Formulation of Emulsion

- A) Emulsifying agents
- The emulsifying agents reduce the interfacial tension between two phases. Ie, oily phase and aqueous and thus make them miscible with each other and form a stable emusion. Emulsifying agent agents are also know as emulgents or emulsifiers.

- An ideal emulsifyung agent should posses the following properties:

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

Classification of Emulsifying Agents

- Emulsifying agents may be classified as follows

1. Natural emulsifying agents from vegetable sources:

- These are carbohydrates which includesgums and mucilaginous substances.
- They are anionic in nature and produce o/w type emulsions.
- The emulsions prepared from these emulsifying agents need suitable preservative to preserve them because the carbohydrates act as a medium for bacterial growth.

- The following are some of the emulsifying agents belonging to this class:

1) acacia:

- It is concidered to be the best emusifying agent for the extemporaneous preparation of the emulsion for internal use
- Emulsions prepared with gum acacia are attractive in apperance, quite palatable and relatively stable over a wide range of pH(2 to 10)
- The emulsion prepared with gum acacia usually have low viscosity, therefore creaming take place quite rapidly. In order to make a stable emusion, the other emulsifying agent such as tragacanrh, agar, pectin are also used along with gum acacia which increases the viscosity of the dispersion medium.

- Gum acacia is used in the following ratio for preparing emulsion from various types of oils

Name of the oil	Oil		Gum
Fixed oil	4	:	1
Volatile oil	2	:	1
Mineral oil	3	:	1

B) Tragacanth :

- Tragacanth alone is rarely used as an emulsifying agent because it prodeuces very coarse and thick emulsion
- The appearance and stability of the emusion can be improved by passing the emusion through a homogeniser,
- A stable emulsion can also be produced if tragacanth is used along with gum acacia as emulsifying agent.

C) Agar :

- it is not a good emulsifying agent, as it forms a very coarse and viscous emulsion. It is used as emulsifying agent by preparing 2% mucilage, by dissolving in boiling water and cooled to 45 C

D) Prectin :

- It is used as emulsifying agent by preparing 1% mucilage in water. It is incompatible with alkalies, strong alchohol, tannic acid and salicylic acid

E) Starch :

- Starch mucilage is rarely used because it forms very coarse emulsions. It is generally used to prepare enemas.

F) Irish moss:

- It I sused as a thickening agent. It is used along with acacia for the emulsification of cod-liver oil and to mask the unpleasent odour and taste of the oil. Its 3% solution is used to emulsify and equal volume of the oil.

2. Natural emulsifying agents from animal sources

a) Wool fat:

It is generally used in emulsion which are meant for external use. It produces o/w type emulsions and can absorb about 50% of water.

b) Egg yolk:

it is mainly used in extemporaneous preparations menat for internal use because it get spoiled during transportation. The emulsion prepared with egg yolk require proper preservation and storage in a refrigerator. It is used as emulsifying agent in the concentration of 12-15%

c) Gelatin :

it is used in the concentration of 1% as emulsifying agent. It is mainly used for the emulsification of liquid paraffin. The emulsion prepared with gelatin is quite white and have an agreeable taste. But it needs proper preservation because emulsions are prone to bacterial growth.

3) Semisynthetic polysaccharides

a) Methyl cellous:

it is synthetic derivative of cellulose. It is widely used assuspending , thickening and emulsifying agent in the concentration of 2%. It is commonly used for emulsification of minerl and vegetable oils, but get precipitated in the presence of large amount of electrolytes.

b) Sodium carboxymethyl:

it is used as an emulsion stabilizer in the concentration of 0.5 to 1.0%. It is soluble in both cold and hot water

4. Synthetic emulsifying agents:

the anionic , cationic and non ionic surface active agents are used as emulsifying agents

a) Anionic :

varoius alkali soaps,metallic soaps, sulphated alcohols and sulphonates are used as anionic emulsifying agents. Soap emulsion are used for external application. Sodium lauryl sulphate is commonly used as emulsifying agent among the sulphated alcohols. It produces o/w emilsions

b) cationic: the quaternary ammonium compounds , such as benzalkonium chloride, benzethonium chloride, cetrimide are used as cationic emulsifying agents. Cationic surface active agents bear positive charge on them. They ar emainly used in the preparations ment for external use, such as , skin lotions and creams.

c) Non ionic: the glyceryl easters, such as glyceryl monostearte, sorbitan fatty acids easters such as sorbitan monopalmitate are commonly used non ionic surface active agents. They are widely used in the preparation of pharmaceutical emulsions, because emulsions prepared with non ionic surfactants remain stable over a wide range of pH changes

5. Inorganic emulsifying agents:

- Several inorganic substances such as milk of magnesium (10-20%), magnesium oxide (5-10%) and magnesium aluminium silicate (1%) are used to prepare coarse o/w emulsion. Bentonite (5%) is used to prepare o/w or w/o when bentonite is used to prepare o/w emulsions. , oil is added to the suspension of bentonite, whereas when it is used to prepare w/o emulsion, oil is plased in the container and then bentonite suspension is added to the oil with rapid stirring

6. alcohols:

a) carbowaxes:

These are mainly used in the preparation of ointments and creams. Carbowaxes having molecular weight between 200-700are viscous, light coloured, hygroscopic liquids. Whereas carbowaxes with molecular weight 1000 and above are wax like solids. A product of desired consistency can be prepared by using right type of carbowaxes or a mixture of carbowaxes

b) cholesterol:

in this category, cetyl alcohol, stearyl alcohol, cholesterol and glyceryl monostearate are used to stabilixe the emulsion. They are used only with some other emulsifying agent.

c) lecithins:

lecithins which forms w/o emulsion, is rarely used as an emulsifying agent because it darken in colour when exposed to light and gets easily oxidised.

(B) Preservation of emulsions

- Emulsions which are prepaed by using emulsifying agent, such as carbohydrates, proteins, sterol and non ionic surfactants may lead to the growth of bacteria, fungi and moulds in the presence of water.
- The contamination of emulsions by these microorganisms may cause unpleasent odour, taste and discoloration, due to breakdown of emulsifying agent changes occur in the consistency of an emulsion which may lead to cracking of emulsion

- The contamination of an emulsion may occur due to any one of the folowing reasons:

1) The equipment used in the prepration of emulsions are carelessly cleaned.
2) By using contaminated natural emulsifying agents such as gums, starches and clays.
3) The ratio of oil and water is not proper.
4) By using not properly stored deionised and purified water.
5) pH of the prepration.

- The following steps can minimised the above factors and helps to maintain a stable emulsion:

1) Use thoroughly cleand equipment.
2) Use ingradients of standard quality.
3) Maintain the prescribed ratio of oil, water and gum while preparing the emilsions.
4) Use freshly boiled and cooled water to destroy microorganism.
5) Use containers and closures of good quality. The closure should fit well on the containers.
6) Maintain the prescribed pH of the emulsion.

- In order to preserve an emulsion properly, it is desirable that along with maintaining above such precautions to avoid conammination, a suitable preservative is also included in the formulation of an emulsion.
- Benzoic acid (0.1-0.2%), methyl paraben and propyl paraben (0.1-0.2%), chloroform (0.25%), chlorocresol (0.1%), cetrimide (0.002 to 0.01%) and phenymercuric nitrate (0.004 to 0.01%) are some of the commonly used preservatives used in emulsions.

(C) Antioxidants:

- During storage of emulsions, the facts (obtained from vegetable and animal sources) and emulsifying agents(such as wool fat, wool alcohol) undergo oxidation by atmospheric oxygen. This can be avoided by using antioxident, such as , tocopherol, gallic acid, propyl gallate and ascorbic acid.
- Sometimes oxidation occurs due to enzymes produced by microorganisms. Such problems should be prevented by adding a suitable antimicrobial preservative.

- The following are some of the qualities of an ideal anti-oxidant:

1. It should be readily soluble or despersible in the medium
2. It should be effective in low concentration
3. It should be non toxic
4. It should be non irritant
5. It should be compatible with other ingradients of emulsion
6. It should be colourless, odourless and tasteless

(D) Flavours

vanillin is good flavouring agent for liquid paraffin emulsion. Benzaldehyde is generally used as a flavouring agent for cod-liver oil emulsionn. A combination of flavouring and sewwtening agent provides greater palatability to emulsion.

Preparation of Emulsion

1. **Emulsions Containing Natural Gums**

(a) Gum acacia containing emulsion:

Acasia is fine powder form is used as an emulsifying agent. The following methods are commonly used for the preparation of emulsions on a small scale:

I. Dry gum method

II. Wet gum method

III. Bottle method

IV. Other methods

i) Dry gum Method:

- Measure the required quantity of **oil in** a dry measure and transfer it into a **dry mortar**
- Add the calculated quantity of **gum acacia** into it **and triturate rapidly** so as to form a uniform mixture
- Add required quantity of **water and triturate vigorously** till a **clicking sound** is produced and the product becomes white or nearly white due to the total internal reflection of light. The emulsion produced at this stage is known as primary emulsion
- Add more of water to produce require volume.

- The folowing thable shows the proportion of oil , water and gum acacia required for different type of oils:

No	Type of oil	Examples	Ratio of oil:water:gum
1	Fixed oil	Caster oil Almound oil Arachis oil Cod liver oil	4 : 2 :1
2	Volatile oil	Turpentine oil Peppermint oil Cinnamon oil	2 : 2 :1
3	Mineral oil	Liquid parafinn	3 : 2 : 1

- Example : Prepare and dispense arachis oil emulsion using dry gum method

Rx

Arachis oil	50.0ml
Purified water add to	200.0 ml
Make an emulsion	

Direction : two teaspoonful to be taken three times a day with meals

- Formula for primary emulsion

Aachis oil	50.0 ml
Water	25.0 ml
Acacia powder	12.5 g

Calculation

Approximate volume of primary emulsion =	87.5 ml
Total volume of emulsion =	200 ml
Volume of water required =	112.5 ml

- Method:
- Measured the required quantity of **arachis oil** in a dry measure and transfer it into a dry mortar.
- Add calculated quantity of **gum acacia powder** and triturate rapidly to form a uniform mixture.
- Add required quantity of **water** and triturate vigorously till a **clicking** sound is produced and product becomes white.
- Add **remaining water** to produce the required volume. Transfer the emulsion into a bottle, label and dispense.

Wet Gum Method

1) Calculate the quantity of **oil, water and gum** required for preparing the primary emulsion.
2) Powder the **gum acacia in a mortar**. Add **water and triturate** it with gum so as to form a mucilage.
3) Add the required quantity of **oil in small portions** with **rapid trituration until a clicking sound** is produced and the product becomes white or nearly white. At this stage the emulsion is known as primary emulsion
4) Add more of **water** in small portions to the primary emulsion with trituration to produce the required volume. Stir thoroghly so as to form a uniform emulsion.
5) Transfer the emulsion to a bottle, cork, label and dispense.

- Example :

Rx

Castor oil 8 ml

Water add upto 30 ml

Make an emulsion

Send 120 ml

Direction : One tablespoonful to be taken before going to bed.

Bottle Method

- Bottle method is used for the preparation of emulsions of **volatile and other non viscous oils.** The proportion of oil : water : gum is 2:2:1.

1) Measure the required quantity of the **oil** and transfer **into a large bottle**. Add the required quantity of **powdered gum acacia**.
2) **Shake the bottle vigorously** untill the oil and gum are mixed thoroughly.
3) Add the calculated amount of **water all at once.**
4) Shake the mixture vigorously to form a **primary emulsion.**
5) Add more of water in small portions with constant agitation to produce the required volume.

Other methods

- Various blenders and homogenisers are used for preparing emulsions.
- **Hand homogeniser, silverson mixer homogeniser and colloidal mill** are some of the homogenisers which are used for the preparation of extemporaneous emulsions.
- These homogenisers are based on the principle that the large **globules in coarse emulsion are broken into smaller globules by passing them under pressure through a narrow orifice.**
- A coarse emulsion is prepared in a mortar which is then transferred into hand homogeniser. The emulsion is passed through a homogeniser many a times till an emulsion fof desired satisfaction is produced.
- The colloidal mills are used to produce a very fine emulsions having particle size less than one micron on a large scale manufacture.

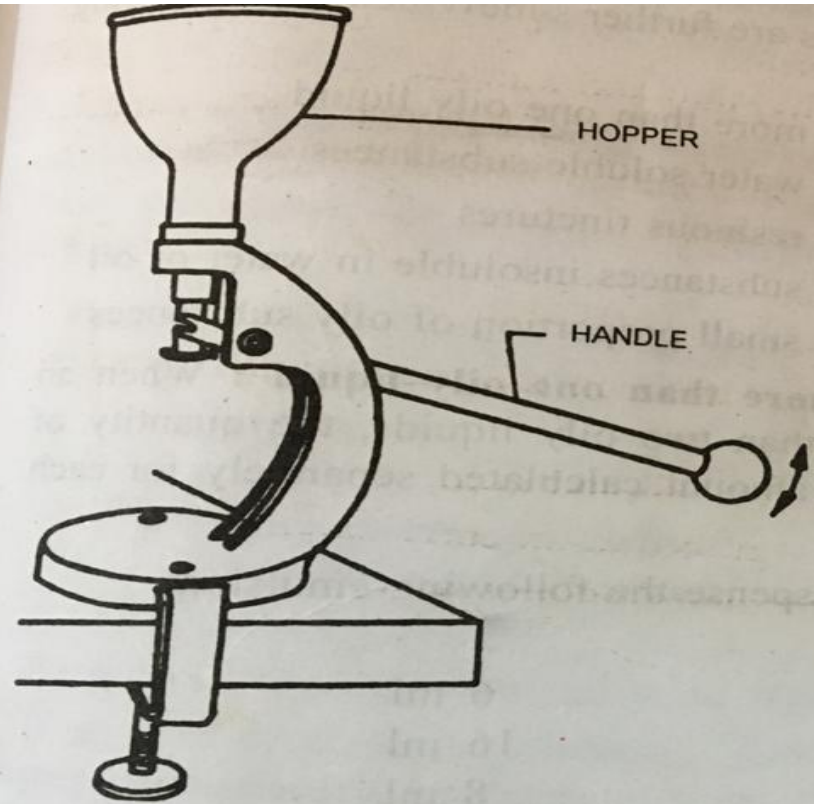

Fig. 10.1 Hand homogeniser

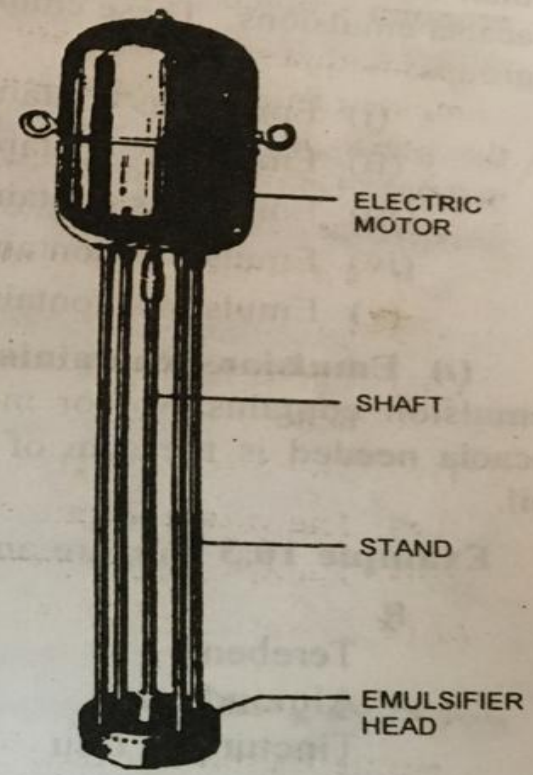

Fig. 10.2 Silverson mixer homogeniser

- **Hand homogeniser :**
- The homogeniser is **hand operated** and the coarse emulsion is passed though a fine orifice. The emulsion is placed in the **hopper of the homogeniser.**
- The **up and down movement of the handle** cause coarse emulsion to draw in through inlet valve and pass through homogenising value.
- In this way the emulsion is **forced to pass though the fine orifice**. The **oil globules are broken into fine globules** of uniform size.

- **Silverson mixer homogemiser:**
- it consists of an **emulsifier head which is covered with fine meshed stainless steel sieve**. The emulsifier head consists of a number of **blades which rotate at a very high speed** in order to produce a powerful shearing action.
- The **blades are rotated by using an electric motor** fitted at the top.
- The **emulsifier head is placed in a vessel containing immiscible liquids**, in such a way that it should get dipped into it.
- When the motor is started , the **liquids are sucked through the fine holes and the oil is reduced** into fine globules **due to the rotation of the blades.**
- So a fine emulsion is produced which is then expelled out. The intake and expulsion of the mixture set up a pattern of circulation.

(b) Compound acacia emulsions:

When emulsions contain **more than one oily** liquids along with other substances are called compound acacia emulsions. These emulsions are further subdivided into following groups:

i. Emulsions containing more than one oily liquid
ii. Emulsions containing water soluble substances
iii. Emulsions contaning resinous tinctures
iv. Emulsions containing substances insoluble in water or oil
v. Emulsions containing small proportion of oily substances

(i) Emulsions containing more than one oily liquid

- When an emulsion **contains two or more than two oily liquids**, the quantity of acacia needed is the sum of the amount calculated separately for each oil.

Example:

Rx

Terebene	6 ml
Almond oil	16 ml
Tincture of tolu	8 ml
Tincture of ipecac	8 ml
purified water to make	180 ml

Prepare an emulsion

- Hint : the emulsion contains terebene (volatile oil) and almond oil

Formula for primary emulsion

Terbene	6 ml
Almond oil	16 ml
Gum acacia powder	3 + 4= 7g
Water	14 ml

- Calulations

Approximate volume of primary emulsion = 6 +16 + 7 +14 = 43 ml

Approximate volume of tincture of tolu and tincture of ipecac = 16 ml

Total volume of primary emulsion and tinctures = 43 +16 = 59 ml

total volume of emulsion = 180 ml

Volume of water needed for dilution Of the primary emulsion = 180-59 = 121 ml

- Method :
- Primary emulsion is prepared by wet gum method. Dilute tincture ipecac with water
- Measure the tincture of tolu in a dry measure and pour it into the centre of the emulsion with rapid stirring.
- Add more of water, to make up the final volume. Transfer the emulsion to a bottle, label and dispense

(ii) Emulsion contining water soluble substances:

In emulsions, water soluble substances, like **salts , syrups and glycerines** are included. These substances are included in the primary emulsion after dissolving in water

Example :

Prepare and dispense the following emulsion.

Rx

Cod liver oil	30 ml
Syrup	12 ml
Ferric ammonium citrate	4 g
Cinnamon water to make	90 ml

Prepare an emulsion .

- Calculation:

Approximate volume of primary emulsion = 30 + 7.5 + 15	=52.5 ml
total volume of emulsion	= 120 ml
Volume of water needed for dilution	= 120 – 52.5 = 67.5 ml

Method:

Measure the required quantity of cod liver oil with a dry measure. Transfer it into a dry mortar. Add gum acacia powder, mix thoroughly by tituration. Add measured quantity of water, little at a time with continuous trituration, until a white product with clicking sound is produced.

- Dilute the syrup with small quantity of cinnamon water.
- To this dissolve ferric ammonium citrate. Add this solution little at a time to a primary emulsion with continuous and rapid trituration.
- Transfer the emulsion to a measure. Add more of cinnamon water to produce the required volume.
- Transfer the emulsion to a bottle, label and dispense

(iii) Emulsion containing resinous tinctures:

when **resinous tinctures** are required to be mixed with emulsions, the gum acacia present in it forms a protective colloidal for those particles of **resin which get precipitated** in a collidal state. Moreover, viscocity of the emusion maintains the large particles in diffused form.

The resinous tincture is added to the primary emulsion after it has been adjusted to final volume, keeping an allowance for tincture itself. Tincture tolu and tincture ipecac is added to the primary emulsion after diluting them with water.

(iv) Emulsions containing substance insoluble in oil or water:

- There are certain substances which are **insoluble both in oil as well as in water** e.g, phenolphthelin in liquid paraffin emulsion or bismuth carbonate in castor oil emulsion.
- These drugs are to be dispensed by mixing with required quality of **gum acacia** powder for primary emulsion. The **oil is then added, a**nd the primary emulsion is prepared in the usual way.
- Carbonate and hydroxides of divalent metals e.g, calcium carbonate must be finally powdered, if required and mixed with previously formed primary emulsion to form a smooth cream, and then emulsion is made in the usual way.
- Direct admixture of the unemulsified oil with the carbonates or hydroxides of divalent metals should be avoided, because the latter may react with the free fatty acid present in all animal and vegetablesoils, forming a divalent soap. This will help in the formaton of water –in-oil (w/o) emulsion opposing formation of desired o/w type of emulsion.

- **Example:**

Rx

Liquid paraffin	60 ml
Phenolphthalein	2.0 g
Agar	1.5 g
Acacia	15 g
Syrup	15 g
Cinnamon water to	180 ml

- **Direction:** one teaspoonful to be taken twice a day

- **Method:**
- **Finaly powder phenolphthelin in a dry mortar**. Mix it with **acacia,** add liquid paraffin and triturate. Mix **cinnamon water** required for primary emulsion in small quantity at time, with trituration until a clicking sound is produced and a white product id formed.
- **Dissove agar in required quantity of water in a tared china dish by gentle heat**. **Add syrup and cinnamon water, stir** so as to form a uniform mass.
- Gradually add the hot agar solution to the warm primary emulsion with constant trituration to form a uniform product. Pass the product through a homogeniser to produce a fine emulsion. Add more of cinnamon water to produce the required volume. Transfer to a bottle, label and dispense.

(v) Emulsion containing a small proportion of oily substances:

- Emulsions containing appreciably **less than 20% of oily liquid** and prepared with the **usual proportion of gum acacia, become unstable** and readily cream.
- Therefore, to pevent creaming, a bland of fixed oil (arachis, olive or almond oil) should be added to raise the proportion of oily liquid to approximately 20%

- Example:

Rx

Calciferol Solution	0.15 ml
Glycerin	0.3 ml
Water add to	5.0 ml

Direction : one teaspoonful to be taken daily.

Arachis oil is added.

- Calculation :

The percentage of oil (calciferol solution)

in each dose = 0.15 x 100 / 5 = 3 percent

20 percent of 5 ml = 1 ml

volume of arachis oil per dose = 1 – 0.15

= 0.85 ml

Formula for primary emulsion

Calciferol solution	1.5 ml
Arachis oil	0.85 ml
Water	5.0 ml
Aracia powder	2.5 g

- Approximate volume of primary emulsion = 1.5+0.85+5.0+2.5 = 9.85
- Total volume of emulsion = 50ml
- Volume of water needed for dilution = 50 – 9.85 = 40.15 ml

- Method:
- Take the required quantity of calciferol solution and arachis oil in adry mortar. Add acacia powder and mix thoroughly. Add measured quantity of water , little at a time with continuous tituration , until a white product having clicking sound is produced.
- Add glycerin with tituration. Add more quantity of water to produced the required volume. Transfer the emulsion to a bottle, label and dispence.

(c) Tragacanth containing emulsions :

Tragacanth alone is not a good emulsifying agent. It produces coarse emulsion. hence., it is used in combimation with acacia. Tregacanth increases the viscosity of emulsion and reduces creaming.

Example:

Prepare and dispense 50 ml of the following emulsion

Rx

Liquid parafinn	50 ml
Indian gum	1.25 g
Tregacanth	0.5 g
Sodium benzoate	0.5 g
vanillin	0.05 g
Glycerin	12.5 ml
Chloroform	0.25 ml
purified water to make	100 ml

- Direction: two tablespoonful to be taken before going to bed.

- Method:
- Triturate liquid paraffin and choloform with indian gum, tragacanth and vanillin. Add the product formed to to water and triturate till creamy emulsion is formed. Add glyderin and sodium benzoate.
- Add water to make the required volume. Transfer the emulsion to a bottle, label and dispense.

(d) Irish moss containing emulsions:

- Irish moss is a sea weed. The mucilage of irish weed is used as an emulsifying agent. It is prepared by washing the dried irish moss with water and then heated with water on a water bath.
- Strain through cotton-wool. The mucilage so formed is cheap and produces stable emulsion which does not undergo creaming.
- It is largely used in making cod-liver oil emulsions. It is not suitable for preparaing small quantites of emulsion unless a hand homogeniser is used.

- Example: prepare and dispense 50.0 ml of emulsion

Rx

Cod liver oil	60 ml
Creosote	0.7 g
Glycerine	16 ml
Mucilage of irish moss	90 ml
water to make	180 ml

- Method :
- Dissolve the required quantity of creosote in cod liver oil. Add mucilage of irish moss and shake vigorously. Add glycerin. Pass the coarse emulsion through hand homogeniser.
- Add required quantity of water to make the final volume. Transfer the emulsion to a bottle, label and dispense.

II. Emulsions Containing Gum Substitute

- **Cellulose derivatives and salts of alginic acid** are also used as emulsifying agent. They can be substituted with gum acacia.

$C_6H_7O_2(OH)_3$ Cellulose

- Cellulose derivatives are used as suspending and thickening and emulsifying agents.
- **Methyl cellulose** is commonly used as emulsifying agent, because it is soluble in cold water and insoluble in hot water. It is available in wide range of viscosity grades to suit the formulation of emulsion.

- Prepare and dispense 100 ml of the following emulsion.
- Rx

Methyl cellulose	2 g
Liquid paraffin	25 g
Vanillin	0.05 g
Syrup	12.5 ml
Chloroform water to make	100 ml

Direction: Two tablespoonful to be taken every night.

- Method:
- Dissolve methyl cellulose in water.
- Add chloroform water in which vanillin has been dissolved and stir until homogeneous.
- Add syrup and liquid paraffin and stir well.
- Pass the product through hand homogeniser.
- Add more of the chloroform water to make the required volume.
- Transfer to a bottle, label and dispense.

iii. Emulsions containing soaps

- Emulsions formed by using **soap as an emulsifying agents** are called as soap emulsion.
- Soaps are not satisfactory for preparing pharmaceutical emulsions for internal use due to their **unpleasant taste and laxative action.**
- These emulsions are further devided into three main classes.
- A) soap emulsion prepared with soft soap
- B) soap emulsions in which soap is formed by chemical interaction
- C) organic soap emulsions

- A) soap emulsion prepared with soft soap
- Soft soap is used as emulsifying agent in the following properties”:

1. For fixed and volatile oils: 10% of the weight of the oil
2. For fats: 20% of the weight of the oil

- Prepare and dispense 100 ml of the following emulsion.
- Rx

Soft soap	9 g
Camphor	5 g
Turpentine oil	65 ml
Water up to	100 ml

Directions: use as directed

- Method:
- Mix soft soap with small quantity with purified water.
- Dissolve the camphor in turpentine oil gradually.
- Add the camphor solution to the soap mixture with trituration till thick creamy emulsion is formed.
- Add more of purified water to produce the require volume. Mix it thorougly.
- Transfer a preparation to a bottle, label and dispense.

B) Soap emulsion in which soap is formed by chemical interaction.

- All **fixed oils contain a small proportion of free fatty acids which can form enough soap to emulsify the oil.**
- paraffin and turpentine oil do not contain any free acid hence, cant be emulsified by means of alkaline substances unless a free fatty acid is added.
- These emulsions can be prepared by using anyone of the following methods.

1. Simple admixture method : In this method **oil or oily mixture containing free fatty acid is shaken** vigorously with the whole of the alkaline liquid until a cream is formed. Add more quantity of water to produce the required volume.

- Ex. Prepare and dispense 100 ml of the following emulsion:

Rx

Oleic acid	1 ml
Dilute solution of ammonia	5 ml
Turpentine oil	25 ml
Water to make	100 ml

Direction: To be used as directed

- Method:
- Shake vigorously oelic acid and turpentine oil with dilute solution of ammonia till emulsion is formed.
- Add water to make the required volume.
- Transfer the emulsion to a bottle, label and dispense.

2. Complex admixture method:

- Calcium hydroxide solution is generally used in this emulsion which are meant for external application.
- The **calcium hydroxide react with fatty acid present in fixed oil to form divalent soap which form W/O type of emulsion.**
- Ex. Prepare and dispense the following emulsion.

Rx

Calamine	1 g
Zinc oxide	1 g
Olive oil	15 ml
Calcium hydroxide solution	15 ml

Direction: T o be used as directed.

- Method:
- Place the calamine and zinc oxide in a mortar and mixed by trituration.
- add olive oil in it and triturate.
- Add calcium hydroxide solution and triturate briskly to form a cream.
- Transfer to bottle, label and dispense.

- C) Organic soap emulsions
- Triethanolamine is a viscous liquid which resembles glycerine.
- It is misscible with water. It usually contains a proportion of diethanolamine and monoethanolamine. It combines with fatty acids to form salts.
- It is less alkaline than ammonia. The proportion of triethanolamine to the usually fatty acid is about 1 to 4. however for the purpose of stability excess of acid can be used.
- Ex.

Rx

Triethanolamine	1 ml
Oleic acid	4 ml
Benzylbenzoate	24 ml
Water to	120 ml

- Method:
- Triethanolamine and oleic acid are triturated togather in a mortar.
- Add benzylbenzoate in small quantities at a time with constant trituration.
- Add more quantity of water to make required volume.
- Transfer the emulsion to a bottle, label and dispense.

iv. Emulsions containing saponins

- **Quillaia liquid extract and tincture of senega is sometimes described with oils as an emulsifying agent.**
- The emulsion prepared using above emulsifying agents are not stable emulsions. Hence unless prescribed such emulsion should not be prepare.
- Quillalia liquid extract and tincture of senega contain saponins which lower the interfacial tension between oily and aqueous phase and helps to disperse the smaller oil globules into the dispersion medium i.e. water.

Rx

Chloroform 5 ml

Tragacanth mucilage 5 ml

Quillaia liquid extract 0.1 ml

Water to make 100 ml

- Method:
- Shake chloroform vigorously with liquid extract of quillaia.
- Add tragacanth mucillage and shake.
- Add required volume of water gradually. Shaking well after each addition.
- Finally add more water to make required volume.
- Transafer to a bottle, label and dispense.

V. Emulsion containing starch

- Starch in the form of mucilage is sometimes used as an emulsifying agent.
- Starch mucilage is a poor emulsifying agent and is only used in preparation of enemas. It is not true emulsifying agent.
- It produses large oil globules which can not agglomerate due to high viscosity of starch mucilage.
- Emulsion prepared with starch mucilage is not stable. It get cracked during storage
- Rx

Castor oil 5 ml

Starch 3 g

Water to 100 ml

Direction: To be used as enemas. As directed by the physician.

- Method:
- Triturate starch with sufficient water to form a smooth cream.
- Transfer to a measure and add water to make required volume.
- Transfer it into a flask and heat to boil with frequent aggitation.
- The starch is gelatinised and formed mucilage. Cool the flask in a stream of cold wate, rotating constantly, until cold. This is done to prevent skin formation on mucilage.
- Add the castor oil, mix by vigorous straining.
- Transfer to bottle, label and dispense.

VI. Emulsion containing natural waxes

- These emulsions possesses semisolid consistency and sometimes called “ointment emulsion”.

vii. Emulsion containing synthetic waxes

- The emulsifying agents commonly termed as emulsifying as emulsifying waxes. They generally consists of two components which combine together, thereby forming a stable complex. These emulsion are o/w type of emulsions.

Stability of Emulsion

- An emulsion is said to be stable if it remains as such after its preparation. i.e. the dispersed globules are uniformly distributed throughout the dispersion medium during its storage.
- The emulsion should be chemically stable and there should not be any bacterial growth during its shelf life.
- The following three changes usually occurs during the storage of an emulsion:

1. Cracking
2. Creaming
3. Phase inversion

1. Cracking

- Cracking means the separation of two layers of disperse and continuous phase, due to the coalescence of disperse phase globules which are difficult to redisperse by shaking.
- Cracking may occur due to the following reasons:

I. By addition of emulsifying agent of opposite type:

- Soaps of monovalent metals produce o/w type of emulsions whereas soaps of divalent metals produce w/o type emulsions.
- But the addition of monovalent soap to a divalent soap emulsion or a divalent soap to monovalent soap emulsion leads to cracking of emulsion.

II. By decomposition or precipitation of emulsifying agents:

- When an acid is added to an alkali soap emulsion (turpentine liniment), it causes the decomposition of an emulsifying agent and thus leads to cracking of an emulsion.
- Similarly, when sodium chloride is added to sodium or potassium soap emulsion, it leads to the precipitation of emulsifying agents and thus cracking of an emulsion take place.

III. By addition of a common solvent:

- When solvent is added to an emulsion which is either miscible with or dissolve the dispersed phase, the emulsifying agent and continuous phase, there is formation of one phase or a clear solution.
- This leads to cracking of an emulsion.
- For. Ex. Addition of alcohol to turpentine liniment leads to the formation of clear solution because turpentine oil, soft soap and water are soluble in alcohol.

IV. By microorganisms:

- If emulsions are not stored properly, they may develop bacterial and mould growth. This may lead to destruction of emulsifying agent and cause cracking of emulsion.
- Therefore, it is desirable that all emulsions which are required to be stored for a long period should be suitably preserved.

V. Change in temperature:

- When emulsions are stored for a long time, an increase in temperature may reduce the viscosity of the emulsion and encourage creaming.
- When emulsions are stored at a very low temperature, freezing of its water content into ice and subsequent melting of the ice and shaking may reform the emulsion.

VI. By creaming:

- A creamy emulsion is more liable to crack than a homogenous emulsion. It is, therefore, necessary to take steps to retard creaming as far as possible.

2. Creaming

- Creaming may be difined as the upward movement of dispersed globules to form a thick layer at the surface of the emulsion.
- Creaming is a temporary phase because it can be re-distributed by mild shaking or stirring to get again a homogenous emulsion.
- As far as possible creaming of an emulsion should be avoided because it may lead to cracking with complete separation of two phase.
- According to Stoke's law, the rate of creaming depends on the number of factors which can be explained by the following equation:
- $$V = \frac{2r^2 \quad (d1 - d2)\, g}{9\,\eta}$$
- $V=$ rate of creaming, r = radius of globules, d1 = density of dispersed phase,
- d2= density of continuous phase, g = gravitational constant, η = viscosity of the dispersion medium.

i. Radius of globules:

- The rate of creaming is directly proportional to the radius of the globules.
- Larger the size of the globules, the more will be creaming and smaller the size of the globules, lesser will be creaming.
- The globules will rise less quickly than large globules. Hence, creaming can be reduced by reducing the size of glubules by passing the emulsion through a homogeniser.

ii. Difference in density of disperse phase and continuous phase:

- The rate of creaming depends upon the difference between the densities of the disperse phase and continuous phase.
- Greater the difference, more will be the creaming. This difference can be reduced but it is not desirable because it is not required therapeutically.
- **iii. Viscosity of the dispersion medium:**
- The rate of creaming is inversely proportional to the viscosity of the dispersion medium.
- The viscosity can be increased by adding tragacanth and methyl cellulose.
- But toomuch viscosity is undesirable because it may become difficult to re-disperse the material which have settled at the bottom. Moreover, it is difficult to pour the emulsion from the container.

iv. Storage condition:

- The emulsion should be stored in a cool place because the rise in temperature reduces the viscosity which may lead to creaming.
- The freezing should be avoided because it may lead to cracking.

3. Phase inversion

- Phase inversion means the change of one type of emulsion into the other type i.e. oil in water emulsion changes into water in oil type and vice versa. It may be due to following reasons:

a. By addition of an electrolyte

b. By changing the phase-volume ratio

c. By temperature change

d. By changing the emulsifying agent

- The phase inversion can be minimised by keeping the concentraion of disperse phase between 30 to 60%, storing the emulsion in a cool place and by using a proper emulsifying agent in adequate concentration.

Containers

- The emulsion should be packed in containers having an adequate air space above the emulsion, so as to permit adequate shaking before its use.
- The emulsion which are meant for internal use should be packed in comparatively wide mouth bottle, so that it is easy to remove it without any difficulty.
- Metallic closures should be avoided. Wide mouthed amber glass are most appropriate for the storage of emulsion.

- **Labelling :**
- A secondary label ‘shake well before use’ is required to be fixed on the container.
- **Storage:**
- An emulsion should be stored in air tight container, protected from light, freezing and high temperature.
- The emulsions are required to be stored in a cool place.

Different between Emulsion and Suspension

EMULSIONS0	SUSPENSIONS
These are biphasic liquid preparation containing two immiscible liquids one of which is dispersed as minute glubles into the other.	These are biphasic liquid dosageform of medicament in which finely divided solid particles are dispersed in a liquid or semisolid vehicle.
The globule size of the dispersed liquid is in the range of 0.25 to 25 µm.	The particle size of the suspended solid is in the range of 0.5 to 5.0 micron.
The emulsifying agent is required to make a stable emulsion.	The suspending agent is required to make a stable suspension.
Emulsion are of two types i.e. oil-in-water type and water-in-oil type.	Suspensions are of two types i.e. flocculated and non-flocculated and non-flocculate.
There are several tests to confirm the type of emulsion.	There is no test to identify the type of suspension.
During storage, freezing should be avoided as it may lead to cracking of emulsion.	During storage, freezing should be avoided as it may lead to aggregation of the sespended particles.