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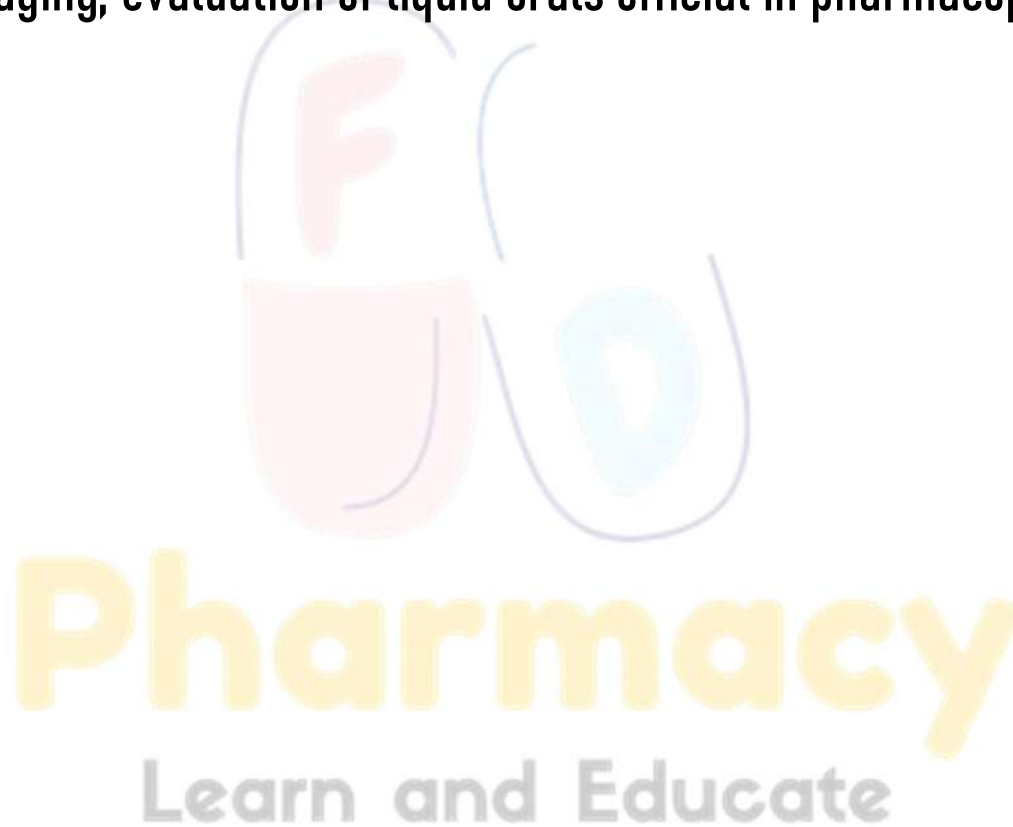
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INDUSTRIAL PHARMACY - I

UNIT 2

TOPIC :

- **Liquid orals :** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia



Liquid Oral Preparations

- Solutions, syrups, suspensions, elixirs, and concentrates are oral liquid dosage forms.
- These dosage forms offer exclusive advantages to numerous patients.
- For example, in patients facing problems in swallowing oral solid dosage forms, liquids offer better compliance for the patients and also provide enhanced dosage control against a fixed dose of tablet.



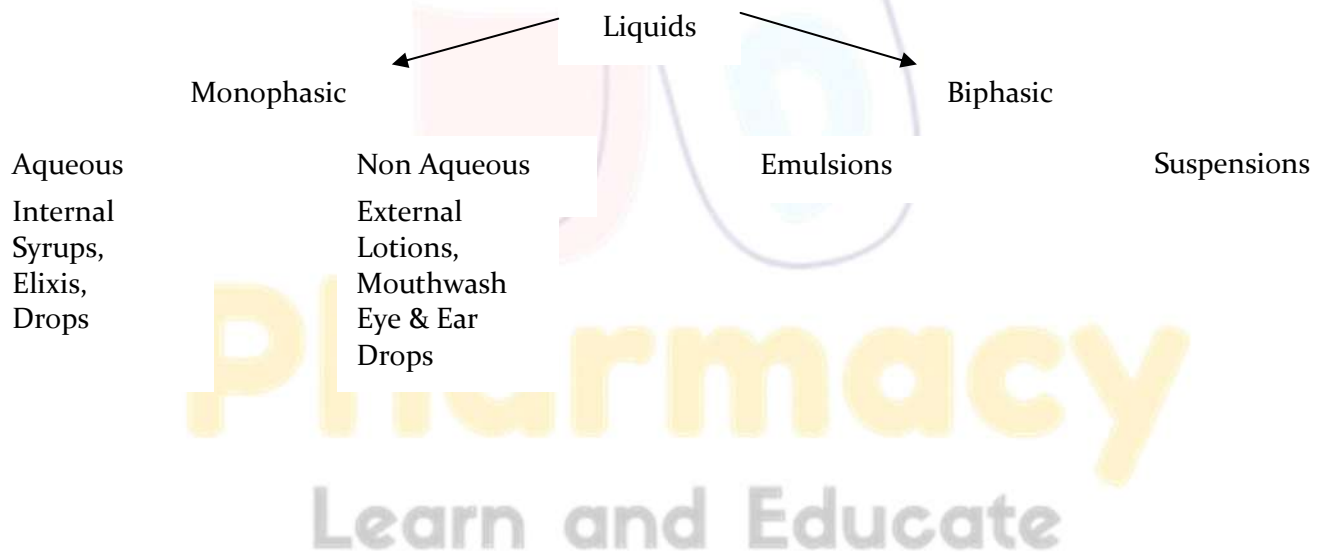
Advantages

- ✓ It is easier to swallow liquids than solids, thus, these dosage forms are more satisfactory and suitable for paediatrics and geriatrics.
- ✓ Solutions get absorbed easily, thus, producing therapeutic response at a faster rate than the solids (which first disintegrates and then getting absorbed from the gastrointestinal fluid).
- ✓ In case a drug precipitates from the solution form under acidic conditions of the stomach, it will become moist and will divide into fine particles, allowing rapid absorption.
- ✓ The drug in solutions is uniformly distributed; whereas in suspensions or emulsions, dose variation may Occur resulting from phase separation during storage.

Disadvantages

- ✚ The transportation and storage of liquids are problematic, as they are bulky.
- ✚ Growth of microorganisms is supported by liquid media, thus, the preparation needs a preservative to be incorporated within it. .
- ✚ Dose inaccuracy may occur if a patient takes a dose using household devices, like a teaspoon, etc.
- ✚ These dosage forms also have flavouring and sweetening properties.
- ✚ The dissolved substances in the liquids may result in incompatible interactions.

Classification



MONOPHASIC LIQUID DOSAGE FORMS

- Monophasic Liquid Dosage Forms: These dosage forms comprise of a single homogeneous phase, e.g., solutions, waters, tinctures, etc.
- Biphasic Liquid Dosage Forms: These dosage forms comprise of two discrete phases, e.g., emulsions and suspensions.

Solution

- Solution can be defined as a homogeneous system made up of a phase containing two or more components.

The two components of a solution are:

- a. Solvent: It is the phase in which dispersion occurs.
- b. Solute: It is the phase which is dispersed in the form of molecules or small ions in the solvent.

Characteristics

1. In any formulation both the phases should be uniformly distributed and clear in composition.
2. The preparation should remain stable before the expiry period.
3. No irritant or toxic effect should be produced by it to the human body.
4. Suitable additives should be present in the product to provide a better patient compliance.
5. During the storage of the solution for a specific period of time, it should not get precipitated or show any type of discolouration.

Advantages

- i. Drug absorption is rapid.
- ii. Being a liquid dosage form they can be swallowed conveniently than the solid dosage form.
- iii. They are a homogeneous system as the drug in the solution remains uniformly distributed throughout the formulation.
- iv. They do not cause damage and irritation to GIT (often caused by tablets or capsules).

Disadvantages

- Their transportation is not easy because the liquids are bulky in nature.
- Loss of complete preparation occurs if during transportation the container breaks.
- Their shelf-life is shorter than tablets or capsules.
- The stability of drugs in aqueous solution is less than those in solid dosage forms.
- Dose accuracy in liquid dosage forms is less than in solid dosage forms.

Syrups



→ A saturated solution of sucrose formed in purified water with the concentration of 66% w/w sugar is known as simple syrup.

Classification

- A) Simple Syrups: These syrups are made up of simple solutions or are admixture of solutions. Examples of simple syrup include syrups (I.P.), ginger syrup, orange syrup, and lemon syrup.
- B) Preparation: Sucrose is added to the purified water and heated with occasional stirring until the sucrose gets dissolved. The solution is then cooled and sufficient purified water is added to make up the desired weight.
- C) Medicated therapeutic agents : Examples of medicated syrups Syrups: These syrups include are chlorpheniramine maleate syrup, ephedrine sulphate syrup, etc.
- D) Flavoured Syrups: These syrups comprise of different flavoured or aromatic substances which give a pleasant smell and taste. These are usually added to the preparation for providing a flavour, as a preservative, or as a vehicle. It does not contain any pharmacological activity.

Preparation

- Hot Process
- Percolation (cold process)

Elixirs

- Elixirs are defined as clear, sweetened, aromatic, hydroalcoholic liquids intended for oral use.
- Elixirs are less sweet and less viscous than syrups and may contain less or no sucrose
- Elixirs are clear preparation and drugs in liquid form to be administered orally.

Classification

- Non-Medicated Elixirs:** Such elixirs do not contain a medicament and are employed as not flavouring vehicles, e.g., aromatic elixir U.S.P., iso alcoholic elixir NF, compound benzaldehyde elixir as NF, etc.
- Medicated Elixirs:** These elixirs are employed for the therapeutic action of the medicinal substances they contain, e.g., chlorpheniramine maleate elixir U.S.P, diphenhydramine hydrochloride elixir U.S.P., piperazine citrate elixir, terpin hydrate elixir, etc.

Preparation

The preparation method for elixirs is the simple dissolution method involving the following steps:

- In this method, either an admixture of two or more liquid components is used or the components are dissolved by agitation.
- The ingredients are dissolved in the respective Solvents, for example, water is used as a solvent for the water-soluble ingredients, and alcohol is used as a solvent for the alcohol-soluble ingredients.
- Always the aqueous solution is added to the alcoholic solution for maintaining the ideal alcoholic strength and preventing the separation of alcohol-soluble ingredients.
- The desired volume is adjusted using the vehicle or solvent specified in the formulation.
- At this point, reduction in alcoholic strength is noted which leads to the separation of a few noted flavouring agents, thus, the product may not be found clear.
- In such a case, the elixir preparation is kept aside for some time so that the hydro-alcoholic solvent saturates resulting in the cluster of globules.
- Filtration facilitates the removal of these globules.
- To absorb the excess oil and removing it from the elixir solution, up to 3% of talc is used.
- Filtration yields a bright and clear product.

BIPHASIC LIQUIDS

- Liquid preparations having two phases are termed as biphasic liquids.
- These preparations essentially require a dispersed phase and a dispersion medium in order to dissolve many insoluble solid and liquid medicaments that are either insoluble in or immiscible with water (mostly used as a vehicle).

Following are the examples of biphasic liquid dosage forms:

- 1) Emulsions: These are biphasic liquid preparations of two immiscible liquids, with one liquid dispersed in the other liquid (continuous phase) in the form of globules.
- 2) Suspensions: These are biphasic liquid preparations in which the finely divided drug particles (with minimum solubility) are uniformly dispersed throughout the vehicle.

Suspensions

- Suspensions are biphasic liquid preparations containing finely divided 0.5-5.0 μ m solid drug particles (discontinuous phase).
- Suspensions are intended for oral administration, external application, or parenteral use.
- A coarse dispersion in which insoluble solids are suspended in a liquid medium is termed as a pharmaceutical suspension.
- In suspensions, water or water-based vehicle are normally used as a liquid medium, in which the insoluble solids (size ranging from 10-1000 μ m) are suspended.

Advantages

- Stability
- Choice of Solvent
- Taste Masking
- Prolonged Action Dosage Forms
- Bioavailability



Disadvantages

- An accurate dose can be attained only if the suspensions are packed in unit dosage forms. Thus, the potent drugs are not administered as suspension.
- Problems related to physical stability, sedimentation, and compaction of sediment can occur. These problems cannot be solved easily.
- Oxidation and hydrolysis may affect the chemical stability of suspension.
- Suspensions are liquid dosage forms, therefore, are need to be protected against microbial attack.

Types of Suspensions

On the basis of their general classes: -

- I. Oral Suspensions: These are meant for oral administration in which one or more insoluble medicaments are dispersed in the liquid vehicle.
- II. Externally Applied Suspensions: These are meant for topical application.
- III. Parenteral Suspensions: These are heterogeneous systems in which the solid phase dispersed within a liquid phase.

Pharmaceutical Applications

The applications of suspensions are as follows:

- a. They are used either for avoiding drug damage or for improving drug stability, e.g, oxytetracycline suspensions.
- b. They are required to conceal the obnoxious taste of certain drugs, e.g., chloramphenicol palmitate suspensions.
- c. They can be modified to control the drug absorption rate for parenteral administration, e.g., penicilin procaine suspensions.
- d. Some of the vaccines containing immunising agents are prepared as suspensions, e.g., cholera vaccine.
- e. They can be formulated with drugs intended for topical use, e.g., calamine lotion

Emulsions

- A biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules into the other, is termed as a pharmaceutical emulsion.
- The liquid in the form of minute globules is the dispersed phase, while the liquid containing the dispersed globules is the continuous phase.



Advantages

- ◆ The inedible oils can easily be administered as edible emulsions.
- ◆ The obnoxious taste of oils can be concealed.
- ◆ The flavouring of aqueous phase of emulsion is possible.
- ◆ They are more rapidly absorbed than the solid dosage forms.
- ◆ Two incompatible ingredients can be incorporated, with one in each phase.

Disadvantages

- 1) The manufacturing process of stable emulsions requires technical experts and calculations of primary emulsion formulae.
- 2) A measuring device is employed for administering emulsions.
- 3) In case they are not shaken well before use, dose accuracy decreases in comparison to solutions.
- 4) The dispersion system may get affected if the emulsions are improperly stored.

Types of Emulsions

Depending on dispersed phase, emulsions can be categorised into:

- 1) Water-in-Oil (w/o) Emulsions:
- 2) Oil-in-Water (o/w) Emulsions :

Pharmaceutical Applications

- ➔ The o/w type emulsions are known to enhance the drug absorption through GIT.
- ➔ The nutrient oils that are difficult to swallow can be injected intravenously as emulsions.
- ➔ Certain o/w emulsions like per-fluorinated hydrocarbons are used for oxygen replacement therapy.
- ➔ Many water-soluble antigens and certain drugs are prepared as w/o type emulsions to be given as depot injection (sustain and release).
- ➔ Certain emulsions comprising different radio opaque elements can be used for diagnosis.

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