

EMULSION

METHOD OF PREPARATION

- After the purpose of the emulsions has been determined, i.e oral or topical use,
 - and the type of emulsions, o/w or w/o,
 - and appropriate ingredients selected
 - and the theory of emulsification considered
- experimental formulations may be prepared by a method suggested by Griffin.

Experimental method

1. Group the ingredients on the basis of their solubilities in the aqueous and nonaqueous phase.
2. Determine the type of emulsion required and calculate an approximate HLB value
3. Blend a low HLB emulsifier and a high HLB emulsifier to the calculated value
[N.B. For experimental formulations, use a higher concentration of emulsifier (e.g. 10 to 30% of the oil phase) than that required to produce a satisfactory product.
4. Dissolve the oil-soluble ingredients and the emulsifiers in the oil. Heat, if necessary, to approximately 5 to 10°C over the melting point of the highest melting ingredient of to a maximum temperature of 70 to 80°C.
5. Dissolve the water-soluble ingredients (except acids and salts) in a sufficient quantity of water. Heat the aqueous phase to a temperature which is 3 to 5°C higher than that of the oil phase.
6. Add the aqueous phase to the oily phase with suitable agitation.
7. If acids or salts are employed, dissolve them in water and add the solution to the cold emulsion.
8. Examine the emulsion and make adjustments in the formulation if the product is unstable.

Large scale industrial method

The preparation of an emulsion requires work to reduce the internal phase into small droplets and disperse them throughout the external phase. This can be accomplished by a mortar and pestle or a high speed emulsifier. The addition of emulsifying agents not only reduces this work but also stabilizes the final emulsion. Emulsions may be prepared by four principle methods:

1. Addition of internal phase to external phase

Let us take a model of o/w emulsion.

- (i) The water soluble substances are dissolved in water and the oil soluble substances are dissolved in oil.
- (ii) The oil mixture is added in portions to the aqueous preparation with agitation (in a colloid mill or homogenizer).

N.B. Sometimes, in order to give a better shearing action during the preparation, all of the water is not mixed with the emulsifying agent until the primary emulsion with oil is formed; subsequently, the remainder of the water is added.

e.g. *Emulsion using Gelatin-type A as the emulsifier.*

Gelatin (Type A)	8g
Tartaric acid	0.6g
Flavour as desired	
Alcohol	60ml
Oil	500ml
Purified water, to make	1000ml

Procedure

- (i) The gelatin & tartaric acid are added to approximately 300ml water, allowed to stand for few minutes, heated until gelatin is dissolve, then temperature is raised to 98°C and this temperature is maintained for about 20 minutes. Cooled to 50°C, flavor and alcohol are added and more water was added to make 500 ml.
- (ii) The oil is added to the aqueous phase (i.e. external phase), and the mixture is agitated thoroughly and passed it through a homogenizer or colloid mill.

2. Addition of the external phase to the internal phase

Let us take a model of o/w emulsion.

In this method water (external phase) is first added slowly to the oil (internal phase) to promote the formation of a more w/o emulsion due to the presence of more oil than water. After further addition of water phase inversion to an o/w emulsion should take place.

This method is especially successful when hydrophilic agents such as acacia, tragacanth or methyl cellulose are first mixed with oil, effecting dispersion without wetting. Water is added and, eventually, an o/w emulsion is formed.

e.g. *Mineral oil emulsion*

Mineral oil	500ml
Acacia, in very fine water	125g
Syrup	100ml
Vanillin	40mg
Alcohol	60ml
Purified water, upto	1000ml

- (i) The mineral oil and acacia are mixed in a dry mortar. Purified water, 250 ml (Phase volume ratio o/w = 2: 1) is added and the mixture triturated vigorously until an emulsion is formed.
- (ii) A mixture of the syrup, 50 ml of purified water and the vanillin dissolved in alcohol are added in divided portions with trituration
- (iii) Sufficient purified water is then added to the proper volume, the mixture well and homogenized.

3. Mixing both phases after warming each

This method is use when waxes or other substances which require melting are used. The oil-soluble emulsifying agents, oils and waxes are melted and mixed thoroughly. The water-soluble ingredients dissolved in the water and warmed to a temperature slightly higher than the oil phase.

The oil phases are then mixed and stirred until cold. For convenience, but not necessity, the aqueous solution is added to the oil mixture.

This method frequently is used in the preparation of ointments and creams.

e.g. *An oral emulsion (o/w) containing an insoluble drug*

1. Cotton seed oil	460g
2. Sulphadiazine	200g
3. Sorbitan monostearate	84g
4. Polyoxyethylene 20 sorbitan mono stearate	36g
5. Sodium benzoate	2g
6. Sweetener	q.s.
7. Purified water	1000g
8. Flavor oil	q.s.

Procedure

- (i) Heat the first three ingredients to 50°C and pass through colloid mill.
- (ii) Add the next four ingredients at 50°C to the first three ingredients at 65°C and stirred while cooling to 45°C.
- (iii) Add the flavor oil and continue stirring until room temperature is reached.

4. Alternate addition of the two phases to the emulsifying agent

Model: Let us prepare an o/w type of emulsion.

- (i) A portion of the oil is added to all of the oil-soluble emulsifying agents with mixing.
- (ii) Equal quantity of water is added to all of the water-soluble emulsifying agents with mixing.
- (iii) Aqueous solution is mixed with oil phase stirred until the emulsion is formed.
- (iv) Further portions of water and oil are added alternately until the final product is formed.

N.B. The high concentration of the emulsifying agent in the original emulsions makes the initial emulsification more likely and the high viscosity provides effective shearing action leading to small droplets in the emulsion.

This method is often used successfully with soaps.