

Karbala'a University
College of Pharmacy

Pharmaceutical Technology I

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Lecture 4

TINCTURES

- Tinctures are alcoholic or hydroalcoholic solutions prepared from vegetable materials or from chemical substances.
- They vary in method of preparation, strength of the active ingredient, alcoholic content, and intended use
- They are prepared from simple solution of the chemical agent in the solvent.
- Tinctures contain alcohol in amounts ranging from approx. 15-80%. The alcohol content protects against microbial growth
- Other solvent, such as glycerol, may be employed

- Tinctures cannot be mixed with some liquids which differ with the solvent's character because the solute may precipitate. For example, compound benzoin tincture, prepared with alcohol, contains alcohol-soluble principles that are immediately precipitated from solution upon addition of water.
- Tincture must be tightly stoppered and not exposed to excessive temperature
- Many tinctures must be stored in light-resistant containers and protect from sunlight.

- **Iodine Tincture**

- It is a reddish-brown colour tincture
- It is prepared from 2% iodine crystal and 2.4% sodium iodide in a vehicle alcohol/water (44-50% alcohol)
- It is a popular local anti-infective agent applied to the skin in general household first aid

- **Compound Benzoin tincture**

- It is prepared from 10% benzoin and lesser amounts of aloe, storax and tolu balsam
- The mixture is macerated in alcohol
- It is used to protect and toughen skin in the treatment of bedsores, ulcers, cracked nipples, and fissures of the anus
- Also used in treatment of venereal warts
- It is also used as an inhalent for bronchitis and other respiratory conditions
- It is best stored in tight, light-resistant containers

- **Lugol's iodine**, also known as **Lugol's solution**, first made in 1829. Lugol's iodine solution is often used as an [antiseptic](#) and [disinfectant](#), for emergency, and as a reagent for starch detection in routine laboratory and medical tests.
- When an alcohol solution is not desirable, Lugol's solution consists of 5 g [iodine](#) (I_2) and 10 g [potassium iodide](#) (KI) mixed with 85 ml [distilled water](#), to make a brown solution (iodine content of 130 mg/mL). (KI) renders the (I_2) [soluble](#) in water through the formation of the I_3^- ion. It is not [Tincture of iodine](#) contains alcohol while Lugol's solution contains no alcohol.

ADDITIVE COMPONENTS

1- Sweetening Agent

Sweeteners are indispensable for liquid oral dosage forms. They are used to mask bitter or unacceptable tastes of constituents.

- ❖ **Sucrose** is the most widely used sweetener. It is a white crystalline powder, soluble in water and alcohol. It inhibits the growth of micro-organisms in solution at a sucrose concentration above 65 wt%. It is stable in the pH range of 4.0–8.0. It is frequently used in conjunction with sorbitol, glycerin.
- ❖ **Saccharin** is a synthetic sweetening agent. It has approximately 500 times the sweetening power of sucrose, depending to some extent on the strength of the solution. Saccharin is a sucrose substitute for diabetics and the obese.
- ❖ **Aspartame** is 200 times sweeter than sucrose and unlike saccharin has no bitter aftertaste. Its solubility is adequate for formulation purposes. It is stable in the solid form, but its stability in solution depends on temperature and pH.

2- Coloring Agents

use of colorants in medicinal products affords no direct therapeutic benefit but psychological effects for the patients. chosen according to the flavor of the product (for example, yellow for lemon or red for cherry)

3- Preservatives:

Most of these preparations are marketed in a multidose form, enhancing the risk of exposure to microbes.

4- Antioxidants

- ❖ Many drugs in solution are subject to oxidative degradation. Such reactions are mediated by free radicals or molecular oxygen and often involve the addition of oxygen or the removal of hydrogen. Drugs possessing favorable oxidation potential are especially susceptible to degradation. Agents with an oxidation potential lower than that of the drug in question is called antioxidants.
- ❖ Sulfites are the most common antioxidants in aqueous solutions. Selection of sulfite salt depends on its final concentration and the final pH of the formulation e.g. metabisulfite is used at low pH.
- ❖ Certain compounds (e.g., ascorbic and citric acids) have a synergistic effect of antioxidant. Chelating agents such as ethylenediaminetetraacetic acid derivatives (EDTA) are used in formulations containing trace amounts of heavy metals that would otherwise catalyze oxidative reaction.

5- Buffers

Table 7 Buffers commonly used in liquid pharmaceutical products

Buffer	pH	Usual concentration (%)
Acetic acid and a salt	3.5–5.7	1–2
Citric acid and a salt	2.5–6	1–3
Glutamic acid	8.2–10.2	1–2
Phosphoric acid salts	6–8.2	0.8–2

(From Ref. 5.)

SPRAYS

- Sprays may be defined as aqueous or oleaginous solutions in the form of coarse droplets or as finely divided solids.
- They are applied topically to the skin and most usually to the nasopharyngeal tract.
- They relieve nasal congestion and inflammation and to combat infection and contain antihistamines, sympathomimetic agents, and antibiotic substances.

SPRAYS

- To break up a solution into small particles so that it may be effectively sprayed or to facilitate the spraying of a powder, several mechanical devices are commonly employed. The plastic spray bottle, gently squeezed to issue a spray of its contents, is familiar to most. It is commonly used for nasal decongestant sprays as well as cosmetically, especially for body deodorant products.

SPRAYS

- The air forced into the reservoir causes the liquid to rise in a small dip tube, forcing the solution up and into the stream of air exiting the system. The air and the solution are forced through a jet opening and the liquid is broken up into a spray, the droplets being carried by the airstream.

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

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

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.

NASAL PREPARATIONS

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

Examples of nasal preparations

1. **Afrin Nasal Spray/drops**- Oxymetazone- Nasal decongestant
2. **Diapid Nasal Spray** – Lopressin- Antidiuretic, prevention of diabetes
3. **Ocean Mist** – isotonic sodium chloride- restore moisture/relieve dry inflamed nasal
4. **Privine HCl solution**- Naphazoline HCl- nasal adrenergic

OTIC SOLUTIONS

preparations frequently used in the ear, usually placed in the ear canal by drops or small amounts for the removal of excessive 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

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.

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. **Vaginal Douche** - used for irrigative cleansing of the vagina therefore for hygienic effects, also called urethral douche or irrigation

EXTRACTION METHODS FOR PREPARING SOLUTIONS

Certain pharmaceutical preparations are prepared by extraction

withdrawal of desired constituents from crude drugs through the use of selected solvents

each crude drug contains a number of constituents that may be soluble in a given solvent

Tinctures, fluidextracts, and extracts are the pharmaceutical products most commonly prepared from extractives.

EXTRACTION METHODS FOR PREPARING SOLUTIONS

Among the varied plant constituents are sugars, starches, mucilages, proteins, albumins, pectins, cellulose, gums, inorganic salts, fixed and volatile oils, resins, tannins, coloring materials, and a number of very active constituents such as alkaloids and glycosides.

the solvent or solvent mixture is referred to as the menstruum, and the plant residue, which is exhausted of active constituents, is termed the marc.

EXTRACTION METHODS FOR PREPARING SOLUTIONS

water has some use in drug extraction, particularly in combination with other solvents. Although water has a great solvent action on plant constituents as sugars, gums, starches, coloring principles, and tannins, most of these are not particularly desirable components of an extracted preparation.

EXTRACTION METHODS FOR PREPARING SOLUTIONS

Hydroalcoholic mixtures are the most widely employed menstruum.

A hydroalcoholic menstruum generally provides inherent protection against microbial contamination

Alcohol is used alone as a menstruum only when necessary because it is more expensive than hydroalcoholic mixtures.

EXTRACTION METHODS FOR PREPARING SOLUTIONS

Glycerin, a good solvent for many plant substances, is occasionally employed as a cosolvent with water or alcoholic menstrua because of its ability to extract and then prevent inert materials from precipitating upon standing.

It is especially useful in preventing separation of tannin and tannin oxidation products in extractives. Because glycerin has preservative action.

it may contribute to the stability of a pharmaceutical extractive.

METHODS OF EXTRACTION

the method of extraction selected for a given drug depends on several factors, including the nature of the crude drug, its adaptability to each of the various extraction methods, and the interest in obtaining complete or nearly complete extraction of the drug.

methods of drug extraction are maceration and percolation

Maceration

It is a process in which the comminuted drug is permitted to soak in the menstruum until the cellular structure is softened and penetrated by the menstruum and the soluble constituents are dissolved.

the drug placed in a wide container with the prescribed menstruum, the vessel is stoppered tightly, and the contents are agitated repeatedly over a period usually ranging from 2 to 14 days.

Maceration

An alternative to repeated shaking is to place the drug in a porous cloth bag that is tied and suspended in the upper portion of the menstruum, The extractive is separated from the marc by expressing the bag of drug and washing it with additional fresh menstruum, the washings being added to the extractive.

Maceration

If the maceration is performed with the drug loose, the marc may be removed by straining and/or filtration, with the marc being washed free of extractive by the additional passage of menstruum through the strainer or filter into the total extractive.

Maceration

For drugs containing little or no cellular material, such as benzoin, aloe, and tolu, which dissolve almost completely in the menstruum, maceration is the most efficient method of extraction.

Maceration is usually conducted at a temperature of 15°C to 20°C for 3 days or until the soluble matter is dissolved.

2. Percolation

- Organized vegetable drug in a suitably powdered form.
- Uniform soaking of the powdered vegetable drugs with menstruum for a period of 4 hours in a separable vessel.
- Packed evenly into the percolator.
- A piece of filter paper is placed on surface followed by a layer of clean
- sand so that top layers of drugs are not disturbed.
- Sufficient menstruum is poured over the drug slowly and evenly to saturate it, keeping the tap at bottom open for passing of occluded gas to pass out.