Elixirs

Elixirs are clear, sweetened hydroalcoholic solutions intended for oral use and are usually flavored to enhance their palatability.

- Nonmedicated elixirs are employed as vehicles, and medicated elixirs are used for the therapeutic effect of the medicinal substances they contain.
- Compared with syrups, elixirs are usually less sweet and less viscous because they contain a lower proportion of sugar and consequently are less effective than syrups in masking the taste of medicinal substances.
- Because of their hydroalcoholic character, elixirs are better able than aqueous syrups to maintain both water-soluble and alcohol-soluble components in solution.
- Also, because of their stable characteristics and the ease with which they are prepared (by simple solution), from a manufacturing standpoint, elixirs are preferred to syrups.
- The proportion of alcohol in elixirs varies widely because the individual components of the elixirs have different water and alcohol solubility characteristics.
- Each elixir requires a specific blend of alcohol and water to maintain all of the components in solution. Naturally, for elixirs containing agents with poor water solubility, the proportion of alcohol required is greater than for elixirs prepared from components having good water solubility.
- In addition to alcohol and water, other solvents, such as glycerin and propylene glycol, are frequently employed in elixirs as adjunctive solvents.
- Although many elixirs are sweetened with sucrose or with a sucrose syrup, some use sorbitol, glycerin, and/or artificial sweeteners.
- Elixirs having a high alcoholic content usually use an artificial sweetener, such as saccharin, which is required only in small amounts, rather than sucrose, which is only slightly soluble in alcohol and requires greater quantities for equivalent sweetness.
- All elixirs contain flavorings to increase their palatability, and most elixirs have coloring agents to enhance their appearance.
Elixirs containing more than 10% to 12% of alcohol are usually self-preserving and do not require the addition of an antimicrobial agent.

A disadvantage of elixirs for children and for adults who choose to avoid alcohol is their alcoholic content.

Because of their usual content of volatile oils and alcohol, elixirs should be stored in tight, light-resistant containers and protected from excessive heat.

**Advantages of elixirs**

- Insoluble drug compounds can be incorporated into the hydroalcoholic vehicle;
- Drug concentrates can be prepared in high-alcohol-containing elixirs;
- Hydroalcoholic vehicles can be self-preserving;
- Elixirs are less viscous and contain a lower proportion of sugar.

**Disadvantages of elixirs**

- They cannot be administered to pediatric patients and patients on antidepressant medication;
- The concentration of active and inactive ingredients may vary if not preserved in cool places;
- Water-insoluble drug compounds may precipitate due to alcohol evaporation.

**Preparation of Elixirs**

Elixirs are usually prepared by simple solution with agitation and/or by admixture of two or more liquid ingredients.

- Alcohol soluble and water-soluble components are generally dissolved separately in alcohol and in purified water, respectively. Then the aqueous solution is added to the alcoholic solution, rather than the reverse, to maintain the highest possible alcoholic strength at all times so that minimal separation of the alcohol-soluble components occurs.
- When the two solutions are completely mixed, the mixture is made to the volume with the specified solvent or vehicle.
Frequently, the final mixture will be cloudy, principally because of separation of some of the flavoring oils by the reduced alcoholic concentration. If this occurs, the elixir is usually permitted to stand for a prescribed number of hours to ensure saturation of the hydroalcoholic solvent and to permit the oil globules to coalesce so that they may be more easily removed by filtration.

- Talc, a frequent filter aid in the preparation of elixirs, absorbs the excessive amounts of oils and therefore assists in their removal from the solution.
- The presence of glycerin, syrup, sorbitol, and propylene glycol in elixirs generally contributes to the solvent effect of the hydroalcoholic vehicle, assists in the dissolution of the solute, and enhances the stability of the preparation. However, the presence of these materials adds to the viscosity of the elixir and slows the rate of filtration.

**Non-medicated Elixirs**

Nonmedicated elixirs may be useful to the pharmacist in the extemporaneous filling of prescriptions involving

- the addition of a therapeutic agent to a pleasant-tasting vehicle and
- dilution of an existing medicated elixir

In selecting a liquid vehicle for a drug substance, the pharmacist should be concerned with the solubility and stability of the drug substance in water and alcohol. If a hydroalcoholic vehicle is selected, the proportion of alcohol should be only slightly above the amount needed to effect and maintain the drug’s solution.

When a pharmacist is called on to dilute an existing medicated elixir, the non-medicated elixir he or she selects as the diluent should have approximately the same alcoholic concentration as the elixir being diluted. Also, the flavor and color characteristics of the diluent should not be in conflict with those of the medicated elixir, and all components should be chemically and physically compatible.

**Medicated Elixirs** are employed for the therapeutic benefit of the medicinal agent. Most official and commercial elixirs contain a single therapeutic agent. The main advantage of having only a single therapeutic
agent is that the dosage of that single drug may be increased or decreased by simply taking more or less of the elixir, whereas when two or more therapeutic agents are present in the same preparation, it is impossible to increase or decrease the dose of one without an automatic and corresponding adjustment in the dose of the other, which may not be desired.

**Spirits**

Spirits are alcoholic or hydroalcoholic solutions of volatile substances. Generally, the alcoholic concentration of spirits is rather high, *usually over 60%*. Because of the greater solubility of aromatic or volatile substances in alcohol than in water, spirits can contain a greater concentration of these materials than the corresponding aromatic waters. When mixed with water or with an aqueous preparation, the volatile substances present in spirits generally separate from the solution and form a milky preparation.

Spirits may be used pharmaceutically as flavoring agents and medicinally for the therapeutic value of the aromatic solute. As flavoring agents, they are used to impart the flavor of their solute to other pharmaceutical preparations. For medicinal purposes, spirits may be taken orally, applied externally, or used by inhalation, depending upon the particular preparation. When taken orally, they are generally mixed with a portion of water to reduce the pungency of the spirit.

Depending on the materials, spirits may be prepared by simple solution, solution by maceration, or distillation. The spirits most recently official in the USP–NF are aromatic ammonia spirit, camphor spirit, compound orange spirit, and peppermint spirit.

**Tinctures**

*Tinctures are alcoholic or hydroalcoholic solutions prepared from vegetable materials or from chemical substances.* They vary in method of preparation, strength of the active ingredient, alcoholic content, and intended use in medicine or pharmacy. When they are prepared from chemical substances (e.g., iodine, thimerosal), tinctures are prepared by simple solution of the chemical agent in the solvent. Depending on the preparation, tinctures contain alcohol in amounts ranging from
approximately 15% to 80%. Traditionally, tinctures of potent vegetable drugs essentially represent the activity of 10 g of the drug in each 100 mL of tincture, the potency being adjusted following assay. The alcohol content protects against microbial growth and keeps the alcohol-soluble extractives in solution. In addition to alcohol, other solvents, such as glycerin, may be employed. The solvent mix of each tincture is important in maintaining the integrity of the product.

Tinctures cannot be mixed successfully with liquids too diverse in solvent character because the solute may precipitate. For example, compound benzoin tincture, contains alcohol-soluble principles that are immediately precipitated from solution upon addition of water. Because of the alcoholic content, tinctures must be tightly stoppered and not exposed to excessive temperatures. Also, because many of the constituents found in tinctures undergo a photochemical change upon exposure to light, many tinctures must be stored in light-resistant containers and protected from sunlight. Medicated tinctures taken orally include camphorated tincture of opium. Usually, patients requiring oral medication nowadays prefer to take a tablet or capsule or a pleasant-tasting elixir or syrup.

- **Herbal tinctures are not always made using ethanol as the solvent, though this is most commonly the case. Other solvents include vinegar, glycerol, ether and propylene glycol, not all of which can be used for internal consumption. Ethanol has the advantage of being an excellent solvent for both acidic and basic (alkaline) constituents.**

- **Glycerin can also be used, but when used in tincturing fashion is generally a poorer solvent. Vinegar, being acidic, is a better solvent for obtaining alkaloids but a poorer solvent for acidic components. For individuals who choose not to ingest alcohol, non-alcoholic e.g., (glycerite) extracts offer an alternative for preparations meant to be taken internally non-alcoholic e.g., (glycerite) extracts offer an alternative for preparations meant to be taken internally.**

**Advantages of Tincture**

Ethanol is able to dissolve substances which are less soluble in water, while at the same time the water content can dissolve the substances less soluble in ethanol. One can sometimes vary the proportion of ethanol and water to produce tinctures with different characteristics due to the distinct solvent properties of these two. Tincture of calendula is commonly
tinctured at either 25% or 90% ethanol. The alcohol content also acts as a preservative.

**Disadvantages of tincture**

Ethanol has a tendency to denature some organic compounds, rendering them so changed as to be ineffective. This is one reason why ethanol is an antimicrobial. This tendency can also have undesirable effects when extracting botanical constituents, for instance, polysaccharides. Certain other constituents, common among them proteins, can become irreversibly denatured. Also, extracted for highly complex aromatic components are denatured by alcohol's intrinsic cleaving action upon an aromatic's complex structure into simpler inert-rendered compounds.

Ether and propylene glycol based tinctures are not suitable for internal consumption, although they are used in preparations for external use, such as personal care creams and ointments.

**General method of preparation**

1. Herbs are put in a container and a spirit of 40% or more ethanol is added,
2. The jar is left to stand for 2–3 weeks and shaken occasionally in order to maximize extraction.
   ❖ More accurate measuring can be done by combining 1 part herbs with a water-ethanol mixture of 2–10 parts, depending on the herb itself. For most tinctures, however, 1 part water to 5 parts ethanol is typical.

**Topical Tinctures**

**Iodine Tincture**

Iodine tincture is prepared by dissolving 2% iodine crystals and 2.4% sodium iodide in an amount of alcohol equal to half the volume of tincture to be prepared and diluting the solution to volume with sufficient purified water. The sodium iodide reacts with the iodine to form sodium triiodide

\[ I_2 + NaI \rightarrow NaI_3 \]

This reaction prevents formation of ethyliodide from the interaction between iodine and alcohol, which would result in the loss of the
antibacterial activity of the tincture. An added benefit of the triiodide form of iodine is its water solubility, which is important for the tincture, which contains between 44% and 50% alcohol, be diluted with water during use.

The tincture is a popular local anti-infective agent applied to the skin in general household first aid.

The tincture should be stored in a tight container to prevent loss of alcohol.

**Compound Benzoin Tincture**

Compound benzoin tincture is prepared by maceration in alcohol of 10% benzoin and lesser amounts of aloe, storax, and Tolu balsam totaling about 24% of starting material. The drug mixture is best macerated in a wide-mouthed container because it is difficult to introduce storax, a sticky semiliquid material, into a narrow-mouthed container. Generally, it is advisable to weigh the storax in the container in which it will be macerated to avoid possible loss through a transfer of the material from one container to another.

The tincture is categorized as a protectant. It is used to protect and toughen skin in the treatment of bedsores, ulcers, cracked nipples, and fissures of the lips and anus. It is also commonly used as an inhalant in bronchitis and other respiratory conditions, 1 teaspoonful commonly being added to a pint of boiling water. The volatile components of the tincture travel with the steam vapor and are inhaled by the patient. Because of the incompatibility of the alcoholic tincture and water, the mixture produces a milky product with some separation of resinous material. Alcohol or acetone may be used as necessary to remove the residue from the vaporizer after use.

- Compound benzoin tincture is best stored in tight, light-resistant containers. Exposure to direct sunlight or to excessive heat should be avoided.
**Thimerosal Tincture (benzalkonium chloride)**

The vehicle of the tincture is water, acetone, and about 50% alcohol. A number of metals, notably copper, cause decomposition of the tincture, and for this reason, it must be manufactured and stored in glass or suitably resistant containers. Monoethanolamine and ethylenediamine are used as stabilizers in the official solution and tincture and are thought to be effective because of their chelating action on traces of metallic impurities that may be present at the time of preparation or may later gain access to the preparation.

It is a commonly used household antiseptic for application to abrasions and cuts and also in the preparation of patients for surgery.

**Fluidextracts**

The USP defines fluidextracts are liquid preparations of vegetable drugs prepared by percolation. They contain alcohol as a solvent, preservative, or both and are made so that each milliliter contains the therapeutic constituents of 1 g of the standard drug that it represents. Because of their concentrated nature, many fluidextracts are considered too potent to
be safely self-administered, and their use per se is almost nonexistent in medical practice. Also, many fluidextracts are simply too bitter tasting or otherwise unpalatable to be accepted by the patient. Therefore, most fluidextracts today are either modified by the addition of flavoring or sweetening agents before use or used as the drug source of other liquid dosage forms, such as syrups

**Extracts**

Extracts are concentrated preparations of vegetable or animal drugs obtained by removal of the active constituents of the respective drugs with suitable menstrua, evaporation of all or nearly all of the solvent, and adjustment of the residual masses or powders to the prescribed standards.

- Extracts are potent preparations, usually between two and six times as potent on a weight basis as the crude drug.
- They contain primarily the active constituents of the crude drug, with a great portion of the inactive constituents and structural components of the crude drug having been removed.
- Their function is to provide in small amounts and in convenient, stable physical form the medicinal activity and character of the bulkier plants that they represent. As such, they have use in product formulation.
- In the manufacture of most extracts, percolation is employed to remove the active constituents from the drug, with the percolates generally being reduced in volume by distillation under reduced pressure to reduce the degree of heat and to protect the drug substances against thermal decomposition.
- The extent of removal of the solvent determines the final physical character of the extract.
- Extracts are made in three forms: (a) semiliquid extracts or those of a syrupy consistency prepared without the intent of removing all or even most of the menstruum, (b) pilular or solid extracts of a plastic consistency prepared with nearly all of the menstruum removed, and (c) powdered extracts prepared to be dry by the removal of all of the menstruum insofar as is feasible or practical.
- Pilular and powdered extracts differ only by the slight amount of remaining solvent in the former preparation, but each has its pharmaceutical advantage because of its physical form. For
instance, the pilular extract is preferred in compounding a plastic dosage form such as an ointment or paste or one in which a pliable material facilitates compounding, whereas the powdered form is preferred in the compounding of such dosage forms as powders, capsules, and tablets.