Composition of an Emulsion

The Aqueous Phase

Water is usually used as aqueous phase. In addition, the aqueous phase may contain water soluble drugs, preservatives, colouring and flavouring agents.

Distilled water or deionised water is often used in emulsions, since calcium and magnesium ions of hard water and other electrolytes may have an adverse effect on the stability of some emulsions, particularly those containing soaps as emulsifying agents.

Examples of drugs which are added to the aqueous phase of an emulsion are potassium iodide, ammonium chloride and chloral hydrate.

The Oil Phase

The oil phase of an emulsion consists of fixed or volatile oils, resins, waxes and fats. It may contain oil-soluble drugs such as phenyl salicylate, camphor and oil-soluble vitamins. Sometimes an antioxidant is added to prevent rancidity of the oil and destruction of the drugs for example vitamin E.

The Emulsifying Agent (EA)

In the absence of an emulsifying agent, oil can be dispersed in water to the maximum extent of about 2%. Emulsifying agents are required for the preparation and the stabilisation of the more concentrated emulsions containing about 10-80% of internal phase.

Emulsifying agents are particular type of surfactants that:

1. Reduce the interfacial tension between oil and water, thus aid in the dispersion of one liquid in the other.

2. Envelop the globules in a sheath to prevent coalescence and separation of the dispersed liquid as a distinct layer.

Ideal characteristics of Emulsifying agents

- It must be compatible with the other formulative ingredients and must not interfere with the stability or efficacy of the therapeutic agent.

- It should be stable and not deteriorate in the preparation.
- It should be nontoxic with respect to its intended use and the amount to be consumed by the patient.
- It should possess little odour, taste, or colour.
- It should be capable to promote emulsification and maintain the stability of the emulsion for the intended shelf life of the product.

Emulsifying agents can be divided into three groups (Natural, synthetic and finely divided solids)

1. **Natural Emulsifying Agents**

e.g. acacia (Arabic gum), tragacanth, gelatin, starch and pectin.

Acacia generally produces o/w emulsions which are not viscous enough to prevent the rapid rise of the globules with subsequent formation of a cream layer on the surface of the emulsion. Thickening agents such as agar and tragacanth sometimes are added to acacia emulsions to minimise the creaming effect.

Gelatine used as an emulsifying agent. It is a negatively charged colloid at pH values above its iso-electric point and is a positively charged at pH values below the iso-electric point.

Since the oil globules in an o/w emulsion are negatively charged, gelatine is readily adsorbed on the surface of the particles if the pH is below the iso-electric point.

The iso-electric point of gelatine varies with the origin of the product. Gelatine (Type A) which is obtained from an acid-treated precursor has an iso-electric point between pH (7 and 9) acts best as an emulsifying agent at pH 3.2 at which it is positively charged.

Gelatine from an alkali-treated precursor (Type B) has an iso-electric point between pH (4.7 and 5) and is used at pH 8 at which it is negatively charged.

The disadvantage of gelatine is that the emulsions prepared from it are too fluid and become more fluid upon standing.

2- Synthetic Emulsifying Agents

Synthetic emulsifiers are superior to natural gums and proteins in that they are not susceptible to decomposition by micro-organisms. Furthermore, the ratio of hydrophilic to lipophilic groups in the molecule may be altered to supply a wide range of emulsifying agents.

Only a limited number of synthetic agents are safe for internal use among these are the sorbitan esters (Spans), polyoxyethylene sorbitan esters (Tweens) and glyceryl monostearate.

A- Anionic Emulsifying Agents

This class includes monovalent, polyvalent, organic soaps, sulphates and sulphonates.

Soaps have a disagreeable taste and produce an irritating and laxative action in the intestinal tract, consequently they are not used in orally administered emulsions.

The alkali soaps including sodium, potassium and ammonium salts of lauric, palmitic, stearic and oleic acid are hydrophilic and form o/w emulsion.

The metallic soaps of calcium, magnesium, zinc and aluminium salts of fatty acids are water insoluble and tend to promote w/o emulsions.

Monovalent soaps tend to form o/w emulsions, where as polyvalent soaps form the w/o type.

Organic soaps (amino soaps) such as triethanolamine oleate produce o/w emulsions. They have the advantage over inorganic soaps in that they represent a better balance between hydrophilic and lipophilic groups and the final emulsion is fine-grained and stable.

Sodium lauryl sulphate is an example of sulphonate group used as anionic emulsifying agent.

B- Cationic Emulsifying Agents

Cationic EAs are those in which the action is dependent on the cationic or positively charged group. Benzalkonium chloride is an important member of this class.

Cationic agents have marked bactericidal properties and are used primarily as local anti-infective rather than as emulsifying agents. They must not come in contact with anionic chemicals such as soaps, since the two types are incompatible. The active group of the cationic agent combines with the anion and although precipitation may not be evident immediately when the substances are used in low concentrations, the germicidal action of the cationic agent is destroyed and the emulsifying property of the anionic emulsifier may be impaired.

C- Non-ionic Emulsifying Agents

The entire undissociated molecule of certain chemicals containing hydrophilic and lipophilic groups on proper balance may act as an EA.

Included in this group are glyceryl esters, fatty acid esters of sorbitan and polyethylene glycol esters.

An important group of non-ionic agents are obtained by partial esterifying the anhydrides derived from sorbitol and other sugar alcohols with various fatty acids. Sorbitan laurate, palmitate, stearate and oleate constitute the series of **Spans**.

Spans are lipophilic in nature and therefore they tend to form w/o emulsions.

The polyoxyethylene derivatives of Spans, known as **Tweens** are water soluble or dispersible and favour the formation of o/w emulsions.

3- Finely Divided Solids

Colloidal clays such as bentonite, veegum, magnesium hydroxide, aluminium hydroxide, magnesium oxide and silica gel are some of the insoluble substances that have been used as emulsifying agents.

The finely divided solids form and stabilise emulsions by concentrating at the interface where they produce a coherent film around the globules and prevent coalescence of the internal phase.

Bentonite may be used to form either an o/w or w/o emulsions depending on the order of mixing.

Methods of Emulsification

Emulsions can be prepared by several methods depending on the nature of the emulsion components and the equipment available for use.

1. Dry Gum Method

(Addition of the external phase to the internal phase containing the EA).

It involves mixing the oil and the powdered acacia in a dry Wedgewood or porcelain mortar, triturating the mixture until the powder is distributed uniformly throughout the oil, then adding a measured portion of water all at one time, followed by rapid trituration to form the nucleus or primary emulsion and finally adding water and other ingredients to complete the product.

The primary emulsion formed with 4 parts by volume of fixed oil, 2 parts by volume of water and 1 part by weight of acacia (4 : 2 : 1) method.

2. Wet Gum Method

(Addition of the internal phase to the external phase containing the EA)

This procedure involves the addition of oil to an aqueous solution of the emulsifying agent. The proportion of fixed oil, water and acacia for the preparation of the primary emulsion is the same ratio used in the dry gum method (4 : 2 : 1).

Water is added all at once to acacia in a Wedgewood or porcelain mortar and the mixture is triturated by light rapid movement of the pestle until a smooth mucilage is formed.

The oil is added slowly in small increments with continuous trituration, so that each portion is distributed and emulsified in the mucilage before the next quantity is added.

The primary emulsion is triturated for at least 5 minutes to ensure complete dispersion of the oil and then it is diluted with water to the required volume.

3. Bottle Method

This method can be used for small-scale emulsification of volatile oils and other liquids of low viscosity. The ratio of volatile oil, water and acacia is 2:2:1, the proportion of acacia being greater than that used for fixed oils because of the low viscosity of the oils.

Powdered acacia is placed in a dry bottle, two parts of oil are added, and the mixture is thoroughly shaken in the capped container. A volume of water approximately equal to that of the oil is then added in portions and the mixture thoroughly shaken after each addition. When all of the water has been added, the primary emulsion thus formed may be diluted to the proper volume with water or an aqueous solution of other formulative agents.

4. In Situ Soap Method

Liniments and lotions may be prepared in a bottle by this method. According to this method, an oil containing sufficient free fatty acid such as linseed or olive oil is placed in a bottle and an equal volume of alkali such as calcium hydroxide solution is added. When the mixture is shaken, the fatty acid of the oil reacts with the alkali to form a calcium soap (EA is calcium oleate) which promotes a w/o emulsion. The soap formed in situ (i.e. at the time of mixing) which is called Nascent soap and the emulsification procedure is called the Nascent soap method and it may be used to prepare either o/w or w/o emulsions.

e.g. Calamine liniment

Calamine	80 g
Zinc Oxide	80 g
Olive Oil	1000 mL
Calcium Hydroxide Solution	1000 mL

Factors influencing Emulsion type

1. The ratio of the two phases.
2. The type of the EA.
3. The order of mixing.

The relative volume of the internal and external phases of an emulsion is important, as the internal phase concentration is increased, there is an increase in the viscosity of the emulsion to certain point, after which the viscosity decreases sharply. At this point, the emulsion has undergone inversion that is it has changed from an o/w emulsion to w/o or vice versa and even it may break. Emulsions may be prepared without inversion with as much as about 75% of the volume of the product being internal phase.