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*Pharmaceutical Technology for
3rd year students; ; Lec 4,*

By:

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Solution using mixed solvent Systems; Spirits, Elixirs and Extracted Products



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Dr. Esraa Ghazy ...

- Products for Internal use may contain ethanol, glycerol, propylene glycol (PG), & certain oils.
- Solvents such as acetone, benzene and petroleum ether are not used internally.



Elixirs

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

✓ Its one of the official & most widely used liquid preparations for oral administration. Their popularity is due to?

- ✓ Each elixir requires a specific blend of alcohol and water to maintain all of the components in solution.
- ✓ The proportion of alcohol in elixirs varies widely because the individual components of the elixirs have different water and alcohol solubility characteristics.
- ✓ In addition to alcohol & water, other solvents, such as glycerin & PG, are employed as adjunctive solvents.
- ✓ 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.

✓ Although many elixirs are sweetened with sucrose or with a sucrose syrup, some use sorbitol, glycerin, and/or artificial sweeteners.

✓ All elixirs contain flavorings agents? & most of them have coloring agents?

✓ Elixirs containing more than 10%-12% of alcohol are usually self preserving & do not require the addition of an antimicrobial agent.

- ✓ One advantage of elixirs over their counterpart drugs in solid dosage forms is the flexibility and ease of dosage administration to patients who have difficulty swallowing solid forms.
- ✓ A disadvantage of elixirs for children and for adults why”??

- The proportion of alcohol in elixirs varies widely because the individual components of the elixirs have different water and alcohol solubility characteristics.
- In official elixirs, the alcohol contents varies from 4-40%.

Types of Elixirs

- **Non-medicated elixirs**
- They are used as **solvents** or vehicles for the preparation of medicated elixirs: aromatic elixirs (**USP**), isoalcoholic elixirs (NF), or compound benzaldehyde elixirs (NF). Active ingredient dissolved in a solution that contains 15 to 50% by volume of **ethyl alcohol**
- **Medicated elixirs**
- Antihistaminic elixirs: used against allergy: chlorampheniramine maleate elixirs (USP), diphenhydramine HCl elixirs.
- Sedative and hypnotic elixirs: sedatives induce drowsiness, and hypnotics induce sleep: pediatric chloral hydrate elixirs.
- Expectorant: used to facilitate productive cough (cough with sputum): Terpin hydrate elixirs.
- Miscellaneous: acetaminophen (paracetamol) elixirs, which are used as analgesics.

➤ Elixirs Classification

A/ Medicated; are employed for the therapeutic benefit of the medicinal agent. Most official and commercial elixirs contain a single therapeutic agent ???

- 1- Antihistaminics (chlorpheniramine maleate Elixir U.S.P.)
- 2- Sedative & hypnotics (Phenobarbital Elixir, U.S.P.)
- 3- Expectorants (Terpine Hydrate & Codeine Elixir, N.F.)
- 4- Miscellaneous (Dexamethasone Elixir, N.F.)

B-Non-medicated elixirs

ex. Aromatic Elixir N.F., Benzaldehyde Elixir N.F.

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

- ✓ 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 nonmedicated 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.
- ✓ In years past, when pharmacists were called on more frequently than today to compound prescriptions, the three most commonly used nonmedicated elixirs were aromatic elixir, compound benzaldehyde elixir, and isoalcoholic elixir.

EXAMPLES OF MEDICATED ELIXIRS BY CATEGORY

ELIXIR	REPRESENTATIVE COMMERCIAL PRODUCTS	USUAL ADULT DOSE/VOLUME OF COMMERCIAL ELIXIR	COMMENTS
Adrenocortical Steroid			
Dexamethasone	Dexamethasone Elixir	500 mg/5 mL	Synthetic analog of hydrocortisone, about 30 times more potent. Commercial elixir is packaged with a calibrated dropper for accurate measurement of small doses; intended primarily for children; also has utility for adults with trouble swallowing tablets. Used for many indications: rheumatoid arthritis, skin diseases, allergies, inflammatory conditions. Commercial product contains 5% alcohol.
Analgesic, Antipyretic			
Acetaminophen	Children's Tylenol Elixir (McNeil)	160 mg/5 mL	Reduction of pain and lowering of fever particularly in patients sensitive to or unable to take aspirin. Elixir is especially useful for pediatric patients and is alcohol-free.
Anticholinergic, Antispasmodic			
Hyoscyamine sulfate	Alaven	0.125 mg/5 mL	Used to control gastric secretion, visceral spasm, hypermotility, abdominal cramps. Commercial product contains 20% alcohol.
Antihistamine			
Diphenhydramine HCl	Diphenhydramine HCl Elixir	12.5 mg/5 mL	Antihistamines are used for a variety of allergic reactions, for example, perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic skin manifestations of urticaria, reactions to insect bites. Commercial product contains 5.6% alcohol.
Antipsychotic			
Fluphenazine HCl	Fluphenazine HCl Elixir (Pharmaceutical Associates)	2.5 mg/5 mL	Management of psychotic disorders
Cardiotonic			
Digoxin	Various	50 mg/mL	Among other effects, increases the force of myocardial contraction. Used in congestive heart failure, atrial fibrillation, other cardiac conditions. Commercial product contains 10% alcohol.
Sedatives, Hypnotics			
Butobarbital sodium	Butisol Sodium Elixir (Medpointe)	30 mg/5 mL	In low dosage, sedatives; in higher dosage, hypnotics. Butobarbital sodium elixir contains 7% alcohol; phenobarbital elixir contains 14% alcohol.
Phenobarbital	Various	20 mg/5 mL	

Preparation of Elixirs

1. Simple solution with agitation &/or
2. By the admixture of two or more liquid ingredients.

- Although most elixirs can be prepared by simple procedure, their small scale manufacture is usually time consuming.
- Frequently, the final mixture will be cloudy???? **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 & 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 & therefore assists in their removal from the solution.

➤ Despite the presence of glycerin, syrup, sorbitol, & PG in elixirs generally contributes to the solvent effect of the hydroalcoholic vehicle, assists in the dissolution of the solute, & enhances the stability of the preparation. But, the presence of these materials may slow the rate of filtration???

□ Phenobarbital Elixir

Phenobarbital	4.0 g
Orange oil	0.25 mL
Propylene glycol	100.0 mL
Alcohol	200.0 mL??
Sorbitol solution	600.0 mL
Color	q.s.
Purified water, to make	1000mL

- The U.S. Food and Drug Administration (FDA) has proposed that insofar as possible manufacturers of over-the-counter (**OTC**) oral drug products restrict the use of alcohol and include appropriate warnings in the labeling.

➤ *Storage conditions*

elixirs should be stored in tight, light-resistant containers & protected from excessive heat due to their content of volatile oils & alcohol.



Elixirs are, sweetened, flavored, hydro-alcoholic solutions intended for oral use.

Types of elixirs:

1. Non-medicated elixir → employed as vehicle.
2. Medicated elixir → employed for therapeutic effect of the drug they contain.

Syrup

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Lower dissolving capacity
capacity

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Elixir

Less sweet

Less viscose

Lower sucrose content

Higher dissolving

Simple manufacturing

More stable



Spirits (Essence)

- ✓ Are alcoholic or hydroalcoholic solutions of volatile substances.
- ✓ Generally, the alcoholic concentration in spirits is rather high, usually more than 60 %.

✓ For medicinal purposes, spirits may be taken orally, applied externally, or used by inhalation. When taken orally, they are generally mixed with a portion of water to reduce the pungency of the spirit.

METHOD OF PREPARATION OF SPIRITS

1- Simple Solution

Majority of spirits are prepared by dissolving the solute in alcohol by agitation. Filtration is generally desirable to obtain a sparkling clear product.

2- Solution with Maceration

Macerate the vegetable materials in a suitable solvent to remove the undesired constituents or to extract one which is desired.

Ex., Peppermint Spirit

➤ When mixed with water or with an aqueous preparation, the volatile substances present in spirits generally separate from the solution & form a milky preparation.

➤ *Uses of Spirits;*

➤ *Storage Condition;*

Spirits should be stored in tight, light-resistant containers and in a cool place.



*Thanks a lot for your
Attention*



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