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Chapter 3
Pharmaceutical Aids

→ The elements having little or no therapeutic value, but are basically used in production or compounding of various pharmaceuticals, are known as pharmaceutical aids or pharmaceutical necessities.

→ The functions of pharmaceutical aids in pharmaceutical dosage form are

- They also modify the API's solubility and bioavailability.
- They also help the APIs to maintain their polymorphic forms or conformations.
- They help the liquid dosage forms in maintaining their pH or osmolarity.
- They prevent aggregation or dissociation (e.g,, of protein and polysaccharide actives).
- They modulate the APIs immunogenic responses (eg., adjuvants).
- They make up the bulk of a potent drug formulation to obtain an accurate dosage form.
- They improve the patient compliance.
- They modify the formulation's safety and effectiveness during its use and storage period.

Ideal Properties

1) Non-reactive and inert,
2) Chemically stable,
3) Non-toxic,
4) Requires less equipment and process-sensitive,
5) Acceptable organoleptically
6) Economical.

Classification

On the basis of their origin, dosage forms, and functions,

Based on their Origin

1) **Animal Source:** Lactose, Gelatin, Stearic acid, Bees wax, Honey, Musk, Lanolin, etc.
2) **Vegetable Source:** Starch, Peppermint, Turmeric, Guar gum, Arginates, Acacia, etc.
3) **Mineral Source:** Calcium phosphate, Silica, Talc, Calamine, Asbestos, Kaolin, Paraffin, etc.
4) **Synthetic Source:** Boric acid, Saccharin, Lactic acid, Polyethylene glycols, Polysorbates, Povidone, etc.1

Based on Dosage Forms

- Solid dosage forms (tablets, capsules, etc.),
- liquid dosage forms (solutions, syrups, etc.),
- semi-solid dosage forms (ointments, pastes, etc.)

Pharnmaceutical Aids Used in Solid Dosage Forms

The pharmaceutical aids commonly used in solid dosage form

Category	Example
Diluents	Lactose,Dextrose,
Binders and Adhesives	Acacia, Gelatin
Lubricants	Talc, Starch paste
Glidants	Corn Starch,Carbosil,
Disintegrants & Superdisintegrants	Starch,Clay,& Cross povidone, Sodium starch glycolate
Colouring Agent	D and c dyes
Flavours	Spray dried and other flavour
Sweeteners	Mannitol,
Sorbents	Silica gel, clay,
Coating Materials	Hydroxypropylmethyl cellulose (HPMC)

Pharmaceutical Aids Used in Liquid Dosage Form

Category	Examples
Solvent	Water, Alcohol
Co-Solvent	Ethanol, Sorbitol
Buffers	Phosphate Buffer,
Antimicrobial Preserative	Benzyl Alcohol,
Antioxidants	Ascorbic Acid
Antifoaming Agents	Paraffin Oil, Alcohols,
Chelating Agent	Citric acid and Tartaric acid
Emulsifyng Agent	Sorbitol esters,
Flocculating Agent	Starch, Carbomer

Pharmaceutical Aids Used in Semi-Solid Dosage Form

Category	Example
Preservative	Benzyl Alcohol,
Solubilisers	Lanolin, Cholesterol
Gelling Agent	Pemulen, Cellulose
Suppository Base	Glycerine, Coconut Oil,

Colours/Colouring Agents

→ In pharmacy, the colourants or colouring agents obtained from plants, animals and mineral sources are particularly used for the purpose of providing colour so as to impart pleasing appearance to the drugs and cosmetics.

→ They are also used as colouring agents in the foods and for other psychological effects.

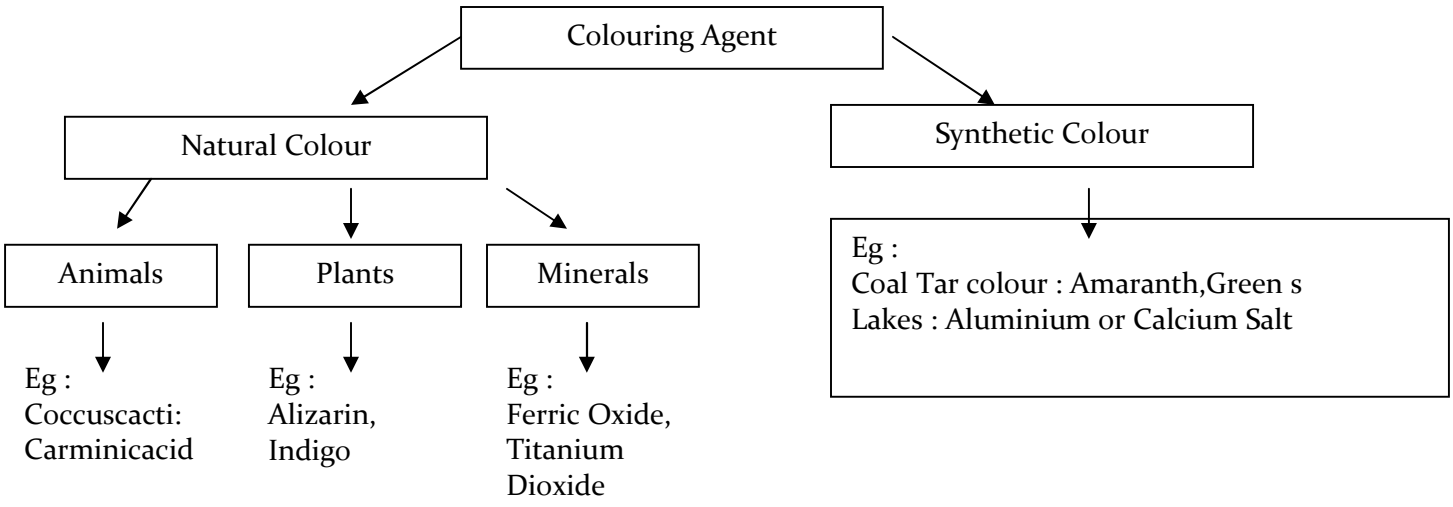
Some of the colouring agents or colourants are given below:

- **Mineral Colours:** These are used to colour cosmetics, lotions, and other preparations for external use, e.g, red and yellow ferric oxides, titanium dioxide, Prussian blue, etc. Mineral colours are generally called pigments.
- **Plant Colours:** These colours are generally obtained by extraction from plants, e.g., chlorophyll, B-carotene, alizarin, indigo, anthocyanin and flavones.
- **Animal Colours:** Carminic acid, a bright red colouring agent is present in cochineal which is obtained from the insect Coccus cacti. These are also used as synthetic colorants.
- **Synthetic Colours:** In the early days, aniline was used for the preparation of synthetic colours. Since, all the synthetic colours are not fit for human consumption; therefore, governments of different countries have approved only some specific colours to be used in the preparations.

The Drugs and Cosmetics Act 1940 and Rules 1945, in India have permitted the use of the following colours in drugs:

- Coal Tar Colours: Amaranth, green S, orange G, patent blue and tartrazine.
- Lakes: Lakes are the aluminium or calcium salts of any water soluble food dye.

Classification



Selection Criteria

- The certification status and the aesthetics of a dye.
- The physicochemical properties of the dye.
- pH and pH stability of the liquid preparations.
- The dye must be photo stabilised.
- Personal preference of the consumer population.

Advantages

- They provide grace and better eye-appealing character to the product.
- For the effective treatment of poisoning in the early stage, colours play an important role in the fast recognition of the medicine.
- Different colours of the medicines can also help the doctor in identifying the drugs given to the patient during previous treatment.
- Doctors become familiar with the colour of the products and this helps in the sale of the medicine.

Disadvantages

- The colouring property was not much elegant.
- They do not show their lasting effect in solutions.
- Sometimes the effect of sunlight fades the colour of coal tar.
- Many colours behave as feeble indicators and alteration in pH may be accompanied by the changes in colour and tinctorial power.

Uses

- For Identification.
- To Increase their Acceptability to Patients.
- To Give Warning.
- To product Standard Preparation.

Flavouring agents

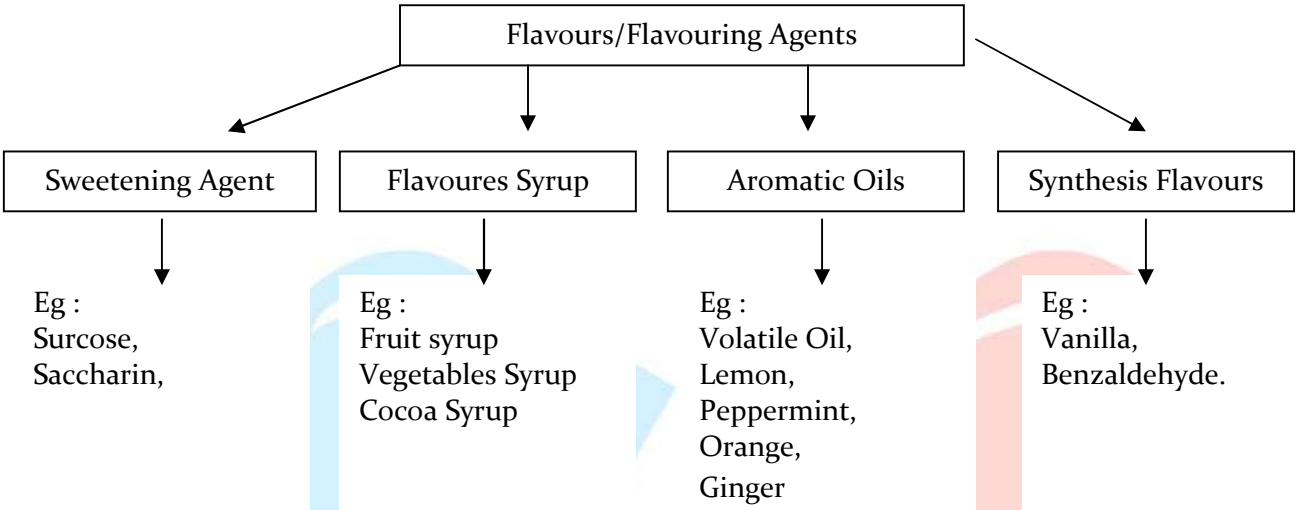
→ Flavouring agents play a vital role in masking the Flavours/Flavouring Agents disagreeable taste of liquid dosage forms used for oral oral purposes.

→ In order to increase the patient compliance, certain antibiotics masticated in the mouth and chewable tablets of antacids are generally sweetened and added with flavouring agent.

Suitable Masking Flavours For Various Product Tastes

Taste of Product	Suitable Masking Flavour
Salty	Apricot,Butterscotch,vanilla,
Bitter	Chocolate, Wild cherry,
Sweet	Vanilla, Fruits, Berries
Sour	Citrus Fruit, Raspberry

Classsification



Selection Criteria

- The qualities of the taste of flavour.
- Suitability of the combination of flavour, colour and sweetener.
- Type of the preparation, whether for internal or external use.
- Patient's age.
- General liking and disliking of the intended users.
- Best flavour for a particular product is usually selected by forming a panel and by the consent of majority.

Advantages

I. The unpleasant taste of the medicament is masked by the flavouring agents.
II. These agents help in increasing patient compliance for tablets that are chewable.

Disadvantages

- There are certain intolerable flavours that cannot be masked, e.g., in case of male fern extract, which is initially sweet, then astringent and finally bitter in taste.
- The formulations meant for patients on reducing diets or diabetics do not contain the sweetening agents that increase calories or blood sugar levels.

Uses

- Flavouring agents aids in masking the disagreeable odour or taste of the medications so as to increase the patient's acceptance towards the drug.
- They induce an acceptable flavour in the medicament.

Sweeteners/Sweetening Agents

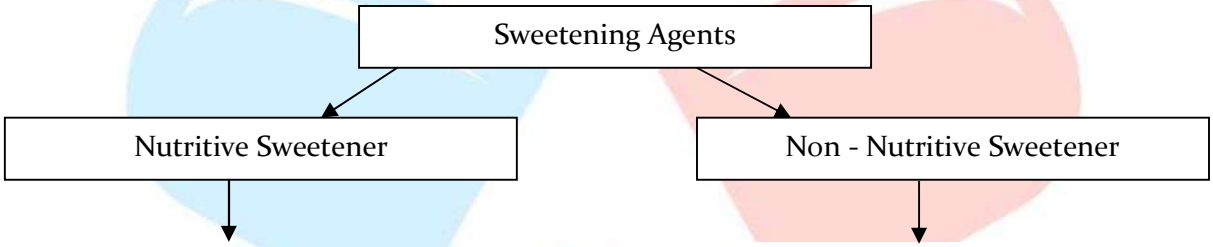
→ Sweetening agents are the constituents that are added to a drug preparation to mask its bitter taste. The most widely used natural sweetening agent is sugar.

→ It gives viscosity to drug and also acts as preservative for liquid dosage form. There are two varieties of substitutes which are used as sweeteners:

- Natural sweeteners
- Artificial sweeteners

Classification

On the basis of Nutritive value



It is Less Sweet and Have Less Calories.

Eg : Sorbitol,Mannitol,etc.

It is Strong Sweeter ,and Have High Calories

Eg : Aspartame, Saccharin, etc.

Selection Criteria

- Sweeteners provide a substitute to sugar without the related energy (kilojoules), for those who mainly have sweet tooth.
- There are various ways by which sweeteners can be added into the diet and the sweetener is selected on the basis of requirement.
- An artificial or table top sweetener can be used in case an individual is resisting sweetness in a cup of tea or coffee.
- In case of stability of the sweeteners, a natural intense sweetener is prefeerred over other sweeteners as they are more heat stable.

Advantages

- Weight Control: An artificial sweetening agent should be used, in case; someone wants to reduce their weight as it contains zero calories. Whereas, one gram of sugar contains 4 calories and one teaspoon of sugar contains about 4 grams of sugar, 16 calories per teaspoon.
- Diabetes: It also assists in monitoring diabetes as it does not increase the blood sugar levels due to absence of carbohydrates in it.

Disadvantages

- They can cause dental cavities, raised blood sugar, calories.
- They increase the risk of cancer and may destroy blood sugar and intestinal health.
- They may result in weight gain and poor nutrition.

Uses

- Saccharine can be utilised to sweeten candies, drinks, and toothpaste.
- Lactose is an additive and filler found in various products to maintain structure and consistency.
- Sorbitol is mainly used as a laxative to relieve constipation.

Preservatives

→ A preservative is a natural or synthetic substance that is added in the products like foods, pharmaceuticals, paints, biological samples, wood, etc., to avoid decomposition by microbial growth or by unwanted chemical changes.

→ These are chemicals that are commonly added to many foods and pharmaceutical products in order to extend their shelf life.

→ Preservatives are added especially, to the products having greater water content to prevent them from alteration and degradation by microorganisms while storing.

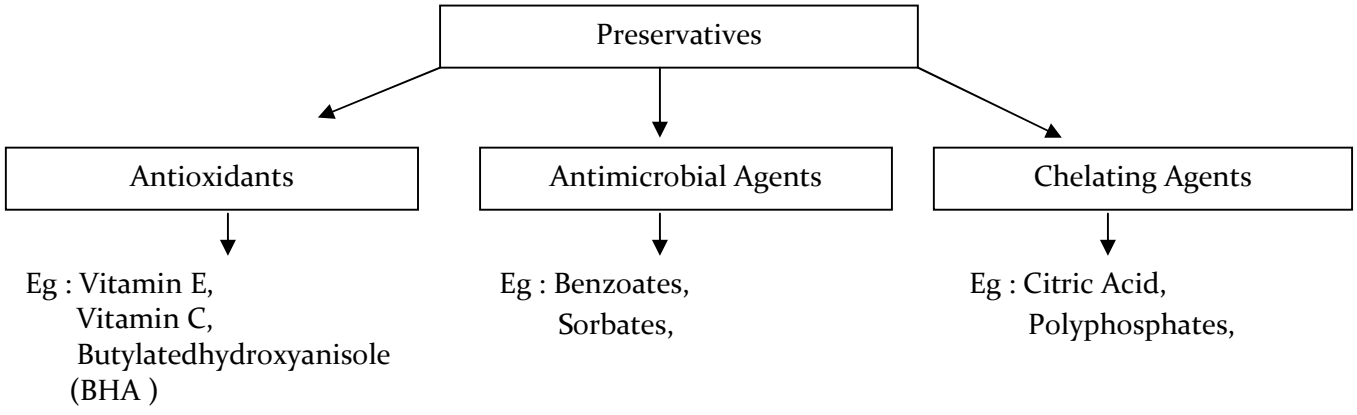
→ Preservatives are added in foods to prevent growth of bacteria, yeasts, or molds that may cause a disease.

Ideal Properties of Preservatives

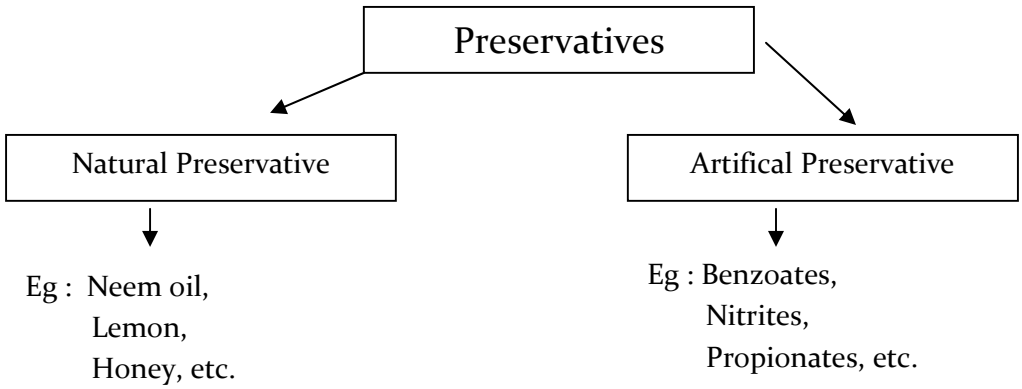
I. It should be non-irritant.
II. It should be non-toxic.
III. It should have physical and chemical stability.
IV. It should be compatible with other ingredients added in formulation.
V. I should be a good antimicrobial agent and should exert wide range of activities.

Classification

<u>On the Basis of Mechanism of Action</u>



Based on Source:



Selection Criteria

- It should be stable and highly effective even in small concentrations.
- It should not react with other ingredients of the product to form any harmful substance.
- It must be easily soluble in the desired vehicle.
- It should be odourless, tasteless, and colourless.
- The physicochemical properties of the preservative should not get affected by the pH.
- It should not produce any sensitising effects. toxic, irritant and

Advantages

- They help in maintaining the consistency with the texture and provide thickness.
- They also increase the appearance of the product to make it look edible and safe to consume for a respectable amount of time.

Disadvantages

- A group of preservatives used in fruit drinks, tea and coffee are benzoates that cause allergic reactions, asthma attacks, skin rashes, and is considered to cause brain damage.

Uses

- Preservatives are added to food to fight spoilage caused by bacteria, molds, fungus, and yeast.
- Preservatives can keep food fresher for longer periods of time, extending its shelf life.
- Food preservatives also are used to slow or prevent changes in color, flavor or texture and delay rancidity.