

# **UNIT IV**

# **SOLUTIONS**

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# Solutions

- In physicochemical terms, solutions may be prepared from any combination of solid, liquid or gas, the three states of matter
- Liquid preparations that contain one or more soluble chemical substances dissolved in a suitable solvent or mixture of mutually miscible solvents
- Homogenous mixture that is prepared by dissolving a solid, liquid or gas in another liquid and represents a group of preparations in which the molecules of the solute or dissolved substance are dispersed.

# Types of Solutions

## 1. Solid Solution – the solvent is solid

### a. Solid in solid

Example: Cu + gold = 12 karat yellow gold

### b. Liquid in solid

Example: Hg dissolved in Ag = amalgam

### c. Gas in solid

Example: air dissolved in soap = floating soap

## 2. Liquid Solution – the solvent is liquid

### a. solid in liquid

Ex: salt in water

### b. Liquid in liquid

Ex: alcohol and water

### c. Gases in liquid

Ex: carbonated beverages

### 3. Gaseous Solutions – the solvent is gas

#### a. Solid in gas

Example: sulfur in air

#### b. Liquid in gas

Example: water vapor in air

#### c. Gas in gas

Example: oxygenated air

### Factors affecting the “rate” of solubility

1. **Particle size** – an increase in surface area to the solvent will increase rate of solution. So the particle size should be reduced by comminution before it is dissolved.
2. **Agitation** – increases the rate of solution by removing from the surface of the solute. The more concentrated solution around it the less concentrated the solvent.

### 3. Temperature

heating a liquid also causes solution to take place more rapidly by increasing the frequency which solvent molecules collide with the surface of the dissolving mixture

## Factors Affecting Solubility of Solute

### 1. Temperature

**Endothermic reaction** – The process of solution where heat is applied and absorption of the heat takes place in the solutes, this increase in temperature will cause more of the solute to go into solution.

**Exothermic reaction** – solute gives off heat during the process of solution; solubility is decreased with an increase in temperature.

**Example:** more soluble in cold than hot water

Methyl cellulose and calcium salts such as  $\text{Ca}(\text{OH})_2$

## 2. Molecular Structure

The general rule: “like dissolves like”

## 3. Effects of other substance

**Example:** Iodine is very slightly soluble in water but when added to a concentrated solution of KI dissolves immediately.

## 4. pH – Many of the organic substances which are used medicinally are either weak acids or weak bases. And their aqueous solubility depend upon the pH of the solvent.

## Examples of Weak Bases

- Alkaloids – atropine, codeine, morphine
- Antihistamines – diphenhydramine, triproleamine
- Local anesthetics – cocaine, procaine, tetracaine

## Examples of Weak Acids

- Barbiturates – phenobarbital, pentobarbital
- Sulfonamides – sulfadiazine, sulfacetamide

**Water and alcohol Solubilities Of some Selected  
Weak Acids, Weak Bases, and Their Salts**

<b>Drug</b>	<b>Number of mL of Solvent Required To Dissolve 1 g of Drug</b>	
	<b>Water</b>	<b>Alcohol</b>
<b>Atropine</b>	455	2
<b>Atropine Sulfate</b>	0.5	5
<b>Codeine</b>	120	2
<b>Codeine Sulfate</b>	30	1,280
<b>Codeine Phosphate</b>	2.5	325
<b>Morphine</b>	5,000	210
<b>Morphine Sulfate</b>	16	565
<b>Phenobarbital</b>	1,000	8
<b>Phenobarbital sodium</b>	1	10
<b>Procaine</b>	200	soluble
<b>Procaine HCl</b>	1	15
<b>Sulfadiazine</b>	13,000	sparingly soluble
<b>Sodium Sulfadiazine</b>	2	Slightly soluble



# Relative Terms of Solubility

Descriptive Term	Parts of Solvent required
Very Soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Practically soluble or Insoluble	From 10,000 and over

**Solubilities Of Selected Organic Compounds in Water as a  
Demonstration of Chemical Structure-Solubility Relationship**

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Compound	Formula	Number of mL of water Required to Dissolved 1 g of compound
Benzene	$C_6H_6$	1430
Benzoic acid	$C_6H_5COOH$	275
Benzyl Alcohol	$C_6H_5CH_2OH$	25
Phenol	$C_6H_5OH$	15
Pyrocatechol	$C_6H_4(OH)_2$	2.3
Pyrogallol	$C_6H_3(OH)_3$	1.7
Carbon Tetrachloride	$CCl_4$	2000
Chloroform	$CHCl_3$	200
Methylene chloride	$CH_2Cl_2$	50

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# Inorganic Molecules

1. *Monovalent cation and anion of an ionic compound are generally water soluble*

Examples: NaCl, LiBr, KI,  $\text{NH}_4\text{NO}_3$

2. Only one of the two ions is monovalent – compounds are water soluble

Examples:  $\text{BaCl}_2$ ,  $\text{MgI}_2$ ,  $\text{Na}_2\text{SO}_4$ ,  $\text{Na}_3\text{PO}_4$

3. Both ions are multivalent - poor water soluble.

Examples:  $\text{CaSO}_4$ ,  $\text{BaSO}_4$ ,  $\text{BiPO}_4$

Exceptions:  $\text{ZnSO}_4$  and  $\text{FeSO}_4$

4. Common salts of alkali metals are usually water soluble

Exception:  $\text{Li}_2\text{CO}_3$

5.  $\text{NH}_4$  and quaternary  $\text{NH}_4$  salts are water soluble
6. Nitrates, Nitrites, acetates, chlorates and lactates are generally water soluble

**Exceptions:** silver and mercurous acetate

7. Sulfates, sulfites and thiosulfates are generally water soluble

**Exceptions:** Calcium and Barium salts

8. Chlorides, bromides and iodides are water soluble

**Exceptions:** salts of silver and mercurous ions

9. Acid salts corresponding to an insoluble salt will be more water soluble than organic salts.

10. Hydroxides and oxides of compounds other than alkali metal cations and the ammonium ion are generally water insoluble.

11. Sulfides are water insoluble except for their alkali metal salts
12. Phosphates, carbonates, silicates, borates and hypochlorites are water insoluble except for their alkali metal salts and ammonium salts

## Organic Molecules

1. Molecules having 1 polar functional group – soluble to the the total lengths of 5C's
2. Molecules having branched chains are more soluble than the corresponding straight-chain compound.
3. Water solubility decreases with increase in MW
4. Increased structural similarity between solute and solvents accompanied by increase solubility.

# Solvents for Liquid Preparations

1. **Water** – has the widest range of usefulness of all the solvents employed in pharmaceutical dispensing or manufacturing. It is a good solvent for most inorganic and organic
2. **Alcohol USP, Ethyl Alcohol, Ethanol** – good solvent for many organic substances both natural and synthetic. Is 94.9 to 96.0% alcohol at 15.56°C.  
**Limit:** 0.5% = 6 to 12 years, 5% = over 12, 10% = adult
3. **Dehydrated Alcohol** – 99.5% absolute alcohol is partially free from water.

4. **Diluted Alcohol NF**- prepared by mixing equal volume of Alcohol USP and purified water.
5. **Alcohol, Rubbing** – contains about 70% of ethyl alcohol by volume the remainder consists of water, denaturants with or without color additives and perfume oils and stabilizers.
6. **Glycerin USP ( Glycerol)** – clear syrupy liquid with sweet taste. It is miscible both with water and alcohol. Excellent solvent for tannins, phenol and boric acid. It has a preservative qualities.
7. **Propylene Glycol** – miscible in water, acetone, alcohol and chloroform
8. **Polyethylene glycol 400** – miscible in water, acetone alcohol and other glycols
9. **Chloroform** – miscible with alcohol, ether, benzene, hexane and both fixed and volatile oils
10. **Acetone** – miscible with water, alcohol, ether, chloroform and most of the volatile oils.

# Methods of Preparing Solutions

1. **Simple Solution** – prepared by dissolving the solute in the solvent

**Examples:** Calcium hydroxide solution USP (lime water), Sodium Phosphate solution and Strong Iodine solution USP (Iugol's)

2. **Solution by Chemical reaction** – prepared by reacting two or more solutes with each other in a suitable solvent.

**Examples:** Aluminum subacetate – prepared by reacting aluminum sulfate sol. with calcium carbonate and acetic acid forming magma.



**Magnesium Citrate** = prepared by reacting official magnesium carbonate with citric acid, flavoring and sweetening agents, filtering talc and carbonating it by potassium or sodium bicarbonate.

**Use:** Saline cathartic

**Sodium Citrate and Citric acid oral solution** = contains 100 mg sodium citrate and 67 mg citric acid in each ml of aqueous solution. **Use:** Systemic alkalinizer

**3. Solution by Extraction** – vegetables or animal origin are often extracted with suitable solvent. Preparation of this type may be classified as solutions but more often **EXTRACTIVES**

# Common Methods of Expressing the Strengths Of Pharmaceutical Preparations

- Percent weight in volume** - number of grams of a constituents in 100mL of preparation  
(1% w/v = 1g of constituent in 100mL of preparation)
- Percent volume in volume** - number of mL of constituent in 100mL of preparation  
(1%v/v 1 mL of constituent in 100mL of preparation)
- Percent weight in weight** - no. of grams of a constituent in 100g of preparation  
(1%w/w = 1g of constituent in 100g of preparation)

# Common Methods of Expressing the Strengths Of Pharmaceutical Preparations

Ratio strength weigh in volume - w/v no. of grams of constituent in stated no. of mL of preparation  
(1:1000w/v = 1g of constituent in 1000mL of preparation)

Ratio strength volume in volume – v/v no. of mL of constituent in stated number of mL of preparation  
(1:1000 v/v = 1mL of constituent in 1000mL preparation)

Ratio strength weight in weight – w/w number of grams of constituent in stated number of grams of preparation  
(1:1000 w/w = 1g of constituent in 1000g of preparation)

# Examples of Oral Solution by Category

## 1. Antidepressants

Notriptylline HCl – Pamelor Oral Solution

Fluoxetine HCl – Prozac Liquid

## 2. Antiperistaltic

Diphennoxyllate HCl and Atropine Sulfate- Lomotil Liquid

Loperamide HCl- Immodium A-D Liquid

## 3. Bronchidilator

Theophylline – Theophylline Oral Solution

## 4. Antipsychotics

Haloperidol – Haldol Concentrate

Perphenazine – Trilafon Concentrate

Thiothixene HCl – Navane Concentrate

## 5. Cathartics

Magnesium citrate

Sodium Phosphate – Phospho-Soda (fleet)

## 6. Corticosteroid

Prednisolone Sodium Phosphate- Pediapreu Oral Solution

## 7. Dental Care Protectant

Sodium Fluoride – Pediaflor Drops

## 8. Electrolyte Replenisher

Potassium Chloride – KaoChlor 10% Liquid

## 9. Fecal Softener

Docusate Sodium- Colace syrup

## 10. Hematinic

Ferrous Sulfate - Fer-in-sol Drops

## 11. Histamine hydrogen Antagonist

Cimetidine HCl liquid – Tagamet HCl Liquid

## 12. Narcotic Agonist Analgesic

Methadone HCl – Methadone HCl

## 13. Vitamin D source

Ergocalciferol – Calciferol drops

# AQUEOUS SOLUTIONS

Is one where water is used as a major ingredient. Water is used as a vehicle and a solvent for the desired flavoring or medical agent.

## CHARACTERISTICS OF WATER

1. Tasteless
2. Freedom from irritating qualities
3. Lack of pharmacologic activity

## DISADVANTAGES

1. Favorable medium for many chemical reactions
2. Support growth of microorganisms when contaminated
3. In pure form add cost to production

## PREPARATION

1. Distillation
2. Demineralization or Deionization
3. Reverse Osmosis

**\*\*Demineralization** – This ionization process is the well known **Zeolite** process of softening water high mineral content. This resin may be acid or cations exchanger and base or anion exchanger.

- **Zeolite** – act as a catalyst such as dehydrated aluminum. Calcium sodium sulfate.
- \* Deionization process do not necessarily produce purified water which will comply with USPHS ( US Public Health Service) requirements for drinking water, the water should be purified before they can used for pharmaceuticals



**\*\*Reverse Osmosis** – Transport of solvent through semipermeable membrane separating 2 solutions of different concentrations (less concentrated and more concentrated)

A reversely new separation process w/c in principle may be applied to the separation, concentration and fractionalization of inorganic or organic substances in aqueous or non-aqueous solutions in the liquid or the gaseous phase is known reverse osmosis.

Also referred as “crossflow or tangential flow” membrane filtration

## PORE SIZE

1. Microfiltration (0.1 to 2 microns) = bacteria
2. Ultrafiltration (0.01 to 0.1 microns) = virus
3. Nanofiltration (0.001 to 0.01 microns) = organic compounds in the MW of 300 to 1000
4. Reverse Osmosis (smaller than 0.001 microns)

# AROMATIC WATERS

Aromatic water is also called *medicated water*, defined in the USP as clear, saturated aqueous solutions of volatile oils or other aromatic or volatile substances.

These are to be free from

1. Smoke like odor and other odors
2. Must have odor and taste similar to those oil or drugs from which they are prepared.

## 2 Components

1. Volatile oil
2. Water

# Official Processes of Preparation

## 1. Distillation

**Cohobation** – is the process of obtaining aromatic water by distillation one or more times from delicate drugs with small quantities of volatile principles.

**Examples:** Stronger Rose( Aqua Rose Fertier, Triple Rose Water)

## 2. Solution Method

### A. Simple Solution Method

**Example:** Peppermint water  
Concentrate

**Synonyms:** Aqua Mint, American Mint

**Latin name:** Aqua Menthae Piperitae

## Formula:

Peppermint oil	20mL
90%Ethanol	600mL
Purified Talc	50g
Purified Water q.s.to make	1000mL

**Uses:** Vehicle for internal aqueous sol. Carminative, flavoring diluent

**Description:** Clear, saturated solution

## B. Alternate Solution by Intervention

- The volatile material is mixed thoroughly with 15g of purified talc.
- The mixture is agitated with purified water for ten minutes prior to filtration.
- The disadvantage of this method is the fineness of the filter aid which passes through the filter paper.

# AROMATIC WATER

## Stability

Aromatic water are not permanently stable preparations

## Preservation of Aromatic Water

Protect from excessive light and heat. Deterioration may due to volatilization. Decomposition or mold growth producing cloudy preparation or disagreeable odor.

## Other examples Of water

Orange Flower Water, NF

**Synonyms:** Aqua Auranti Florum, Shanger Orange Flower, Triple Orange Flower water

**Formula:** It is a saturated solution of odoriferous principles of flowers of Citrus Aurantium Linne.

**Uses:** A Flavored vehicle and perfume in solutions, syrup and elixirs.

## Cinnamon Water

*Preparation:* Cinnamon Water

*Synonym:* Casio Nare, Cassia Oil

*Latin Name:* Aqua Cinnamoni

*Formula:*

Cinnamon oil	20mL
Ethanol 90%	600mL
Purified Talc	50g
Purified water q.s. to make	1000mL

*Procedure:* Alternate Solution Method

*Uses:* As flavored vehicle for internal aqueous solution, antiseptic in eye lotion, carminative

*Description:* Clear, Saturated Solution

# AQUEOUS ACIDS

Inorganic and organic acids such as HCl, HNO<sub>3</sub>, HI, HBr, H<sub>2</sub>SO<sub>4</sub>, and Hac., of great importance in chemical and pharmaceutical manufacturing

## **Division of inorganic acids**

1. Hydroacids – no oxygen
2. Oxygen containing acids



## **Diluted Acetic Acid**

*Synonym:* Dilute Acetic acid

*Latin Name:* Acidum Aceticum Dilatum

*Formula:*

Acetic Acid	158mL
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Purified water q.s. to make	1000mL
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*Uses:* Bactericidal and occasionally used in 1% solution for surgical dressings of the skin; 1% spermatocidal, as vaginal douche

*Description:* Clear, colorless, having a strong characteristic odor and sharply acid taste, miscible with water.

# Examples of Official Acids Although Not All of them are Aqueous acids

- |                              |                     |
|------------------------------|---------------------|
| 1. Acetic Acid               | 7. Folic Acid       |
| 2. Diluted Acetic Acid       | 8. Citric Acid      |
| 3. Glacial Acetic Acid       | 9. Folic Acid       |
| 4. Diluted Hydroiodic Acid   | 10. Phosphoric Acid |
| 5. Diluted Hydrochloric Acid | 11. Tartaric Acid   |
| 6. Hypophosphorous Acid      | 12. Salicylic Acid  |

# GARGLES

Are aqueous solutions used for treating the pharynx and nasopharynx by forcing air from the lungs through gargle which is held in the throat. Many gargles must be diluted with water prior to use.

# Gargles

*Examples:* Phenol Gargle and Potassium Chlorate (also known as Golden Gargle) and Phenol Gargle are official in B.P.C

*Preparation:* Phenol Gargle

*Synonym:* Phenolic Solution, Carbolic gargle

*Latin name:* Gargarisma Phenol

*Formula:* Contains 50mL of Phenol Glycerin (16% w/w phenol and 84% w/w glycerin), 10mL amaranth solution(1%w/v in chloroform water) and water to make 1L. This is diluted with warm water equal volume before use . For external use

*Uses:* antiseptic and soothing effect

# WASHES (LAVATIO ORI)

A **mouthwash** is an aqueous solution which is most often used for its

1. Deodorant
2. Refreshing
3. Antiseptic effect

It may **contain** alcohol, glycerin, synthetic sweeteners, surface active agent, flavoring and coloring.

**Commercial preparations** contain local anti-infective agents: hexetidine and cetylpyridinium chloride.

## Examples:

1. **Dobell's solution or compound Sodium Borate NF**  
– contains Sodium borate. Liquified Phenol and Glycerin and sodium Bicarbonate –  
**use:** antiseptic
2. **Compound Sodium Chloride Mouthwash** – Zinc sulfate and  $\text{ZnCl}_2$

## Special Washes

1. Eye washes (*Collyrium*) - as anesthetic, anti-infective, diagnostic, myotic and anti-inflammatory
2. Mouthwash (*Collutorium*)- antibacterial
3. Nasal wash (*Collunarium*) - antibacterial and antiseptic

# JUICES

Juices are formerly known as *INPISSATED JUICES*. A juice prepared from ripe fruit, aqueous in character, and it is used in making syrups employed as vehicle.

**Examples:** Cherry juice and Raspberry juices are official in USP

# SPRAYS

- Aqueous solutions in the form of coarse droplets or as finely divided solids to be applied topically, most usually to the nasal- pharyngeal tract or to skin
- Applied to the mucous membrane of the nose and throat by means of an *atomizer or nebulizer*
- Such sprays may **contain** antibiotics, antihistamine, vasoconstrictor, alcohol and suitable solubilizing and wetting agents
- Another device to deliver spray is called “**spray-o-mizer**”, this is for throat

**Examples:** Nasalide(Syntex), Nostrilla



# COLLODIONS

Are liquid preparation composed by **pyroxillin** dissolved a solvent mixture. Usually composed of alcohol and ether with or without added substances

**Pyroxillin (nitrocellulose soluble gun cotton, collodion cotton)** is obtained by the action of mixture of nitric acid and sulfuric acids on cotton and consists chiefly of cellulose tetranitrate.

## Uses Of Collodion

1. As a protective coating to the skin
2. As medication where a thin layer of the medication is firmly placed against the skin

## Direction Of Use

Collodion are applied to the skin by means of a **soft brush or other suitable applicators**. The solvent rapidly evaporates, leaving a film residue of pyroxillin.

# Example Of Official Collodion

## 1. Which provides protective coating

**A. Collodion, USP** is a clear or slightly opalescent viscous liquid prepared by dissolving 4% W/V pyroxillin in 3:1 mixture of ether and alcohol.

**B. Flexible Collodion, USP** is prepared by adding 2% of Camphor and 3% castor oil to the Collodion

## 2. Which provides medication

**A. Salicylic acid Collodion, USP** is 10% solution of salicylic acid in flexible collodion. Used as keratolytic effect (topical drug that softens the superficial keratin-containing layer of the skin and promotes its desquamation) especially in the removal of corns from the toes

**Synonym:** Corn solvent

# SPIRITS

Formerly called “Essences”

alcoholic or hydroalcoholic solutions of volatile substances.

## First Spirits

1. Brandy – *Spiritus Vini vitis* – 48 to 54% alcohol from grapes
2. Whisky - *Spiritus frumenti* – 47 to 53% of alcohol from cereals

## Uses:

1. As flavoring agents pharmaceutically
2. For therapeutic value of the aromatic solute medicinally

# 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.

**Example:** Aromatic Spirit - 62 to 68% hydroalcoholic solution of ammonia and ammonium carbonate flavored and perfumed with lemon, lavender and myristica oil.

## 2. Solution with Maceration

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

**Example:** Peppermint Spirit (Spiritus Menthae Piperitae) – 79 to 85% hydroalcoholic solution containing 10% peppermint oil

**Use:** digestive aid or carminative

# Preparation of Spirits

## 3. Solution by Chemical Reaction

Only the preparation of Aromatic Spirit of Ammonia NF, involves a chemical reaction where the official Ammonium carbonate

## 4. Distillation

No spirits currently official are prepared by distillation, However, two products of historical significance which is official in NF are prepared by distillation.

Examples: Brandy and whisky

# TOOTHACHE DROPS

Are preparations used for the temporary relief of toothache by application of a small cotton saturated with the product into the tooth cavity

**Example:** Clove oil and mixture of phenol with camphor or creosote

## DENTAL ORAL SOLUTION

A variety of medicinal substances are employed topically in the oral cavity.

**Examples:**

1. **Benzocaine** – Topical anesthetic Indicated for temporary relief of pain, soreness and irritation in the mouth associated with teething and others
2. **Caphorated Parachlorophenol** – Dental anti-infective. A eutectic liquid composed of 65% camphor and 35% parachlorophenol. Use in the dentistry of the sterilization of deeproot canals.

3. **Carbamide Peroxide** – Dental anti-ineffective . Acts as chemomechanical cleansing and debriding agent through the release of bubbling oxygen. Commercial product **Gly-Oxide** - contains 10% carbamide in flavored anhydrous glycerin.
4. **Cetylpyridinium Chloride Solution and Lozenges**- Local anti-infective. Commercial counter parts. **Cepacol** Mouthwash/Gargles and Lozenges
5. **Erythrosine Sodium Solution/tablets**-Diagnostic Aid. Solution applied to the teeth to reveal plaque left by inadequate brushing. Tablets same purpose and are not to be swallowed.
6. **Eugenol** - Dental Analgesic. Applied to dental cavities and dental protectives



7. **Lidocaine Oral Spray** – Topical dental anesthetic.  
Applied through metered spray in the amount of 10mg per spray.
8. **Nystatin Oral Suspension** – Antifungal
9. **Na Fluoride /Tablets** - Dental carries prophylactic
10. **Saliva Substitutes** – contains electrolytes in CMC base and indicated for the relief of drymouth and throat in xerostomia
11. **Triamcinolone Acetonide Dental Paste** – Topical Anti-inflammatory
12. **Zinc Oxide-Eugenol Mixtures** – A temporary filling mix

# INHALATIONS

- drugs or solutions of drugs administered by the nasal or oral respiratory route.

- A widely used instrument capable of producing fine particles for inhalation therapy is the *nebulizers*

=When volatile medication is added to the water in the chamber, the medication is volatilizes and also inhaled by the patient and *Humidifiers* will be used

=The common household *vaporizer* produces a fine mist of steam that may be used to humidify a room will be used also

## Examples:

1. Isoetharine inhalation- bronchial asthma
2. Isoproterenol inhalation- bronchial asthma

# INHALANTS

A drugs or combinations of drugs the by virtue of their high vapor pressure can be carried by a current into the nasal passage where they exert their effects.

The device in which they bare administered is termed an *inhaler*

## Examples:

1. Amyl Nitrite inhalant – treatment of anginal pain
2. Propylhexedrine inhalant – nasal decongestant

# 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

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

# Classification of syrups

## A. Medicinal Classification

1. **Non-medicated/Flavoring syrups** – are used as vehicles and have no official formulas and therefore no detailed descriptions of the product are found in compedia.

## B. Pharmaceutical Classification

Based on their basic formula

1. **sugar based syrups** – syrups which are concentrated solutions
2. **artificial sweeteners and non-nutritive syrups** – formulated with artificial sweetening agents and viscosity builders

## Examples of Flavoring Syrups

**1. Orange Syrup** - This sucrose - based syrup utilizes sweet orange peel tincture, and citric acid as the source of flavor and tartness.

**Syrupus Aurantii, syrup of orange peel**, sweet orange peel 50 mL; citric acid 5 g; talc 15 g; sucrose 820 g; purified water q.s to make 1000 mL

**2. Ora - Sweet and Ora-Sweet SF** - Commercially available vehicles for the extemporaneous compounding of Syrups. Ora sweet SF syrup is sugar free.

**3. Raspberry Syrup** - A sucrose - based syrup containing about 48% by volume of raspberry juice

**4. Glycyrrhiza Syrup** - Licorice syrup, Glycyrrhiza fluid extract 250 mL; Fennel oil 0.55 mL; Anise oil 0.5 mL; syrups, q.s to make 1000 mL

**5. Cocoa Syrup** - Syrupus cacao, Cacao syrup, chocolate flavored, cocoa 180 g; sucrose 600 g; liquid glucose 180 g; glycerin 50 mL; Sodium chloride 2 g; Vanilla 0.2 g; Sodium benzoate 1 g; water q.s. to make 1000 mL

**6. Cherry Syrup** - Syrupus Gerasi - Cherry juice 475 mL; sucrose 800 g; alcohol 20 mL; water q.s. to make 1000 mL

**7. Acacia Syrup** - Syrupus acaciae - Acacia powder 100g; Sodium benzoate 1 g; Vanilla tincture 5 mL; Sucrose 800 g; Purified water q.s to make 1000 mL.

**8. Citric acid Syrup** - Syrupus Acidi Citrici, Syrup lemon - Lemon tincture 10 mL; Citric acid 10 g; Purified water q.s to make 1000 mL

**9. Simple Syrup** - This is an 85% of sucrose in purified water. This simple syrup may be used as the basis for the preparation of flavored or medicated syrup.

**2. Medicated Syrups** - contain ingredients giving them therapeutic value

**Example: Ephedrine Sulfate Syrup** -(for cough) - Ephedrine sulfate 4 g; Citric acid 1 g;Amaranth solution 4 mL; Caramel 0.4 g; Lemon oil 0.125 mL; orange oil 0.25 mL; Benzaldehyde 0.06 mL; Vanillin 0.016 g; alcohol 25 mL; Sucrose 800 g; Purified water, q.s to make 1000 mL

**Ipecac Syrup** - emetic

**Note:** Some syrup are use as Cathartic, Cholinergic, Decongestant, Expectorant, Fecal Softener, Sedative and others

### **Examples Of Medicated Syrups By Category**

**1. Analgesic** Meperidine HCl Syrup - Demerol Syrup

**2. Anticholinergics**

Dicyclomine HCl Syrup - Bentyl Syrup

Oxybutynin Chloride - Ditropan syrup



### **3. Antiemetics**

Chlorpromazine HCl Syrup - Thorazine Syrup

Dimenhydrinate Syrup - Childrens Dramamine Liquid

Prochlorperazine Edisylate - Compazine Syrup

Promethazine HCl - Phenergan Syrup

### **4. Anticonvulsant**

Sodium Valproate Syrup - Depakene Syrup

### **5. Antipsychotic**

Lithium Citrate - Lithium Citrate Syrup

### **6. Antihistamines**

Chlorpheniramine Maleate - Chlor-Trimeton

Cyproheptadine HCl - Periactin Syrup

Hydroxyzine HCl - Atarax Syrup

## **7. Antitussives**

Dextromethorphan - Benylin Syrup

Diphenhydramine - Benelyn Allergy Liquid

## **8. Antiviral**

Amantadine HCl - Symmetrel Syrup

## **9. Bronchodilators**

Albuterol Sulfate - Proventil, Ventolin Syrup

Metaproterenol Sulfate - Alupent syrup

## **10. Cathartic**

Lactulose - Chronulac Syrup

## **11. Cholinergic**

Pyridostigmine Bromide Syrup - Mestinon Syrup

## **12. Decongestant**

Pseudoephedrine Hydrochloride -Children's Sudafed Liquid

## **13. Expectorant**

Guaifenesin Syrup - Guaifenesin Syrup

## **14. Fecal Softener**

Docusate Sodium - Colace syrup

## **15. Gastrointestinal stimulant**

Metoclopramide Syrup - Amicar Syrup

## **16. Hemostatic**

Aminocaproic Acid - Amicar Syrup

## **17. Hypnotic/Sedative**

Chloral Hydrate - Chloral Hydrate Syrup

# Example Of Non Sugar Based Medicated Syrup

## 1. Antihistamine

Chlorpheniramine Maleate	0.4 g
Glycerin	25.0 mL
Syrup	83.0 mL
Sorbitol Solution	282.0 mL
Sodium Benzoate	1.0 g
Alcohol	60.0 mL
Color and Flavor	q.s
Purified water, to make	1000.0 mL

# Example Of Non Sugar Based Medicated Syrup

## 2. Ferrous Sulfate

Ferrous Sulfate	135.0 g
Citric acid	12.0 g
Sorbitol Solution	350.0 mL
Glycerin	50.0 mL
Sodium Benzoate	1.0 g
Flavor	q.s
Purified water, to make	1000.0 mL

# Example Of Non Sugar Base Medicated Syrup

## 3. Cough and Cold Syrup

Dextromethorphan HCL	2.0 g
Guaifenesin	10.0 g
Chlorpheniramine Maleate	0.2 g
Phenylephrine HCl	1.0 g
Sodium Benzoate	1.0 g
Saccharin Sodium	1.9 g
Citric acid	1.0 g
Sodium Chloride	5.2 g
Alcohol	50.0 mL
Sorbitol Solution	324.0 mL
Syrup	132.0 mL
Liquid Glucose	44.0 mL
Glycerin	50.0 mL
Color/Flavor	q.s
Purified Water to make	1000.0 mL

# **Example Of Non Sugar Base Medicated Syrups**

## **4. Acetaminophen Syrup**

<b>Acetaminophen</b>	<b>24.0 g</b>
<b>Benzoic Acid</b>	<b>1.0 g</b>
<b>Disodium Calcium EDTA</b>	<b>1.0 g</b>
<b>Propylene glycol</b>	<b>150.0 mL</b>
<b>Alcohol</b>	<b>150.0 mL</b>
<b>Saccharin Sodium</b>	<b>1.8 g</b>
<b>Purified water</b>	<b>200.0 mL</b>
<b>Flavor</b>	<b>q.s</b>
<b>Sorbitol Solution, to make</b>	<b>1000.0mL</b>

# Components Of Syrups

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



# 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.

## 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%

# 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.

# 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 also serves to increase viscosity.
2. Sweeteners
3. However, glycerin tends to develop a butyric odor on aging

## **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 possess sufficient water solubility

## Colorants for Syrup

To enhance appeal of the syrup, a coloring agent is generally used which correlates with the flavorant employed. 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.

## Sweeteners

- Non-nutritive, synthetic sweetening agents required in the formulation
- Saccharin sodium is 300 - 550 times as sweet as sucrose. It may be used in concentration of 0.1 to 0.2% but characterized by a bitter after taste.
- Aspartylphenylalanine methyl ester is a potential low calories – 160 times sweeter than sucrose in aqueous solution.

# Sweeteners and Viscosity Builders-Sorbitol Based Syrup

Sorbitol, A hexahydric alcohol,  $C_6H_{14}O_6$ , made by hydrogenation of glucose is used mostly in the 70% aqueous solution USP trademark **“Sorbo”**

## 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

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.
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.

# 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 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.



# 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.

# 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)

## 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

### 3. Percolation

In this method, either sucrose may be 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

#### **4. 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

# HONEY

- Honey is also called “Clarified honey” or “Strained Honey”
- Honey instead of syrup was used as a base for thick liquid preparation known as **Honeys or Mels**.
- Honey is the secretion deposited in the honeycomb of the bee and consists of a mixture of invert sugar – 62-83%; sucrose – 8%; dextrin – 0.2%

**Examples:** Oxymel (acid honey) – contains acetic acid – 150 mL; Purified water 150 mL; honey q.s to make 1000 mL

Squill Oxymel = squill, water, acetic acid and honey

# MUCILAGES

- Are thick, viscid, adhesive liquids, produced by dispersing gum in water or by extracting with water mucilagenous principle from vegetable substances.
- Mucilages are used primarily to aid in suspending insoluble substances in liquids due to their
  1. colloidal character
  2. viscosity which prevents the immediate sedimentation

## Example:

**Preparation:** Acacia Mucilage NF

**Synonym:** Mucilago Acaciae; Mucilage of Gum Arabic

<b>Formula :</b> Acacia, in small fragments	350 g
Benzoic acid	2 g
Purified water, q.s to make	1 000 mL

**Method:** Place acacia in wide mouth graduated bottle with capacity not exceeding 1 000 mL. Wash the drug with cold water, drain and add sufficient quantity of purified water in which benzoic acid has been dissolved to make 1 000 mL, Stopper and lay the bottle, rotate occasionally, and when acacia has been dissolved, strain the mucilage

**Uses:** Demulcent, suspending agent, excipient in making pills and troches, and as emulsifying agent for cod liver oil



## Example:

**Preparation:** Tragacanth Mucilage NF

**Synonym:** Mucilago Tragacanthae

<b>Formula :</b> Tragacanth	6.0 g
Benzoic acid	0.2 g
Glycerin	18.0 g
Purified water, q.s to make	100 g

**Method :** Mix 75 mL of purified water with glycerin in a tared vessel, heat to boiling, discontinue application of heat, add Tragacanth and the Benzoic acid and macerate during 24 hours, stirring occasionally. Add sufficient quantity of purified water to make the mucilage 100 g, stir actively until uniform consistency and strain through muslin cloth

**Uses:** excipient for pills or troches, suspending agent for insoluble substances for internal mixtures and as protective agent

# ELIXIRS

Are clear, pleasantly flavored, sweetened hydroalcoholic liquids intended for oral use as compared to syrup, elixirs are less sweet and viscous since they contain a lower portion of sugar and consequently less effective in masking the taste of medicinal substances

## Advantages of elixirs

1. Because of their hydroalcoholic character, elixirs are better able than the aqueous syrups to maintain both water soluble and alcohol soluble components in the solutions
2. More preferred than syrups due to the stability character
3. Easy to prepare which is by simple solution
4. Pleasant flavor

## Characteristics of Elixir

1. The main ingredient of elixirs are ethanol and water but glycerin sorbitol, propylene glycol, flavoring agents, preservatives and syrups are often used in preparation of the final product
2. The alcohol content vary from 3 to 41% depending on the water alcohol solubility of the ingredients
3. Although many elixirs are sweetened with sucrose, some utilize sorbitol, glycerin, and artificial sweeteners such as saccharin for this purpose.
4. Elixirs having a high alcoholic content usually use as artificial sweeteners as saccharin which is used in small quantities only.

## Preparation of Elixirs

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

# Classes of Elixirs

1. **Non-medicated** - used in the extemporaneous filling of prescriptions involving
  1. The addition of a therapeutic agent to a pleasant tasting vehicle
  2. The dilution of an existing medicated elixir

**NOTE:** There should be no incompatibilities between the above and the component of the formula

Example: Aromatic elixirs, Compound Benzaldehyde Elixir, Iso - alcoholic Elixir

2. **Medicated Elixirs** – are employed for the therapeutic benefit of the medicinal agent present.

## **Example:**

1. **Phenobarbital elixir**= Phenobarbital 4g; Orange oil 0.25mL; Propylene Glycol 100mL; Alcohol 200mL; Sorbitol Solution 600m; Color q.s purified water to make 1000mL.

The official and commercial **elixirs** contain a single therapeutic agent except : ***Terpene hydrate and Codein Elixir***

The advantage of Single therapeutic agent: Dosage taken may be increased or decreased by taking more or less of the elixir without much problem.

**Examples: *Antihistamine Elixir; Hypnotic and Sedative Elixirs (Barbital)***

2. **Theophylline Elixir:** Theophylline 5.3g; Citric Acid 10g; Liquid Glucose 44g; Syrup 132.0mL; Glycerin 50mL; Sorbitol Solution 324mL; yellow No. 5 0.1g; purified water to make 100mL
3. **Diphenhydramine Hydrochloride Elixir:** Diphenhydramine HCl 2.5g; Orange oil 0.24mL; Cinnamon oil 0.11mL; Clove oil 0.08mL; Coriander oil 0.03mL; Anethole 0.03mL; Amaranth solution 1.6 mL; alcohol 350 mL; Purified water, q.s to make 1000 mL

## Example Formulations for some non-medicated elixirs

1. **Aromatic elixir:** Compound Orange spirit 12mL;  
Syrup 375mL; Talc 30g; Alcohol and purified water  
to make 1000mL
2. **Compound Benzaldehyd Elixir:** Benzaldehyde  
0.5mL; Syrup 400mL; Purified water, q.s to make  
1000mL
3. **Iso-alcoholic elixir** contains low and high alcoholic
  1. Low alcoholic- Compound orange spirit 10mL;  
Alcohol 100mL; Glycerin 200mL; Sucrose  
320mL; Purified water q.s to make 1000mL
  2. High Alcoholic- Compound orange spirit 4mL;  
Saccharin 3g; Glycerin 200mL; Alcohol, q.s to  
make 1000mL

# Examples of medicated Elixirs by Category

## 1. Adrenocortical steroid

Dexamethasone Elixir- Decadron Elixir

## 2. Analgesic/Antipyretic

Acetaminophen Elixir- Children's Tylenol Elixir

## 3. Anticholinergic/Antispasmodic

Hyoscyamine Sulfate Elixir –Levsin Elixir

## 4. Antiasthma

Diphenhydramine HCl – Benadryl Elixir

## 5. Antipsychotic

Fluphenazine HCl – Fluphenazine HCl

## 6. Cardiotonic

Digoxin – Lanoxin Pediatric Elixir

## 7. Sedative/Hypnotics

Butabarbital Sodium- Butisol Sodium  
Phenobarbital – Phenobarbital Elixir

# GLYCERITES

Solutions of mixtures of medicinal or pharmaceutical substances in glycerin

## Characteristics:

1. Generally a minimum of 50% of glycerin is present in glycerites
2. Due to high concentration of glycerin and the presence of large amount of dissolved or undissolved substances. Glycerites are generally quite viscous with some of them reaching a jelly like consistency
3. Glycerites are considered to be stable preparation and are not usually as prone to microbial contamination because it possesses preservative properties



## Examples of Glycerites

1. **Starch Glycerite** – Glyceratum Amyli; starch glycerin- used as an emollient; starch 100g; water 200mL; Benzoic acid 2g; Glycerin 700mL
2. **Tannic acid Glycerite** - as an astringent  
Tannic acid 20g; Exsiccated Sodium sulfite 02.g and Sodium citrate 1g; Glycerin q.s to make 1000g
3. **Phenol Glycerite** - 40mL is official in BPC diluted with Glycerin q.s 100mL
4. Boroglycerin Glycerite – antibacterial
5. Iodine and Zinc Iodide Glycerite – Glyceritum Iodi et Zinci Iodi
6. Tragacanth Glycerite – Glyceratum Tragacanthae

## Storage of Glycerites

Glycerites are hygroscopic, therefore, should be stored in tightly closed containers.

# MIXTURES

Are aqueous liquid preparations which contains suspended insoluble solid substances and are intended for external use

## Characteristics:

1. Should have finely divided particles to suspend more readily and settle out much slowly than larger particles thus uniform dosage.
2. The more nearly colloidal it is better as protective and adsorbent on inflamed surfaces.
3. Palatability associated with colloidal agents
  - \*\*\*mixtures should have “shake well” label

# EXAMPLE OF MIXTURE

## 1. **Brown Mixture** - Compound mixture of Glycyrrhiza –

Glycyrrhiza extract	120 mL
Antimony Potassium Citrate	0.24 g
Paregoric	120 mL
Alcohol	30 mL
Glycerin	120 mL
Purified water q.s. to make	1000 mL.

# Example of Mixture

## 2.Kaolin Mixture (Ka-Pek) - for diarrhea

Kaolin	200g
Pectin	10 g
Tragacanth	5 g
Benzoic acid	2 g
Sodium Saccharin	1 g
Glycerin	20 mL
Peppermint oil	0.75 mL
Purified water, q.s. to make	1000 mL

# EXTRACTIVES

Extraction involves the separation of medicinally active portions of plant or animal tissues from the inactive components through the use of selective solvents

Galenicals include classes of preparations known as:

1. Decoction
2. Infusion
3. Fluidextracts
4. Tinctures
5. Pilular (semi solid) extracts
6. Powdered extracts

# Methods of Extraction

## 1. Maceration

- term derived from latin word “macerare” meaning to soak.
- Process in which the properly comminuted drug is permitted to soak in the menstruum and the soluble constituents are dissolved

### Examples: (Process M)

Compound Benzoin, Sweet orange Peel  
Tincture; Compound Cardamon; Tolu Balsam  
Tincture

# Methods of Extraction

## 2. Percolation – Per = “through”; Colare = “strain”

The process in which the comminuted drug is extracted of its soluble constituents by the slow passage of a suitable solvent through a column of drug.

The drug is packed in a special extraction apparatus termed as percolator with the extractive collected called the *percolate*

### Different shapes of percolator

1. Cylindrical with little if any taper except for the lower orifice also called Oldberg percolator
2. Cylindrical like but with a definite taper downward
3. Conical or funnel shape

## The choice of type of Percolator depends upon

1. Nature of the drug
2. Type of product prepared
3. Quantity of drug to be extracted

## Processes and steps of Percolation

1. Preparation of the dried crude drug for percolation
  - a. Powdering
  - b. Moistening
2. Packing the percolator
3. Period of Maceration
4. Percolation and collection of percolate
5. Adjustment of concentration of percolation as required



## The rates of flow

1. Percolate slowly – rate will not exceeding 1 mL of percolate/minute
2. Percolate at a moderate rate - rate of 1 to 3mL/minute.
3. Percolate rapidly – rate of 3 to 5 mL per minute.

## Methods of Extraction

### 3. Digestion

form of maceration with gentle heat

### 4. Infusion

process in which vegetable drugs, generally coarsely comminuted, are extracted of the water-soluble constituents

### 5. Decoction

process of boiling vegetable substances with water to extract the soluble principles

# EXTRACTS

Are concentrated preparations of **vegetable or animal drugs** obtained by removal of **the active** constituents of the respective drugs with suitable menstruum, evaporation of all or nearly all the solvents, and adjustment of the residual masses or powders to the prescribed standards.

## **Methods of Preparation**

Prepared by percolation then evaporation off the solvent either by distillation under pressured and using reduced heat.

## 3 Forms of Extract (depending upon the extent of the removal of solvent)

1. Semiliquid extracts are those of a syrupy consistency
2. Pilular or solid extracts of a plastic consistency
3. Powdered extracts prepared to be dry by the removal of all the solvent

## Packaging and Storage of Extracts

Must be packaged in wide mouth containers or plastic tubes and closely tight to prevent loss of moisture which would result in its becoming hard and unstable for use

**Examples:** Belladonna Extract NF; Cascara Sagrada Extract NF and Pure Glycyrrhiza Extract

# TINCTURES

Are defined as alcoholic or hydro alcoholic solution prepared from vegetable material or from chemical substance.

## TOPICAL SOLUTIONS AND TINCTURES

Topical solutions employ an **aqueous vehicle**, whereas the topical tinctures characteristically employ an **alcoholic vehicle**. As required, co-solvents or adjuncts **to enhance** stability or the solubility of the solute are employed.

Topical solutions and Tinctures are prepared by **simple solution and self -preserved**.

Are usually packaged in **glass bottles having an applicator tip** as part of the cap assembly, or in plastic squeeze bottles which deliver the medication in drops.

All medication intended for external use should be clearly labeled **“FOR EXTERNAL USE ONLY”** and kept out of the reach of youngsters.

# Examples Of Solutions Applied Topically

1. **Aluminum acetate** - Aqueous vehicle - Astringent (Burow's Solution)
2. **Aluminum Subacetate** - Aqueous vehicle - Astringent (Modified Burow's)
3. **Calcium Hydroxide** - Aqueous vehicle - Astringent - (Lime Water; Liquor Calcis)
4. **Coal Tar** - Alcoholic vehicle - Antieczematic, antipsoriatic (Liquor Carbonis    Detergens: Liquor Picis carbonis; LCD)
5. **Hydrogen Peroxide Topical Solution** - Aqueous vehicle - Anti-infective (Peroxide)

6. **Chlorhexidine Gluconate Solution** - for skin wound and general skin cleanser, surgical scrub, and preoperative skin preparation, effective in gram negative and positive such as *Pseudomonas aeruginosa*
7. **Povidone-Iodine** - Aqueous vehicle - Anti-infective (Betadine Solution)
8. **Thimerosal** - Aqueous vehicle - Antibacterial and mild fungistatic (Merthiolate Solution)

## **Examples Of Tinctures Applied Topically**

1. **Green soap Tincture** - Alcohol vehicle - Detergent. Also contains 2% lavender oil as perfume
2. **Iodine Tincture** - Alcohol - water vehicle - Anti-infective
3. **Compound Benzoin Tincture** - alcohol - Topical protectant

## Variations of Official Tinctures are on:

1. Method of Preparation
2. Strength of their active constituent
3. Alcohol content
4. Intended use in medicine or pharmacy

### Method of Preparation of Tinctures

1. *By simple solution* - tinctures prepared from chemical substances.

*Example:* Iodine, Thimerosal, Nitromersol  
green soap tinctures

2. *By extraction* - by maceration or percolation

*Examples:* Compound Cardamon  
Tincture

# Preparation of Tinctures

## 1. Maceration

**Examples:** Compound Benzoin Tinctures; Sweet Orange Peel Tincture and ToLu Balsam Tincture

## 2. Percolation

**Examples:** Belladonna Tincture and Vanilla Tincture

### Strength of their Active components

- There is no set strength for compound tincture. They vary with particular preparation.
- The amount of crude drugs used to prepare each 100mL of tincture is generally as follows: (Belladonna Tincture)
  - Potent drugs: **Balledona leaf** –10 g
  - Non potent drug: **Tolu Balsam** – 20 g
  - Undried fresh fruit peel: **sweet orange peel** – 50 g



## Alcohol Content

Tinctures are considered to be stable preparation containing alcohol to protect against microbial growth.

Green soap Tincture - 28 to 32% alcohol

Tolu Balsam Tincture - 77 to 83% alcohol

## Pharmaceutical Uses

As **flavoring tinctures** like vanilla, sweet orange peel, Tolu balsam tinctures.

**Medicinal use** - Iodine Tincture, Thimerosal, Nitromersol Tinctures - **Anti-infective**; Compound Benzoin Tincture - **Topical protectant**; Green soap Tincture - **Topical detergent**; Paregoric Tincture - **Antiperistalsis**; Belladonna Tincture - **Anticholinergic**

## Disadvantages of Tinctures

1. Unpleasant tasting
2. Physician will prefer single drug instead of preparation from plants
3. High alcohol content

## FLUIDEXTRACT

Are liquid preparations of vegetable drugs containing alcohol as a solvent or as a preservative or both, and so made that each mL contains the therapeutic constituents of 1g of the standard drug that it represents

## Characteristics of Fluidextract

1. Because they contain alcohol and are highly concentrated, fluidextracts are sometimes referred to as “*100% tinctures*”
2. Fluidextracts of potent drugs are ten times as concentrated or as potent as corresponding tincture

Example: Belladonna Tincture is 0.6mL while its fluidextract is 0.06mL

## Disadvantages of Fluidextract

1. Because of their concentrated nature, many fluidextracts are considered too potent for safe self administration
2. Too bitter tasting or otherwise unpalatable

## Preparations of Fluidextracts

- Percolation is preferred in all cases because of the exhaustive extraction required.

### **3 Processes labeled A, D, or B and C or E**

**Process A** - entails exhaustive percolation with an alcoholic or hydroalcoholic menstruum.

**Example:** Senna Fluidextract

**Process B or D** - is used in the preparation of fluidextract with boiling water as the menstruum and alcohol generally added to the concentrated percolate as preservative. A heat resistant or metallic percolator is used.

**Example:** Aromatic Cascara Sagrada

**Process C and E** - is intended to facilitate total drug extraction by collecting 1000 mL of percolate from each 1000 g of drug, uses long narrow column of drug and percolation under pressure

## **Official Preparation**

- 1. Glycyrrhiza Fluidextract - Licorice root  
Fluidextract - flavoring agent**
- 2. Eriodictyon Fluidextract - Yerba Santa  
Fluidextract - cathartic**
- 3. Cascara Sagrada Fluidextract -  
Rhamnus Purshiana Fluidextract**
- 4. Aromatic Cascara Sagrada Fluidextract**
- 5. Senna Fluidextract - Fluidextratum  
Sennae**

# NASAL PREPARATIONS

Are aqueous preparations rendered isotonic to nasal fluids and stabilized and preserved as required

## Example of Some Nasal Preparations

1. **Afrin Nasal Spray/drops**- Oxymetazone- Nasal decongestant
2. **Beconase AQ Nasal Spray**- Beclomethasone dipropionate- synthetic corticosteroid
3. **Diapid Nasal Spray** – Lopressin- Antidiuretic, prevention of diabetes
4. **Nasalcrom spray** – Cromolyn- allergic rhinitis
5. **Ocean Mist** – isotonic sodium chloride- restore moisture/relieve dry inflamed nasal
6. **Privine HCl solution**- Naphazoline HCl- nasal adrenergic
7. **Syntocinon Spray** – Oxytocin -synthetic, preparatory to breast feeding

8. Neo-Syneprine – Oxymethazoline HCl- nasal adrenergic

9. Nasalide Nasal Solution- Flunisolide –perennial/seasonal rhinitis

## OTIC SOLUTIONS

As sometimes referred to as *ear or Aural preparations* preparations frequently used in the ear, with suspensions or ointments also finding some application. Usually placed in the ear canal by drops or small amounts for the removal of excessive cerumen (ear wax), or treatment of ear infections, inflammation or pain.

### Examples of Some Commercial Otic Solutions

1. Americaine- Benzocaine – Local anesthetic

2. Auralgan- Antipyrine, Benzocaine – Acute Otitis Media

3. Cerumenex drops – Triethanolamine – Cerumenolytic agent; removes impacted earwax

4. Chloromycetin – Chloramphenicol – Anti-infective
5. Cortisporin Solution – Polymyxin B sulfate- antibacterial
6. Debrox Drops- Carbamide Peroxide – Ear wax removal
7. PediOtic - Polymyxin B sulfate, neomycin sulfate -  
Antibacterial
8. Metreton - Prednisolone sodium phosphate -  
Antiinflammatory
9. Otobiotic Solution - Polymyxin B Sulfate, hydrocortisone -  
Antibacterial
10. VoSol Solution - Acetic acid -  
Antibacterial/Antifungal



# DOUCHES

A douche is an aqueous solutions which is directed against a part or into a cavity of the body. It functions as a **cleansing or antiseptic**.

## Characteristics

Douches are usually directed to the appropriate body parts by using **Bulb syringe**. **Example:** vaginal syringe is made up of an 8 to 10 ounce capacity bulb syringe with a large vulcanite or rubber spray tube.

## KINDS OF DOUCHES

1. **Eye Douche** - used to removed foreign particles and discharges from the eyes, is directed gently at an oblique angle and is allowed to run from the inner to outer corner of the eye.
2. **Pharyngeal Douche** - are used to prepare the interior of the throat for an operation and to cleanse it in suppurative conditions (formation of discharge of pus).
3. **Nasal Douche** - used to cleanse nasal passage
4. **Vaginal Douche** - used for irrigative cleansing of the vagina therefore for hygienic effects, also called urethral douche or irrigation

## Characteristics

Douches are more frequently dispensed in the form of powder with directions for dissolving in a specified quantity of water, usually warm

**Dobell's Solution Tablets** (Compound Sodium Borate Solution NF) used for nasal or pharyngeal douches.

Douches are not official as a class of preparations but general substances in the USP and NF are frequently employed as such in weak solution. **Example: Benzalkonium Chloride** used in various douches

# ENEMAS

Enemas are also known as **CLYSTER**, they are rectal injections employed to:

1. Evacuate the bowel
2. To influence the general system by absorption
3. Affect locally the seat of disease and for
4. For diagnostic visualization of GIT

**USES:** antihelmintic, nutritive, sedative or stimulating properties or they may contain radiopaque substances for roentgenographic examination of the lower bowel

## Characteristics:

Enemas are usually given at body temperature in quantities of 1 to 2 pints injected slowly with enema syringe.

If they are to be retained in the intestine, they should not be used in larger quantities than 6 fluid ounces for an adult.

## Examples:

1. Enema of soft soap - prepared by dissolving 50 g of soft soap with purified water to make 1000 mL.

## Example

**Preparation:** Barium Sulfate Enema

**Synonym:** Barium Salt

**Latin Name :** Baric Sulfae

<b>Formula :</b> Barium Sulfate	120 g
Acacia Mucilage	100 mL
Starch Enema, q.s	
To make	500 mL

**Procedure:** Prepared by mixing Barium Sulfate (120 g) with 100 mL of acacia mucilage and sufficient Starch Enema to make 500 mL. Starch Enema is made by triturating 30 g of powdered starch with 200 mL cold water then sufficient quantity of water added to make 1 Liter.

**Use:** For diagnostic visualization of GIT

## 2 Types Of Enema

**1. Evacuation Enemas** - are rectal enemas employed to promote evacuation of bowel and to cleanse the colon for retention and for diagnosis. Available in disposable plastic squeeze bottles containing a pre measured amount of enema solution.

The agents present are solutions of **sodium phosphate, sodium biphosphate, glycerin and docusate potassium and light mineral oil.**

**2. Retention Enemas** - a number of solutions are administered rectally for the local effects of the medication

**Examples:** Hydrocortisone - local; aminophylline - systemic effect

## Types Of Retention Enema

1. **Nutritive Enema** - supply nutrient to the patient
2. **Medicated Enema** - supply medication for systemic effect
3. **Disgnostic Enema** -  $\text{BaSO}_4$  and Fleet Enema

## Other Enemas

1. **Aminophylline Enema** - NLT 90% and NMT 110% of  $\text{C}_6\text{H}_{24}\text{N}_{10} \cdot 2\text{H}_2\text{O}$
2. **Methyl Prednisolone Acetate** - NLT 90% and NMT 110% of  $\text{C}_{24}\text{H}_{32}\text{O}_6$
3. **Cortisol Enema** - NLT 90% and NMT 110% of  $\text{C}_{21}\text{H}_{30}\text{O}_5$



# Miscellaneous Preparations for Topical Application

1. **Rubbing Alcohol** contains about 70% of ethyl alcohol by volume, the remainder consisting of water, denaturants with or without color additives and perfume oils, and stabilizers.

**Uses:** employed as rubefacient externally, as a soothing rub for bedridden patients, a germicide for instrument, and skin cleanser prior to injection

**Synonym:** Alcohol Rubbing Compound

2. **Isopropyl Rubbing Alcohol** is about 70% by volume of isopropyl alcohol, the remainder consisting of water with or without color additives, stabilizers, and perfume oils.

**Uses:** as rubefacient and soothing rub; 91% isopropyl alcohol - employed by diabetic patients in preparing needles and syringes for hypodermic injections of insulin and for disinfecting the skin

## Miscellaneous Preparations for Topical Application

3. **Hexachlorophene Liquid Cleanser** - is an antibacterial sudsing emulsion containing colloidal dispersion of hexachlorophene 3% W/W in a stable emulsion consisting of entsufon sodium (synthetic detergent), petrolatum, lanolin, cholesterol, methylcellulose, polyethylene glycol, PG monostearate, lauryl myristyl diethanolamide, sodium benzoate and water

**Uses:** bacteriostatic cleansing agent, surgical scrub

# LINIMENTS

Are alcoholic or oleaginous solutions or emulsions of various medicinal substances intended for external application to the skin, generally with rubbing. Formerly called **“embrocations”** for substance applied with rubbing.

## Types Of Liniments

1. Alcoholic liniments
2. Oil
3. Dental liniments - not official

**Alcoholic liniment** - used as rubefacient ( induce mild irritation with reddening of the skin), counterirritant, mildly astringent, and penetrating effect.

**Oily liniment** are milder in action and less irritating to the skin than the alcoholic, used as protective coating and use as rubefacient for muscular pain

### **Different Forms by which Liniments can occur**

1. As a emulsion
2. As a suspension
3. As a solution

### **Components of Liniments**

- |                    |                      |
|--------------------|----------------------|
| 1. Counterirritant | 3. Local Anesthetics |
| 2. Antiseptic      | 4. Analgesics        |

## **Methods of Preparation**

Liniments are prepared in the same manner as solutions, emulsions or suspensions

## **All liniments Must Bear A Label Indicating**

1. For external use only
2. Shake well for emulsion or suspension
3. Store in tight containers
4. Not to be applied to bruises or broken skin areas

## Factors to be considered in using solvents or vehicle

1. Type of action desired, whether rubefacient, counterirritant or just massage - alcohol or oil
2. Solubility of the desired components in the various solvents. For oleaginous liniments - the solvents may be fixed oil, almond oil, peanut oil, sesame oil or cotton seed oil or volatile oil such as wintergreen or turpentine oil or combination of fixed or volatile oil.

**NOTE:** There are presently no official liniments in the USP and NF

## White Liniment BPC

Ammomiun chloride	12.5 g
Dil. Ammonia Solution	45.0 mL
Oleic acid	85.0 mL
Turpentine oil	250.0 mL
Water	625.0 mL

Mix oleic acid with the turpentine oil, add the diluted Ammonia mixed with 45 mL of previously warmed water. Shake. Dissolve the ammonium chloride in the remainder of the water, add to the emulsion and mix.

## **Calamine Liniment/Lotion. Oily BPC**

Calamine	50 g
Wool fat	10 g
Oleic acid	5 mL
Arachic oil	500 mL
Ca(OH) <sub>2</sub> solution to make	1000 mL

Triturate the calamine with the wool fat, the arachis oil and oleic acid, previously melted together. Transfer to a suitable container, add the Ca(OH)<sub>2</sub> solution and shake vigorously.



## CAMPHOR LINIMENT

Linimentum Camphoras; Camphorated Oil

Camphor	200 g
Cottonseed oil	800 g
to make	1 000 g

Place the cottonseed oil into a suitable dry flash or bottle, heat on the steam bath. Add camphor and stopper the container securely. Agitate to dissolve the camphor without further heating.