

## Experiment 3

### Liquid dosage forms: solutions Hydro- alcohol solutions

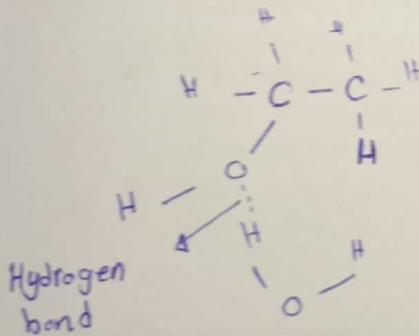
#### I. Spirits:

Are alcoholic and hydro-alcoholic solutions of volatile substances.

- Generally, the alcoholic content of spirits is rather high, usually over 60 %.
- Because of greater solubility of aromatic substances in alcohol, spirits can contain a greater concentration of these materials than in corresponding aromatic water.
- They are most frequently used as flavoring agents, e.g. Peppermint Spirit USP.
- Some spirits are used for their medicinal effect, but most spirits are used as stock solutions for obtaining a proper amount of flavoring oil.

- ✓ *Spirits should be stored in tight, light-resistant containers and in a cool place.*
- ✓ *Spirits are preparation of high alcoholic strength and when diluted with aqueous solutions or liquids of low alcoholic content turbidity may occur.*
- ✓ *The addition of water invariably causes turbidity and separation (alcohol soluble drugs or oils precipitate out of the diluted alcohol).*

clear (alcohol + oil)  
turbidity → when water is Added



←  
bonding  
water + alcohol  
- oil separat

**Formula (1):**

Rx <sup>25</sup> ml peppermint spirit B.P.1980

$$F = \frac{25}{1000} = 0.025$$

Ingredients	Master formula	Scaled formula
Peppermint oil	100ml	2.5 ml
Ethanol 90%	q.s. 1000ml	25 ml

**Procedure**

1. Dissolve peppermint oil in alcohol and mix
2. Complete to the required volume with ethanol
3. If not clear add talc, shake well
4. Then filter solution with paper wetted with alcohol.
5. Keep in a dispensing bottle to use it in the preparation of the next formula (medicated syrup)

Use of ingredients:

- (1) **Peppermint oil:** carminative, flavoring agent.
- (2) **Talc** to clarify solution.
- (3) **Ethanol (Alcohol):** vehicle (or solvent) and preservative

labeling:

- Main label:-
- Auxiliary label:  
*Keep out of reach of children*

Storage:

*'Store in a cool place',  
'Preserve in amber glass well-closed containers'.*

Use of preparation

Carminative.

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**II. Tincture:**

Alcoholic or hydroalcoholic solutions prepared from animal or vegetable drugs or from chemical substances.

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Ex: Rx 15 mL Iodine Tincture USP. 1980. used as antiseptic.

Solvent Concentration 25-60% may run to 90%  
↳ Alcohol

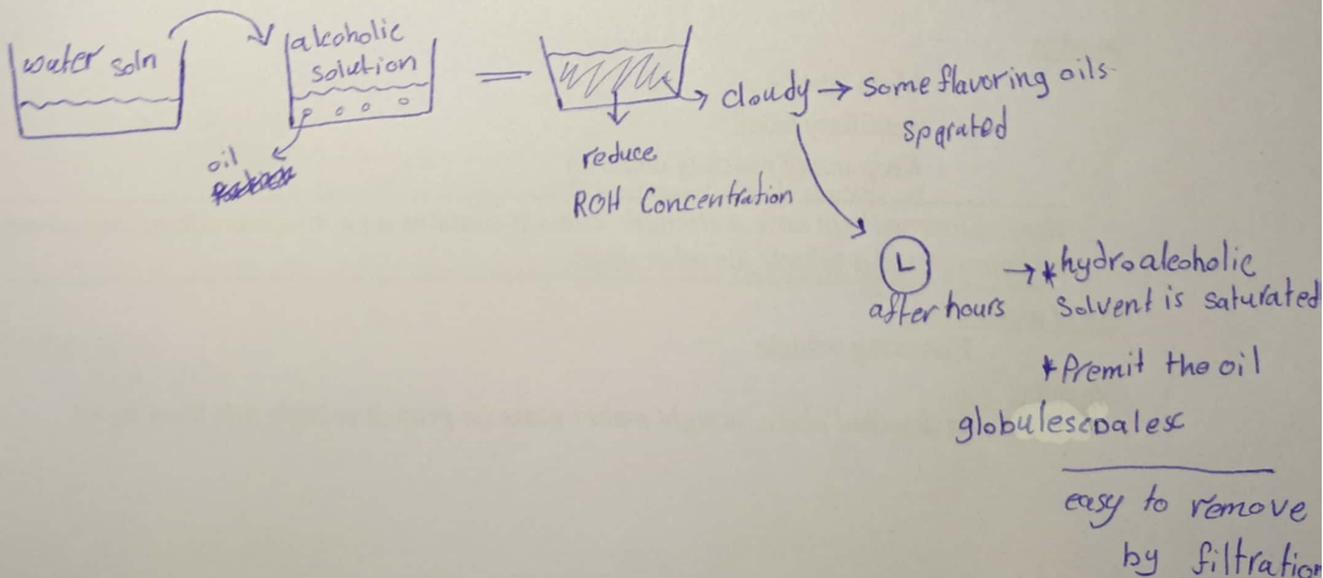
### III. Elixirs: Defined by the USP as:

"Clear, sweetened, hydroalcoholic liquids intended for oral use".

- Nonmedicated elixirs are employed as vehicles and medicated elixirs for the therapeutic effect of the medicinal substances
- In comparison with syrup elixirs are:
  - (1) Less sweet
  - (2) Less viscous
  - (3) Less effective in masking bitter taste
  - (4) Better able to maintain both water soluble and alcohol soluble components in solution
  - (5) Easier to prepare, thus, from a manufacturing standpoint, elixirs are preferred to syrups.
- Elixirs containing over 10-12% of alcohol are usually self-preserving and do not require the addition of antimicrobial preservative.
- Because of their usual content of volatile oils and alcohol, elixirs should be stored in tight, light-resistant containers and protected from excessive heat.

#### Preparation of Elixir:

- 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.
- Frequently, the final mixture will be cloudy, principally because of separation of some of the flavoring oils by the reduced alcoholic concentration when an aqueous solution is added to the elixir.
- 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.



**Formula (2):**

Rx <sup>50</sup> ml Aromatic elixir N.F. 1980

$$F = \frac{50}{1000} = 0.05$$

Ingredients	Master formula	Scaled formula
Compound Orange Spirit* (Prepared by the lab instructor)	12ml	0.6 ml (---drops)
Syrup	375ml	18.75 ml
Talc	30gm	1.5 gm
Ethanol (Alcohol)	240ml	12 ml
Water	q.s. 1000ml	50 ml

\*Compound orange spirit

Orange oil	200 ml
Lemon oil	50 ml
Coriander oil	20 ml
Anise oil	5 ml
Alcohol q.s	1000 ml

Procedure:-

1. Mix orange spirit with alcohol in E. Flask.
2. Add syrup portion wise with vigorous shaking
3. Add water portion wise until reaching the required volume
4. Use talc as a clarifying agent (If needed).
5. Filter the elixir using filter paper wetted with alcohol (to get rid of talc).

*Note: Filtration require wetting of the filter paper with the solvent to avoid cellulose fibers from breaking out during filtration.*

**Notes on procedure:** Elixir should be clear after filtration, if not (i.e. separation of volatile oil) this could happen due to either hurrying up in adding water or syrup, or not mixing well with talc.

Use of the ingredients:-

- (1) **Compound orange spirit:** flavoring agent.
- (2) **Syrup:** sweet vehicle, sweetening agent, preservative.
- (3) **Talc:** clarifying agent
- (4) **Alcohol:** co solvent, preservative
- (5) **Water:** vehicle (or solvent)

labeling:

- Main label:-
- Auxiliary label:  
*Keep out of reach of children*

*Note: Elixir will not have a strength unless it contains an active ingredient, but alone it is considered a vehicle for other drugs .*

Use of preparation:

Flavoring vehicle

Storage:-

*In dry cool place, in tight amber glass (to protect volatile oils from light)*

#### IV. Linctus:

A viscous liquid preparation for oral use only usually used to relief cough. It usually contains sucrose and is administered in small dose volume. It should be sipped and swallowed slowly without addition of water.

- The viscous nature of the preparation coats the throat and helps to alleviate the irritation which is causing the problem.

التخفيف أو الإذابة  
Formula (3):

بتنظي  
الحالت

تخفيف  
من

Rx 50. mL Pediatric Codeine Linctus BP.1980

Ingredients	Master formula	Scaled formula
Codeine	3 gm	0.15 gm
Water	20 ml	1 ml
Compound tartrazine solution	10 ml	0.5 ml
Benzoic acid	20 ml	1 ml
Chloroform	20 ml	1 ml
Lemon syrup	200 ml	10 ml
Syrup	q.s. 1000 ml	q.s. 50 ml

$$F = \frac{50}{1000} = 0.05$$

#### Procedure:

- Dissolve codeine in water, mix well.
- Add compound tartrazine.
- Add Benzoic acid, mix.
- Add Chloroform (CHCl<sub>3</sub>) and mix.
- Add lemon syrup, mix.
- Complete volume with syrup up to 50 ml.

#### Use of Ingredients:

- (1) **Codeine phosphate:** antitussive
- (2) **Lemon syrup:** flavoring agent
- (3) **Benzoic acid:** preservative
- (4) **CHCl<sub>3</sub>:** expectorant
- (5) **Compound tartrazine:** coloring agent
- (6) **Syrup:** sweetening vehicle.

no need to add preservative

#### Labeling:

- Main label
- Auxiliary label:  
*Shake well before use.*  
*The linctus should be sipped and swallowed slowly undiluted.*

#### Storage:

'Store in a cool, dry place.' And Store in amber glass container (why)

#### Use of preparation:

Antitussive