Formulation Development
Definition of Solutions

Solution preparations include oral, topical, parenteral, rectal, vaginal, ophthalmic, otic, nasal and others.

Definitions
Solutions
Solutions are liquid preparations containing one or more drug substances molecularly dispersed in a suitable solvent or mixture of mutually miscible solvents.

Oral Liquids
Oral liquids are intended for oral administration and contain one or more substances with or without flavouring, sweetening or colouring agents dissolved in water or co-solvent-water mixtures. They may be formulated for direct oral administration to the patient or to be diluted by the patient.

Parenteral Solutions
Parenteral solutions may be either aqueous or non-aqueous and must be prepared to ensure sterility and non-pyrogenicity. They may be administered intravenously, intramuscularly, subcutaneously or intrathecally or by other routes.

Topical Solutions
Topical solutions are generally aqueous but may contain co-solvent systems such as various alcohols or other organic solvents with or without added active ingredients; some solutions are non-aqueous, using organic solvents or oils as the vehicle. Often the term lotion is used to designate solutions or suspensions applied topically.

Syrups
Syrups are concentrated aqueous preparations of a sugar or sugar substitute with or without flavouring agents and medicinal substances. Syrups can serve as pleasant-tasting vehicles for active drugs.

Elixirs
Elixirs are clear, sweetened, hydro-alcoholic solutions that are usually flavoured and are suitable for drugs that are insoluble in water alone but soluble in water-alcohol mixtures. They are usually less sweet and less viscous than syrups and are generally less effective in masking taste. Elixirs may also contain different solvents as co-solvent systems, e.g., water, alcohol, glycerin, sorbitol, propylene glycol and polyethylene glycol 300. Generally, the term oral liquid is used now to designate both syrups and elixir-type dosage forms.


The above instructions are provided solely for use by compounding professionals for the purpose of providing instructions in the preparation of the above oral suspension. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Eaststone.
Formulation Development
How are Solutions made

Physico-chemical considerations for formulation of successful preparation.

When formulating a solution dosage form several technical difficulties must be confronted and overcome in order to prepare a successful liquid preparation.

These considerations include:

- Unstable drugs are even more unstable in solution.
- Drug degradation eg oxidation, reduction, hydrolysis etc.
- Poorly soluble drugs must be solubilised or suspended.
- Bad-tasting drugs must be masked and a palatable preparation prepared.
- Correct Solvent selection e.g. Water, Alcohol, glycerin, glycol, mannitol, sorbitol.
- Physical and chemical properties of ingredients.
- Order of mixing and adjuvants.
- Incompatibilities in preparation and storage.
- Stability and potency of ingredients.
- Major physical and chemical considerations include the drug form (base, salt, ester), pH, Solubility and stability.
- Vehicle considerations include pH, internal vs external use, flavour sweetener, colour, preservative, viscosity; compatibility; and, if indicated, suspending and emulsifying agents.

Specific Quality Control

Quality control evaluations that should be performed include final volume, appearance, odour, clarity, specific gravity, pH, active drug assay and rheological properties.

Storage/Labelling

Liquids should generally be stored at room or refrigerated temperature, depending upon the characteristics of the active drug. If saturated solutions are stored in the refrigerator, precipitation may occur. In many cases, the precipitate will be redissolved upon returning to room temperature.

Counselling

Patients should be counselled about measuring the dose of a liquid preparation and about shaking the preparation (if necessary), administering the preparation, replacing and tightening the cap and storage. The patient should be instructed to check for physical stability and store out of the reach of children.


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