clear, aromatic, sweetened, hydroalcoholic liquids intended for oral use.
- They are generally less sweet and less viscous than syrup
- They can contain 4-40% alcohol.
- They are self preservative

Types of elixers

① Medicated : Contain medicament such as antibiotics.

② Non-medicated : Do not contain medicament.

Method of Preparation

Elixers are prepared by simple dissolution method

Procedure :

- Ingredients dissolved in their respective solvent.
- Alcohol is added.
- Mixture is then made upto desired volume
- Preparation is filtered
- Filteration gives clear elixer.

Additives used in formulation of elixer

Vehicles : Water, alcohol, glycerin etc. generally used as vehicle.

Chemical Stabilizer : Various chemicals like citric acid etc. used in elixer to make it stable.

Colouring Agent : Amamath, Tartarazine etc. used as colouring agent.

Flavouring Agent : Lemon, Orange etc. used as flavouring agent.

Preservatives : They are self preservative due to presence of alcohol.

Packing : Packed in well closed, air tight glass bottle

Storage : Store in a cool and dry place.

LIQUID FOR EXTERNAL USE

For Skin

Liniments

- Liniments are liquid or semi-solid preparations
- They are meant for external application (skin)
- They are applied to the skin with friction and rubbing.
- They should not be applied to the broken skin.

Labelling : For external use only

Packing : Packed in tightly closed container

Storage : Store in a cool and dry place

Lotions

- Lotions are liquid preparation meant for external application without friction or rubbing
- They are generally applied with help of some absorbant material such as cotton etc.
- They should not be applied to the broken skin, it may cause irritation.

Labelling : For external use only

Packing : Packed in well closed container

Storage : Store in a cool dry place

For Mouth

Gargles

- Gargles are aqueous solution used to prevent mainly throat infection.
- They are usually available in concentrated form.
- They are brought into close contact with mucous membrane of the throat
- retained for few seconds and then spit out.
- example : Phenol gargles, $KClO_3$ gargles

Storage : Store at room temperature

Labelling : For external use only, Not to be swallowed

Packing : Anti-bacterial, Mild anaesthetic effect

Mouth wash

- They are aqueous solution with pleasant taste
- Use to clean and deodorize the buccal cavity.
- It has refreshing, Anti-bacterial and anti-septic cavity.
- Can be used directly or dilute with water before application.
- example : Zinc chloride Mouth wash, Flouride Mouth wash.

Labelling : Not to be swallowed, For External Use

Packing : Packed in clear fluted bottle

Storage : Store in a cool and dry place

Throat Paint

- Throat paints are viscous liquid preparation used for mouth and throat infections
- They are generally prepared by using glycerin.
- Glycerin makes it viscous and also provide sweet taste.

Labelling : For external use only, Not to be swallowed

Packing : Packed in air tight container

Storage : Store at a cool dry place

Body Cavity

Ear Drops

- They are liquid preparations meant for application into the ear.
- In ear drops ingredients are generally dissolved in solvents such as glycerol, alcohol etc.
- Aqueous solvent is generally not preffered for ear drops.
- They are generally used for their cleansing & antiseptic properties.
- Example: Chloramphenicol ear drops.

Eye Drops

- They are liquid preparation meant for application into eyes.
- They are generally used to treat eye infections.
- It has antiseptic, anaesthetic property
- They are generally available in concentrated form.
- Example: Atropine eye drops.

Nasal Drops

- Nasal drops are liquid preparations meant for application into nose.
- They are generally used to treat nasal inflammations and infections.
- It having antiseptic and local analgesic property.
- Example: Otrivin nasal drops.

EMULSION

An emulsion is a biphasic liquid dosage form in which two immiscible liquids are mixed together with the help of an emulsifying agent. Emulsion generally contain two phases in which one is 'dispersed phase' and other one is 'continuous phase' or 'dispersion medium'.

Examples : Milk (oil in water)
Butter (water in oil)

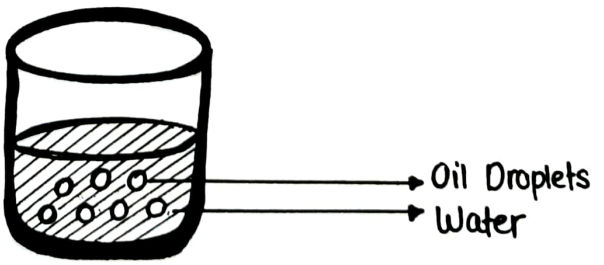
Types of Emulsion

They are of basically three types

① Oil in water (O/W) Emulsions
② Water in Oil (W/O) Emulsions
③ Multiple Emulsions

Oil in Water (O/W) Emulsions

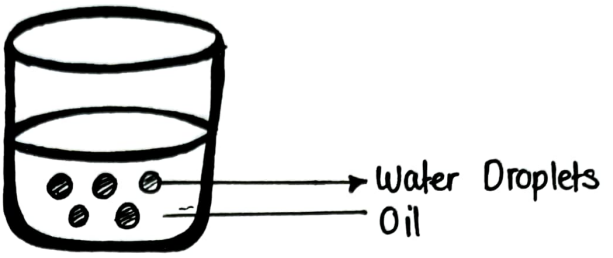
These are emulsions in which oil is present as 'dispersed phase' and water is present as 'continuous phase'/ dispersion medium.



O/W Emulsion

Water in Oil Emulsions (w/o)

These are emulsions in which water is present as dispersed phase and oil is present as dispersion medium/ continuous phase.



w/o Emulsion

Multiple Emulsions

They are of two types

① Oil in water in oil (o/w/o)
② Water in oil in water (w/o/w)

Advantages

- Easy masking of unpleasant taste (caster oil, cod-liver oil)
- Emulsion increase the absorbtion of oil when taken internally.
- Used for many external preparations.
- They are generally cost effective

Disadvantages

- Packing, handling and storage is difficult
- Thermodynamically unstable
- Leads to creaming and cracking
- Leads to phase inversion

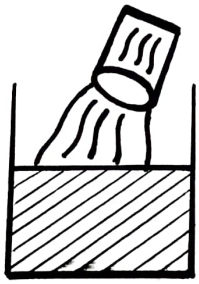
Identification Test For Emulsions

The following identification test are performed to check whether the emulsion is o/w or w/o

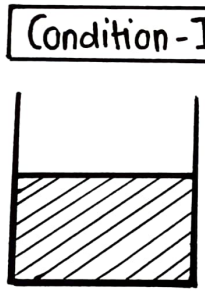
- Dilution Test
- Conductivity Test
- Dye test
- Fluorescence test

Dilution Test

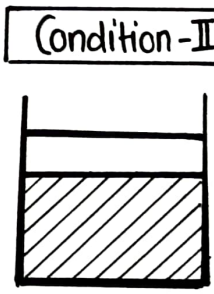
The test is based upon the solubility of external phase of emulsion. As let we take an unknown emulsion and we add water in it Now if emulsion is w/o then we will see two clear separated phases and if emulsion is o/w type then there will be no change



Unknown Emulsion



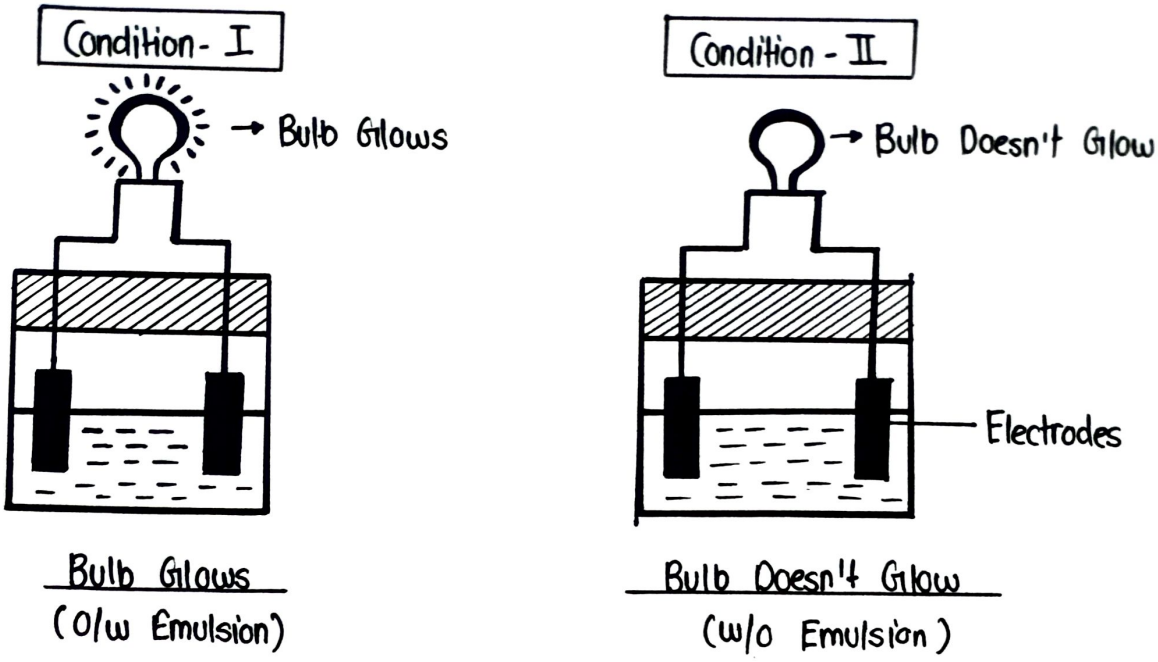
No Change
(o/w Emulsion)



Separated Layer
(w/o emulsion)

Conductivity Test

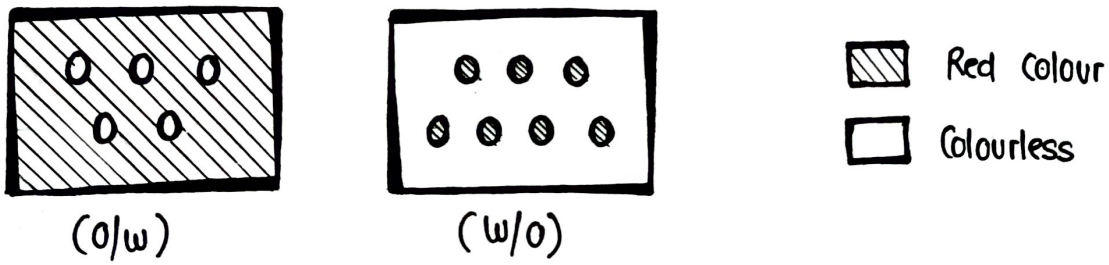
The test is based on the principal that water is a good conductor of electricity, so if the emulsion is o/w test will be positive and bulb glows and if emulsion is w/o test will be negative and bulb doesn't glow.



Dye Test

In this test emulsion is mixed with water soluble dyes such as Amarnath and then changes observed

- If the continuous phase shows red colour and dispersed globules shows colourless means emulsion is O/w type
- If continuous phase appears colourless and dispersed globules shows red colour, then emulsion is w/o type.



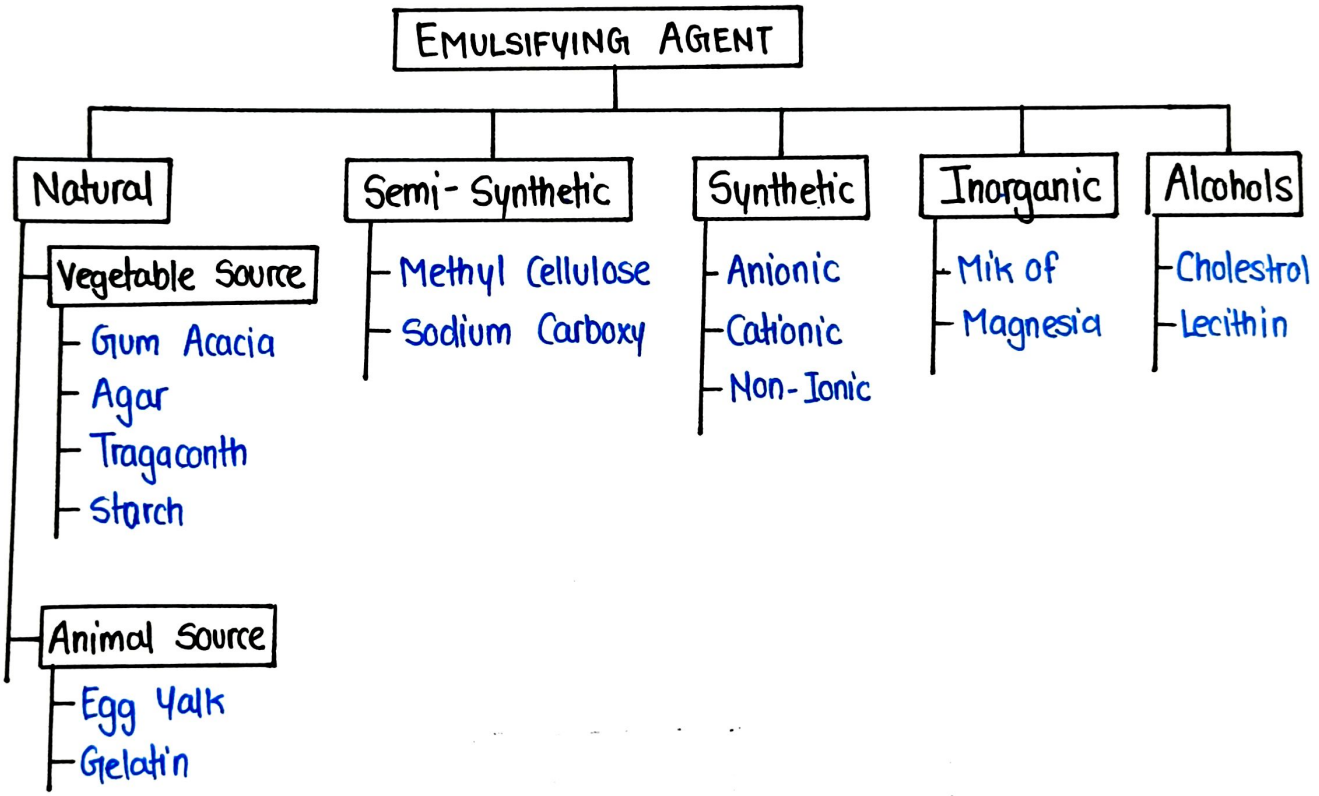
Fluorescence Test

Oil gives fluorescence under uv light while water doesn't, Now if under uv observation emulsion gives fluorescence then it is w/o and if not then O/w

EMULSIFYING AGENTS

Emulsifying agents are those chemical compounds which reduces the interfacial tension between two immiscible liquids (oil and water) and make them miscible to form a stable emulsion.
Emulsifying Agents are also known as 'Emulsifiers'

Classification



Properties of Emulsifying Agents :

- It should be chemically stable.
- It should be compatible with other ingredients of the emulsion
- It should be Non-toxic
- It must be capable of reducing interfacial tension.

Preparation Of Emulsions

Emulsions are usually prepared by using three methods :

- Dry Gum Method
- Wet Gum Method
- Bottle Method

Dry Gum Method

- The ratio of Oil : Water : Gum is 4 : 2 : 1
- It requires Mortar and Pestle
- First Oil is mixed with Gum and triturated
- Little amount of water is added and trituration continued till a 'clicking' sound is heard and thick cream is formed.
- Once primary emulsion is formed, remaining water is added to form the final emulsion.

Wet Gum Method

- The Ratio of Oil : Water : Gum is 4 : 2 : 1
- It also requires mortar and pestle
- First water is mixed with Gum and triturated
- Required amount of oil is added and trituration continues to form the primary emulsion
- Once primary emulsion is formed, remaining water is added to form the final emulsion.

Bottle Method

- The ratio of Oil : water : Gum is 2 : 2 : 1
- The method is basically used for volatile and Non - viscous oils
- First oil is mixed with gum and shaken throughly
- Required amount of water is added and shaking continued to form a primary emulsion
- Once the primary emulsion has been formed remaining quantity of water is added slowly to form the final emulsion.

Stability Of Emulsions

The following changes usually occurs which affects the stability of emulsions.

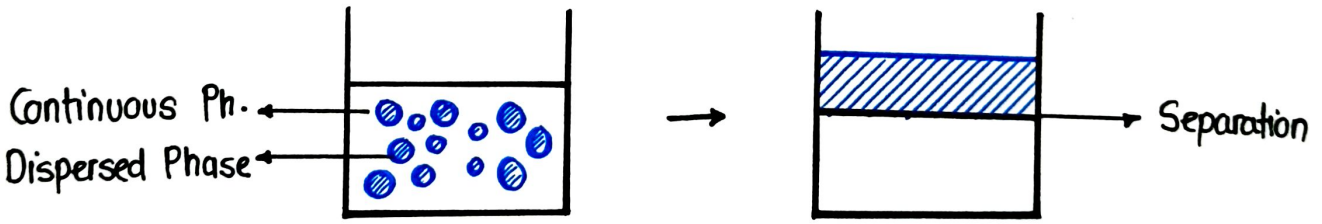
- Cracking
- Creaming
- Phase Inversion
- Coalescence

Cracking

Cracking means the separation of two layers / phases of the emulsion (dispersed phase and continuous phase

Cracking may be occur due to :

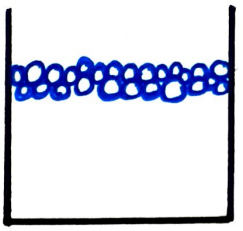
- Addition of wrong emulsifying agent
- Growth of microorganism
- Change in Temperature



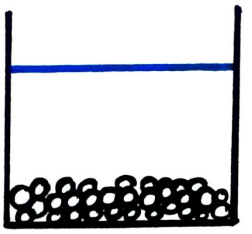
Creaming

Creaming can be defined as upward or downward movement of dispersed phase (dispersed globules) to form a thick layer at surface or bottom of the emulsion.

- O/w Emulsion → Upward Creaming
- w/o Emulsion → Downward Creaming



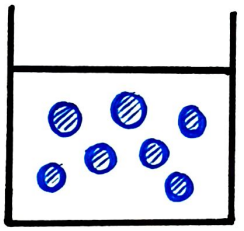
Upward Creaming
(O/w Emulsion)



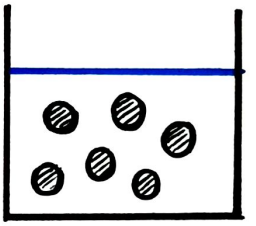
Downward Creaming
(w/o Emulsion)

Phase Inversion

Phase inversion is simply defined as conversion of O/w Emulsion into w/o Emulsion, or vice versa (w/o Emulsion into O/w)



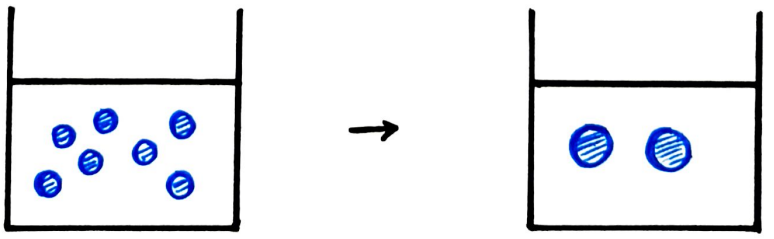
(O/w Emulsion)



(w/o Emulsion)

Coalescence

Coalescence is the process in which two or more droplets merge together to form a single large droplet.



Methods To Overcome the Stability Problems

- Selection of proper emulsifying agent.
- By increasing the viscosity of the emulsion
- By proper storage of the emulsion
- Maintaining appropriate temperature
- By maintaining minimum density difference
- By reducing size of dispersed globules.

SUSPENSIONS

- A suspension is a biphasic liquid dosage form in which finely divided solid particles dispersed into the liquid.
- In suspensions, Dispersed phase → Solid particles
  Continuous phase → Liquid

- The size of solid particles in the suspension ranges from 0.5 µm to 5 µm.

Classification of Suspensions

Suspensions can be classified on the basis of 3 categories

① On the basis of general classes
② On the basis of proportion of solid particles
③ On the basis of electrokinetic nature of solid particles

On the Basis of General classes

- Oral Suspensions
- Topical Suspensions
- Parentral Suspensions
- Opthalmic Suspensions

Oral Suspensions :

These suspensions are administered orally (by mouth)
example : Paracetamol Suspensions

Topical Suspensions :

These are suspensions that are used for external purposes. They are mainly applied on the skin.

Parentral Suspensions :

These suspensions are administered via intravenous or intramuscular routes through injections. Particle size of solid particles in these suspensions should be very less.

Opthalmic Suspensions :

These are the suspensions in the form of eye drops. Its particle size should be very fine, nor irritating, steoile and isotonic.

On the basis of proportion of solid Particles

- Dilute Suspensions
- Concentrated Suspensions

Dilute Suspensions :

The ~~size of solid~~ range of solid particles in dilute suspensions is 2 - 10 % per volume. example : Cortisone Acetate Suspension.

Concentrated Suspensions :

The range of solid partides in concentrated suspensions is ~~50%~~ per volume. example : Zinc oxide suspensions.

On the basis of electrokinetic nature of solid Particles

- Flocculated Suspension
- Deflocculated Suspension

Advantages of Suspensions

- Suspension improves the chemical stability of certain drugs such as procaine, penicilin G
- Easy masking of unpleasant taste.
- Used for both internal and external preparations
- Drugs in the suspension form shows higher rate of bioavailibility. (Solution > Suspension > Capsule > tablet)

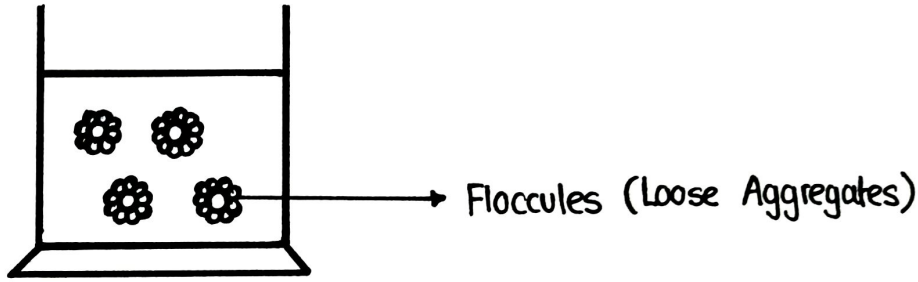
Disadvantages of Suspensions

- Require shaking before use
- Inaccuracy of dose
- Packing, handling and storage is difficult
- Sedimentation of particles.

Flocculated And Deflocculated Suspensions

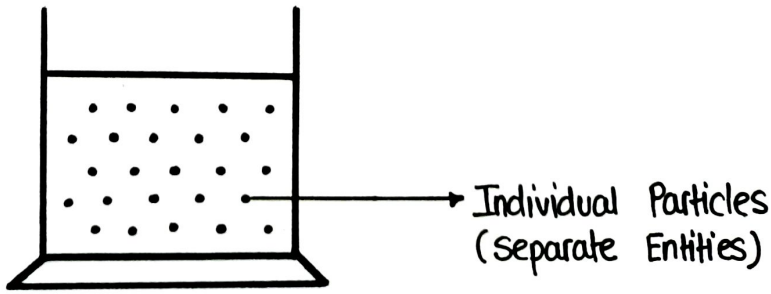
Flocculated Suspension

- A flocculated suspension is a suspension in which particles of the suspension has undergone flocculation.
- In flocculated suspension solid particles of dispersed phase combine together and make 'floccules'.
- In flocculated suspension rate of sedimentation is very high due to the heavy size of floccules.



Deflocculated Suspension

- A deflocculated suspension is a suspension in which no flocculation takes place
- In deflocculated suspension solid particles exist as separate entities.
- In deflocculated suspension rate of sedimentation is slow due to smaller size of dispersed solid particles.



Sedimentation

Sedimentation is the settling down of solid particles of suspension to the bottom of the liquid (suspension)

Difference between Flocculated and Deflocculated Suspension

Flocculated Suspensions	Deflocculated Suspensions
• Particles form loose aggregates • Rate of sedimentation is high • Sediment form rapidly • Doesn't form hard cake • Sediment easily redispersed • Unpleasant appearance • More stable Pharmaceutical Suspension	• Particles exist as separate entities • Rate of sedimentation is Low • Sediment form slowly • Form hard cake • Sediment difficultly redispersed • Pleasant appearance • Very less stable Pharmaceutical Suspension

PREPARATION OF SUSPENSION

Additives / Excipients used in formulation of suspension

Following ingredients are used in the formulation of suspension :

- Suspending / Flocculating Agents.
- Wetting Agents
- Viscosity Enhancing Agents
- Buffers
- Preservatives
- Colouring Agents
- Flavouring Agents
- Sweetening Agents

} [Organoleptic Agents]

Suspending Agents : They are added in the suspension to disperse solid particles in continuous liquid phase. They also helps to make suspense flocculated.

Wetting Agents : These are the substances that reduces surface tension between solid particles and liquid medium and make suspension stable.

Viscosity Enhancing Agents : They are added to increase the viscosity of the suspension so that solid particles do not easily settle down.

Buffers : They are added in the suspension to stabilize the suspension to a desired pH range

Preservatives : They are added in the suspension to prevent the microbial growth.

Colouring Agents : Tartarazine , Erythrosine

Flavouring Agents : Vanila, Strawberry, Orange

Sweetening Agents : Sucrose , Saccharin

Method of Preparation

- First convert the solid particles in fine powder form
- Take insoluble powder in a mortar
- Add sufficient liquid / vehicle to produce smooth paste
- Now add any non- volatile solid ingredient , if required.
- Add any volatile solid ingredient , if required .
- Now add other ingredients and mix well
- Transfer the mixture in a measuring cylinder and make up to the required volume by adding sufficient vehicle.

Packaging : Thick container with wide mouth

Storage : Store in a cool dry place

Stability Of Suspension

The following stability problems occurs during storage of a suspension :

- Caking
- Cap Locking
- Colour Change
- pH Change
- Rapid Settling of Particles

Caking

Caking is the formation of hard sediment in deflocculated suspensions Due to small particle size of solid particles, they come very close to each other which leads to a very hard cake formation.

Prevention : By adding flocculating agents which prevents hard cake formation by making Floccules

Cap Locking

Cap locking problem occurs when particles of dispersed phase spreads over the surface of the bottle cap

Prevention : By using different vehicles containing sucrose, glucose sorbital etc.

Colour Change

Light sensitive colour in solvent (liquid phase) maybe changed in the presence of light.

Prevention : Can be prevented by keeping the bottle in a dark place.

pH Change

During long storage the acidity or basicity of suspension can be increase or decrease which leads to the pH change.

Prevention : By adding buffering agents, which helps to maintain pH of the suspension.

Rapid Settling of Particles

Due to large particle size of flocculated suspension, the particles of the suspension very rapidly settle down at the bottom of liquid (continuous phase)

Prevention : By adding viscosity enhancing agents, rapid settling can be prevented.

THANK YOU

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