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Pharmaceutical Technology

Aims: Pharmaceutical technology teaches the different dosage forms with respect to their raw materials, composition, and method of preparation, stability, storage and uses.

References:

- Ansel, H., Allen, L. and Popovich, N., "Pharmaceutical dosage forms and drug delivery system",10th ed., Lippincott Williams and Wilkins, (2014).
- James Swarbrick, "Encyclopedia of Pharmaceutical Technology" 3rd ed., Informa Health Care, (2007).

1

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No	Lecture title	hours
1.	Dispersed systems: their classification; comparisons between different systems.	2
2.	Solutions and types of solutions.	2
3.	Solubility: Factors affecting solubility; expression of dissolution; dissolution rate versus solubility; preparation of solutions containing non-volatile materials.	4
4.	Official solutions; classification of official solutions; preparation and uses.	4
5.	Aqueous solutions containing aromatic principles; aromatic waters; methods of preparations; stability.	4
6.	Syrups: sugar based syrups; artificial and sorbitol based syrups; stability of syrups.	4
7.	Definition and methods of clarification; filter aids in clarification.	3
8.	Preparation of solutions using mixed solvent systems; spirits, and elixirs.	3
9.	Extraction; maceration and percolation.	3
10.	Tinctures; fluid extracts; extracts of resins and oleoresins.	4
11.	Colloidal dispersions; lyophilic; lyophobic.	6
12.	Coarse dispersion; suspensions.	6

Table 1 Classification of oral solutions

Type	Description
Syrup	Solutions containing high concentrations (near saturation) of sucrose or other sugars
Elixir	Sweetened solutions containing alcohol as a cosolvent
Spirit	Hydroalcoholic solutions of aromatic or volatile substances
Aromatic water	Aqueous solutions of aromatic or volatile substances
Tincture	Alcoholic or hydroalcoholic solutions prepared from vegetable materials or chemical substances by dissolution or extraction
Fluid extract	Concentrated alcoholic solutions of animal or vegetable drugs obtained by removal of active constituent by extraction (maceration, percolation)

3

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Syrups: sugar based syrups; artificial and sorbitol based syrups; stability of syrups.

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2016/2017

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Outlines

- Syrups; compositions and classifications
- Flavoring and coloring.
- Sweeteners
- Preservative
- Method of preparations

5

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Syrups

- Syrups are concentrated solutions of sugar (such as sucrose) in water or other aqueous liquids with or without added flavoring agents and medicinal substances

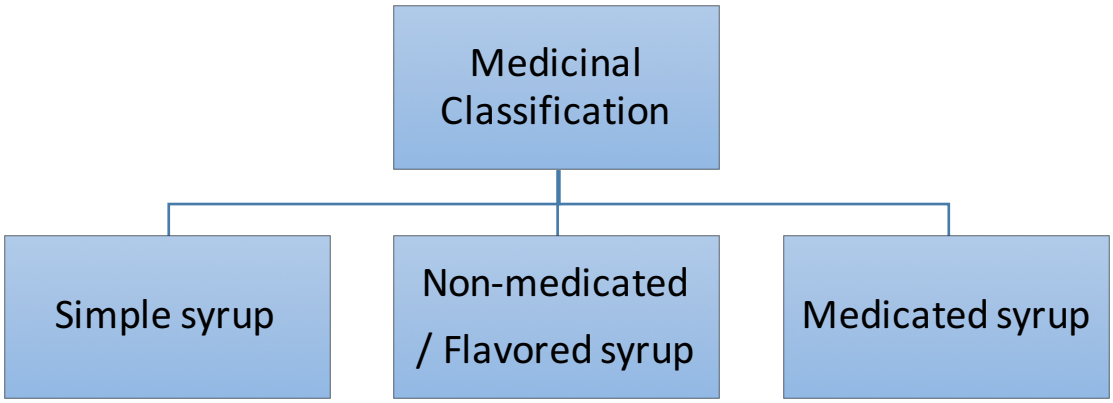
6

Syrup composition

1. Sugar - usually sucrose and other substitutes for sweetness and viscosity
2. Antimicrobial preservatives
3. Flavorants
4. Colorants
5. Miscellaneous - special solvents, solubilizing agents, thickeners or stabilizers

7

Classification of syrups



8

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Types of syrups

1. Simple syrup – concentrated solution of sucrose in purified water alone

2. Medicated syrup – aqueous solution of sucrose containing other substances as polyols(glycerin and sorbitol) and API.

3. Non-medicated/Flavored syrup – contained various aromatic and pleasantly flavored substances and is intended as a vehicle or flavor for preparations.

9

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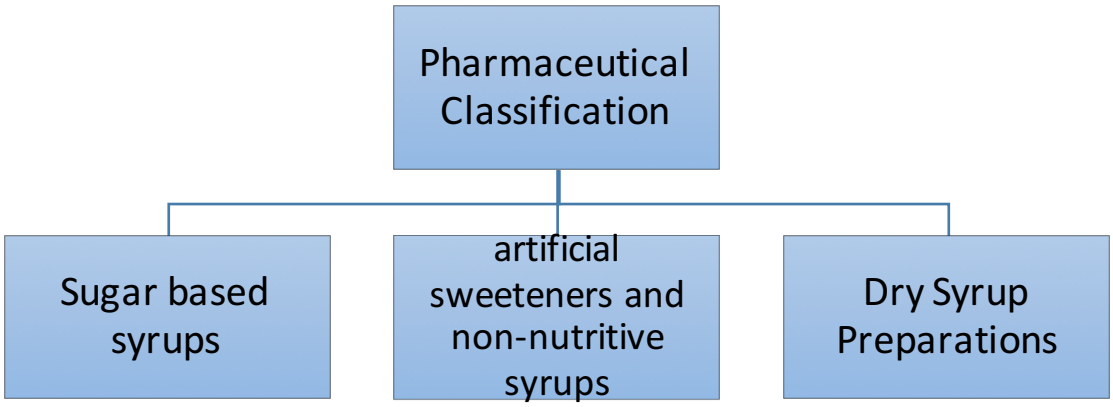
Classification of syrups



10

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Pharmaceutical Classification based on their basic formula

1. Sugar Based syrups – **sucrose** and **dextrose** are usually employed in the preparation of syrups

2. Artificial sweeteners – sugar-free syrups which are intended as substitute for sugar-based syrups and are intended to be administered to persons who must regulate their sugar/calorie intake.

11

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Example of syrups

Home work from Ansel

- **Examples Of Non-medicated Syrups (Vehicles) Page: 412**
- **Examples Of Medicated Syrups By Category Page: 413**
- **Examples of non sugar based syrup: Page 416**

12

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Sucrose

- Sucrose is the most widely used sweetener, with a long history of use.
- It is a white crystalline powder, soluble in water and alcohol.
- It inhibits the growth of m.o. in solution at concentrations above 65wt% by reducing the water-activity coefficient.
- Official simple syrup is an 85% w/v solution of sucrose in water.
- During the preparation of sucrose solution, care should be taken to avoid charring and caramelization caused by heat.
- Sucrose is chemically and physically stable in the pH range of 4.0–8.0.
- It is frequently used in conjunction with sorbitol, glycerin, and other polyols, which reduce its tendency to crystallize.

13

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Sucrose

- Sugar syrups promote significant "**cap-locking**"—the crystallization of the sugar on the cap and bottle thread, but the addition of glycerin (10–20%) minimizes this effect.
- Glycerin is seldom used as a single sweetener in pharmaceuticals because it has a characteristic mouth warming and burning effect.

14

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Sucrose

- Syrup, USP contains 850 gm sucrose and 450 ml of water in each liter of syrup. Although very concentrated, the solution is not saturated. Since 1 gm sucrose dissolves in 0.5 ml water, only 425 ml of water would be required to dissolve 850 gm sucrose. This slight excess of water enhances the syrup's stability over a range of temperatures, permitting cold storage without crystallization.
- The high solubility of sucrose indicates a high degree of hydration or hydrogen bonding between sucrose and water. This association limits the further association between water and additional solutes. Hence, syrups have a lower solvent power than water and "salting out" may be a problem.

15

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Dextrose

- Dextrose may be used as a substitute for sucrose in syrups containing strong acids in order to eliminate the discoloration associated with caramelization.
- Example: **Hydroiodic syrup**

The difficulty or problem with dextrose are as follows

1. It forms a saturated solutions in water at 70%w/v which is less viscous than simple syrup.
2. Dextrose dissolves more slowly
3. Dextrose is less sweet
4. Saturated solution supports growth of microorganism and therefore more easily fermented.

16

Dextrose

So with the use of dextrose, it is necessary to improve the keeping qualities by adding:

1. Preservatives which may be glycerin in 30 to 45% which is also serves to increase viscosity.
2. Sweeting agent.
3. However, glycerin tends to develop a butyric odor or aging

17

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Liquid glucose

- Liquid glucose is an extremely viscid substance that imparts both body and sweetness to liquid formulations.
- It is obtained by the incomplete hydrolysis of starch and consists chiefly of dextrose, dextrins, maltose, and water.
- It imparts a characteristic odor and flavor to the formulation in similar fashion to honey and molasses, but to a lesser degree.
- Although liquid glucose is not a pure chemical entity, its method of manufacture can be well controlled, and batch-to-batch variability is usually not significantly problematic. The same is not true of honey in which quality depends on uncontrollable natural factors.

18

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Flavorants for syrup

- Most syrups flavored with synthetic flavorants or with naturally occurring materials as volatile oil, vanillin, and others, to render the syrup pleasant tasting.
- Since syrups are aqueous preparations, these flavorants must be possess sufficient water solubility.
- Of the many tastes that must be masked in pharmaceuticals, bitterness is most often encountered; to mask it completely is difficult.

19

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Flavor and taste

- A tropical fruit has been used for centuries in central Africa to mask the bitter taste of native beers.
- This so-called ‘‘miracle berry’’ contains a glycoprotein that transiently and selectively binds to bitter taste buds.
- Due to stability challenges, attempts to isolate the compound for commercial exploitation have been unsuccessful.
- Yet, many fruit syrups are relatively stable in pharmaceuticals if formulated with antimicrobial preservative agents.
- Syrups of cinnamon, orange, citric acid, cherry, cocoa, wild cherry, raspberry, or glycyrrhiza elixir can be used to effectively mask salty and bitter tastes in a number of drug products.

20

Flavor and taste

- The extent to which taste-masking may be achieved is not usually predictable due to complex interactions of other flavor elements in these products.
- The degree to which bitterness may be masked by these agents ranks in a descending order:

cocoa syrup is most effective, followed by raspberry syrup, cherry, cinnamon, citric acid, licorice, aromatic elixir, orange.

21

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Flavor and taste

- Sour and metallic tastes in pharmaceuticals also can be reasonably masked.
- Sour substances containing hydrochloric acid are most effectively neutralized with raspberry and other fruit syrups.
- Metallic tastes in oral liquid products (e.g., iron) are usually masked by extracts of gurana, a tropical fruit.
- Gurana flavor is used at concentrations ranging from 0.001 to about 0.5% and may be useful in solid products as well (e.g., chewable tablets and granules).

22

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Flavor and taste

- Flavors that may be used to mask a salty taste include:

1. apricot
2. peach
3. vanilla
4. wintergreen mint.

23

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Flavor and taste

- **Usually a combination of flavors is used to achieve the optimal taste-masking property.**
- **Certain excipients may added to oral solution formulations, referred to as flavor adjuncts (e.g. menthol, chloroform) that add flavor to the formulation but, in addition, act to desensitize the taste receptors. In so doing these agents augment the taste-masking properties of conventional flavors.**
- **Because syrups are aqueous preparations, these flavorants must be water soluble. However, sometimes a small amount of alcohol is added to a syrup to ensure the continued solution of a poorly water soluble flavorant.**

24

Colorants for Syrup

- To enhance appeal of the syrup, a coloring agent is generally used which correlates with the flavorant employed.
- When used in combination with flavors, the selected color should 'match' the flavor of the formulation, e.g. green with mint-flavored solutions, red for strawberry-flavored, brown for chocolate-flavored formulations.
- The colorant used is generally water-soluble, non-reactive with other components, and color stable at the pH range and under intensity of light that the syrup is likely to encounter during its shelf life.
- It is preferred to use color grade FD&C but it is still acceptable to us D&C.
- The intensity of the resultant color assayed by visible spectroscopy.

25

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Sweeteners

- Non-nutritive, synthetic sweetening agents required in the formulation
- Saccharin sodium may be used in concentration of 0.1 to 0.2% but characterized by a bitter after taste.
- Others like Na cyclamate, aspartame, and sucralose.

26

Saccharin

- Saccharin is a non-nutritive synthetic sweetening agent.
- It has approximately 500 times the sweetening power of sucrose, depending in extent on the strength of the solution.
- The relative sweetening power is greatest in dilute solution.
- Saccharin is a sucrose substitute for diabetics, the obese, and others who do not wish to ingest sucrose.
- It is commonly found in its sodium salt form, which is more palatable than saccharin and comparatively free of unpleasant after-taste.

27

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Sodium cyclamate

- Sodium cyclamate is another synthetic sweetening agent that is approximately 30 times as sweet as sugar.
- However, its use as an artificial sweetener is banned in the U.S.A. because of the possible toxicity of its metabolite cyclohexylamine.
- Artificial juices in our markets!

28

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Aspartame

- Aspartame, N-L-a-Aspartyl- L-Phenylalanine methyl ester, is 200 times sweeter than sucrose and, unlike saccharin, has no aftertaste.
- Its aqueous solubility is adequate for formulation purposes.
- It is stable in the solid form, but its stability in solution depends on temperature and pH.
- It hydrolyzes to aspartylphenylalanine and diketopiperazine, with a loss in sweetness.
- Aspartame synergistic with saccharin, sucrose, glucose, and cyclamate.
- In addition, its taste can be improved by adding sodium bicarbonate, gluconate salts, and lactose.

29

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Sucralose

- It is newer non-caloric sweetening agents have come to market in the last decade.
- Sucralose is approximately 600 times sweeter than sucrose and differs from sucrose by the substitution of three chlorines for hydroxyl groups.
- Sucralose is heat-stable and stable over a wide pH range affording its utility in formulations prepared at high temperatures.

30

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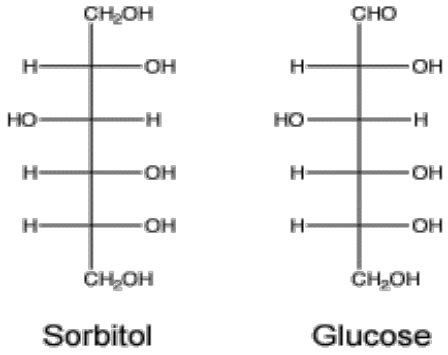
Sorbitol Based Syrup

- Sorbitol, A hexahydric alcohol, C6H14O6, made by hydrogenation of glucose is used mostly in the 70% aqueous solution USP trademark **"Sorbo"**



Sorbitol Glucose

31

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Characteristics of Sorbitol

1. Sorbitol solution is not irritating to the membrane of the mouth and the throat
2. Unlike sucrose, it does not contribute to the formation of dental caries
3. Although it is metabolized and converted into glucose it is not absorbed from the GIT as rapid as sugars, so no significant hyperglycemia is formed

32

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Characteristics of Sorbitol

4. Although it is 60% as sweet as sucrose and half as viscous as simple syrup, it has excellent “mouth feel” and lacks acrid characteristics.
5. Sorbitol is compatible with other polyol and simple syrup
6. Sorbitol is chemically stable and practically inert.

33

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Characteristics of Sorbitol

7. Sorbitol inhibits the sticking and locking of bottle caps which occurs with high concentration of sucrose so they are usually combined
8. Many drugs are more stable in sorbitol than in sucrose solution thus may have extended shelf-life
9. As much as 10% v/v of alcohol can be added before crystallization is observed same as sucrose.

34

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Dry Syrup Preparations

- Dry syrup preparations are powdered or granular formulations prepared for reconstitution.
- They are filled up to volume by a liquid, normally water, just before use.
- During production and storage, they are solids and during administration they are either solutions or suspensions.
- The main reason for the development of dry syrups is the instability of the active ingredient in the liquid state.
- They have to be used within a limited period of time after conversion into a suspension or solution.
- Most of the medicaments formulated as dry syrups belong to the group of antibiotics. It was shown that the bioavailability of dry syrup could be superior compared with an oily suspension.

35

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Dry Syrup Preparations

- In addition to the active ingredient, the formulations contain:

1. Carriers like sorbitol, and xylitol, acting also as sweeteners,
2. Viscosity enhancers as micro- crystalline cellulose, starch, and xanthan gum,
3. artificial sweeteners,
4. preservatives,
5. Wetting,
6. complexing agents, and
7. buffer substances.

36

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Uses Of Syrups

1. Due to sweetness, can mask the taste of salty and bitter drugs and therefore serve as pleasant tasting vehicle
2. Used as vehicle for pediatric use due to to their high viscosity and the

"smoothness" and mouth feel qualities.

3. Due to the wide variety of flavors of syrups such as orange, lemon, peppermint, these are widely acceptable.

37

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Preservation and Storage of Syrups

- Generally, syrups are stored at room temperature in tightly closed bottle and well-filled bottles.

Antimicrobial Preservatives

- The amount of preservatives required in a syrup varies with the proportions of water available for microbial growth.

Among the preservatives

1. Benzoic acid-0.1% to 0.2%
2. Sodium benzoate – 0.1 to 0.2%
3. Combination of methyl, propyl, butyl parabens totaling 0.1%

38

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Preserving Syrups

- Syrup, USP is protected from bacterial contamination by virtue of its high solute concentration.
- More dilute syrups are good media for microbial growth and require the addition of preservatives.
- Industrially formulated syrups often contain ingredients to improve solubility, stability, taste or appearance which also contribute to product preservation.
- It is necessary, from an economic standpoint, to consider the additive preservative effects of such ingredients as alcohol, glycerin, propylene glycol, and other dissolve solids.

39

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Preserving Syrups

- Syrup USP, having a specific gravity of **1.313** and a concentration of **85%** w/v is a **65%** w/w solution. This 65% by weight is the minimum amount of sucrose which will preserve neutral syrup.
- If one wants to formulate a syrup containing less sucrose, the quantity of alcohol, or other preservatives, may be estimated by considering the *USP Syrup equivalent* and the *free water equivalent*.
- One may assume that free water is preserved by **18%** alcohol.
- **e.g. How much Alcohol USP is required to preserve 1L of syrup containing 500 g sucrose?**

40

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Preserving Syrups

- To calculate the free water equivalent,:
- Subtract the **volume of ingredients (Vi)** from the **total volume (Vt).**
- The **Vi** is the volume occupied by the sucrose **+** the volume preserved by the sucrose **+** the volume occupied and/or preserved by other additives
- In Syrup, USP 850 g sucrose occupies an apparent volume of 550 ml; so each gram of sucrose will occupy 550/850 or 0.647 ml. If the 850 g sucrose preserves 450 ml of water, then each gram of sucrose will preserve 450/850 = 0.53 ml of water.

41

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$$Volume\ preserved\ by\ sucrose\ =\ 500\ g \times 0.53\ ml/g\ =\ 265\ ml$$

$$Volume\ occupied\ by\ sucrose\ =\ 500\ g \times 0.647\ ml/g\ =\ 324\ ml$$

$$Free\ water\ equivalent\ =\ 1000\ ml\ -\ 265\ ml\ -\ 324\ ml\ =\ 411\ ml$$

$$Volume\ of\ alcohol\ required\ to\ preserve\ the\ product\ is\ 411\ ml \times 18\%\ =\ 74\ ml$$

$$74\ ml\ Absolute\ alcohol\ \div\ 95\%\ =\ 78\ ml\ Alcohol\ USP$$

42

Preserving Syrups

- If other dissolved solids are present, their volume (often estimated) is subtracted from the free water volume.
- If glycerin is present, its volume preserves an equal volume of free water.
- If propylene glycol is present, it is considered equivalent to ethanol.

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Example , HW

Rx

Active drug		**5ml volume occupied**
Other drug solids		**3 ml volume occupied**
Glycerin		**15 ml**
Sucrose		**25 g**
Ethanol		**95% q.s.**
Purified water	**q.s.**	**100 ml**

How much alcohol would be required to preserve this prescription?

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❑ Ideally, preservatives should exhibit the following properties:

• Possess a broad spectrum of antimicrobial activity encompassing Gram-positive and Gram-negative bacteria and fungi.

• Be chemically and physically stable over the shelf-life of the product.

• Have low toxicity.

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❖The amount of a preservative required to protect syrup against microbial growth depends on:

1. The proportion of water available for growth.
2. The nature and inherent preservative activity of some formulative materials (e.g., many flavoring oils that are inherently sterile and possess antimicrobial activity).
3. The capability of the preservative itself.

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❖ Among the preservatives commonly used in syrups with the usually effective concentrations are :

☑Benzoic acid and sodium benzoate (0.1% to 0.2%)

☑Sorbic acid and its salts (0.05–0.2%)

☑Alkyl esters of parahydroxybenzoic acid (0.001–0.2%). Usually a combination of two members of this series is employed in pharmaceutical solutions, typically methyl and propyl parahydroxybenzoates (in a ratio of 9:1). The combination of these two preservatives enhances the antimicrobial spectrum.

☑Alcohol is used in syrups to assist in dissolving the alcohol-soluble ingredients, but normally it is not present in the final product in amounts that would be considered to be adequate for preservation (15% to 20%).

☑Glycerin 45%.

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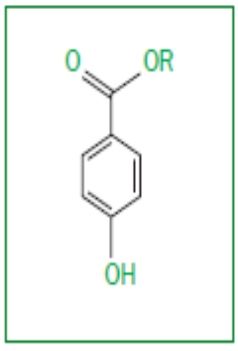
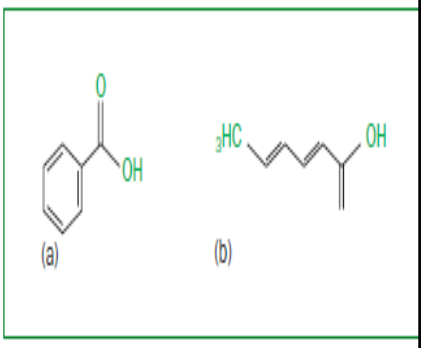


Figure 1.5 Structural formula for the parahydroxybenzoate esters (parabens, where R refers to an alkyl group).

Figure 1.4 Structural formula of (a) benzoic acid and (b) sorbic acid.



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Factors affecting preservative efficacy in oral solutions

- **The activity of a preservative is dependent on the correct form of the preservative being available in the formulation at the required concentration to inhibit microbial growth (termed the minimum inhibitory concentration: MIC).**
- **Factors that directly affect the efficacy of preservatives in oral solutions include: (1) The pH of the formulation; (2) The presence of micelles; and (3) The presence of hydrophilic polymers.**

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(1) The pH of the formulation

- In some aqueous formulations the use of acidic preservatives, e.g. benzoic acid, sorbic acid, may be problematic.
- The antimicrobial properties are due to the unionized form of the preservative; the degree of ionization being a function of the pH of the formulation.
- The activity of the unionized form of the acid is due to the ability of this form to diffuse across the outer membrane of the microorganism and eventually into the cytoplasm. The neutral conditions within the cytoplasm enable the preservative to dissociate, leading to acidification of the cytoplasm and inhibition of growth.

(2)The presence of micelles

The role of micelles for the solubilisation of lipophilic therapeutic agents. If the preservative exhibits lipophilic properties (e.g. the unionized form of acidic preservatives, phenolics, parabens), then partition of these species into the micelle may occur, thereby decreasing the available (effective) concentration of preservative in solution.

To correct this problem, the preservative concentration must be increased to ensure that the free concentration within the formulation is MIC of the preservative.

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(3) the presence of hydrophilic polymers

- ✓The free concentration of preservative in oral solution formulations is reduced in the presence of hydrophilic polymers, e.g. polyvinylpyrrolidone, methylcellulose.
- ✓This is due to the ability of the preservative to interact chemically with the dissolved polymer.
- ✓This problem is solved by increasing the concentration of preservative in the formulation.
- ✓In certain circumstances the preservative may be incompatible with hydrophilic polymers in the formulation due to an electrostatic interaction. Therefore, cationic hydrophilic polymers should not be used in conjunction with acidic preservatives in oral solution formulations.

Preparation Of Syrups

Syrups are most frequently prepared by any one of the four methods depending upon the physical and chemical characteristics of the ingredients.

1. Solution of the ingredients with the ***aid of heat***
2. Solution of the ingredients ***by agitation without the use of heat*** or the simple admixture of liquid components
3. ***Addition of sucrose*** to a prepared medicated liquid or to a flavored liquid
4. ***By percolation*** of either the sucrose of the medicating substance or of the sucrose.

53

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1. Solution of ingredients with the aid of heat

Syrups are prepared by this method for the following reasons:

A. When desired to prepare the syrup as quickly as possible

B. When the syrups components are not damaged or volatilized by heat

Procedure

1. Add the sugar to the purified water and heat until solution is affected.
2. Heat stable components are added to the hot syrup
3. Cool and made up to volume.
4. If other components are heat labile, they are added after cooling like alcohol and oil.

Caution: Do not apply excessive heat - inversion of sucrose causing discoloration due to caramelization

Examples : Acacia syrup, NF; Cocoa Syrup, NF; Syrup USP (85% sugar, made by cold and hot process, percolation)

54

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2. Solution of ingredients by agitation without the aid of heat

To avoid heat-induced inversion of sucrose, a syrup maybe prepared without heat by agitation

Procedure:

1. Sucrose and other formulative agents maybe dissolved in purified water.
2. Place the ingredients in a bottle of greater capacity than the volume of syrup.
3. Agitate the mixture

Examples: Ferrous Sulfate Syrup, Ephedrine Sulfate, Citric acid Syrup, and Glycyrrhiza Syrup

55

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3. Addition of Sucrose to a Medicated liquid or to a Flavored liquid

Occasionally, a medicated liquid, as a tincture of fluidextract is employed as the source of medication in the preparation of a syrup.

Many such tinctures and fluidextract contain alcohol- soluble constituents and are prepared with alcoholic vehicles.

Examples: Senna Syrup, NF and Cherry Syrup

56

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4. Percolation

- In this method, either sucrose maybe percolated to prepare the syrup or the sucrose of the medicinal component may be percolated to form an extractive to which sucrose or syrup may be added
- **Procedure:**

1. Purified water or aqueous solution of a medicating or flavoring liquid is allowed to pass slowly through a column of crystalline sucrose to dissolve it.
2. The percolate is collected and returned to the percolator as required until all of the sucrose has been dissolved.
3. Percolator with a pledget of cotton at the bottom is used

Example: Tolu Balsam syrup - flavor for cough syrup

57

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Review questions and notes

- Define, give an example of, and/or classify examples of each of the following: Pharmaceutical Solution, Solute, Solvent, Saturated Solution, Supersaturated Solution, Macromolecular Solution, Syrups, Aromatic Waters, Mucilages, Aqueous Acids.
- State at least six (6) pharmaceutical uses or applications of solutions.
- Identify commonly used pharmaceutical solvents.
- Identify at least three (3) necessary criteria of pharmaceutical solvents.
- Make necessary calculations for, prepare, label, and dispense pharmaceutical solutions.
- Define simple syrups, flavoring syrups, medicinal syrups, syrup USP, and caramelization.
- List three (3) methods of preparing syrups.
- Describe and demonstrate how to prepare a syrup by the "agitation with heat" method.
- Describe alternative formulations for "syrups" prepared with non-sugar sweeteners and state their advantages and limitations.
- Make necessary calculations and describe how to preserve a syrup using Alcohol USP.

58

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Notes

- Effect of concentration on various factors is as follows:
- If the solution is saturated and if the temperature decreases, it results in the crystallization.
- The sugar solution should be nearly to saturation point, but should not be saturated.
- The solution at low concentration favours the growth of molds but at higher concentration stops the growth of organism.

59

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Thanks for your attention