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## 3.1 PHARMACEUTICAL AID

### ORGANOLEPTIC PHARMACEUTICAL AIDS

Organolectic aids are incorporated to improve their colour, flavour and taste, especially for products prescribed for paediatric and geriatric patients.

- Bitter and acrid taste drugs are avoided by patients through oral route because of unpleasant taste and odour as well as colour.
- The flavouring, sweetening and colouring agents are grouped together as organoleptic aids.
- Organolectic substances promote appearance and palatability of pharmaceutical dosage form and contribute to the acceptance of the pharmaceutical products.

### Colouring Agents

- Colouring agents are added to provide distinctive colour with pleasing appearance or elegance to the dosage form.
- Colour helps the manufacturer to control the product during its preparation as well as serving as a means of identification to the user.
- Colouring agents may be soluble in the solvent system or suspended as insoluble powders.
- All colouring agents used in pharmaceutical formulations must be approved and certified by FDA as per D & C Act 1940.

#### Various types of colouring agents are:

##### A. Natural colours:

Natural colours are obtained from minerals, plants and animals.

**(1) Mineral:** Minerals are frequently termed as pigments and are used to colour lotions, cosmetics and other preparation for internal and external use.

##### (i) Titanium dioxide (TiO<sub>2</sub>):

- Naturally occurring oxide of titanium is used in cosmetics and skin care products as a pigment and a thickener.
- It is mostly commonly used in sunscreen products because of its strong UV light absorbing capabilities and its resistance to discolouration in UV light.

##### (ii) Ferric oxide:

- Iron oxide is a mineral produced by fine grinding of ores.
- Iron oxide is light fast, chemically stable and colour controlled within narrowly defined parameters.
- Red and yellow iron oxide is used in manufacturing of coloured cosmetics.

**(2) Plant:** The colour constituents from plants are obtained through extraction.

##### (i) Indigo:

- It is obtained from plant *Indigofera tinctoria*.
- The colour spectrum is 420-450 nm.

- The colour wavelength is in between blue and violet.

**(ii) Beta - Carotene:**

- It is a carotenoid comes under natural pigments found in carrots, spinach and broccoli.
- The orange colour is masked by green colour of chlorophyll.
- Carotenoid a source of vitamin A, can protect body against oxidative damage and can protect the product from UV light.

**(3) Animal colours:** These are obtained from animal source.

**(i) Tyrian Blue:** This is obtained from oxidizing of a colourless secretion from the gland of snails.

**(ii) Cochineal:** This is obtained from an insect Coccus cactus and has a brilliant red colour (carminic acid).

**B. Synthetic Colours:**

- Synthetic colouring agents are used in pharmaceutical and cosmetic products to enhance their appearance without any toxicity.
- It is mainly used today under D & C Act 1940.

**(1) Caramel:**

- It is commonly known as burnt sugar.
- It is a dark brown material obtained by controlled thermal application on carbohydrates.
- The process of caramelization consists of heating sugar slowly to around 170°C (340°F). As the sugar heats, the molecules break down and re - form into compounds with a characteristic colour and flavour.

**(2) Coal tar dyes:**

- These are mostly aromatic azo dyes.
- These are obtained from petrochemicals and coal.
- Coal tar dyes are used in medicated shampoo, soap and ointment, etc.

**(3) Lake dyes:**

- A lake pigment is manufactured by precipitating a dye with metallic salt.
- These are aluminium or calcium salts of any water-soluble colour.
- Many lake pigments are azo dyes which have sulfonate and carboxylate substituent, which confer negative charge to the chromospheres.
- Lake pigments are organic and are fugitive because the dyes involved are unstable when exposed to light.

## Flavouring agents

- Flavouring agents are usually used to mask the saline, bitter, sour, sweet taste sensations.
- Flavouring agent is required in order to increase the patient acceptance and are significant particularly in orally administered liquid dosage forms, chewable tablets of antacids, vitamins and antibiotics.
- The selection of the flavouring agents depends on taste of drugs and the age of the patient, for examples, children like sweet candy like preparations with fruit flavour but adults may prefer less sweet preparation with a tart.
- Some flavouring agents are more effective over others in masking the particular taste. As an **example**, cocoa flavours are preferred for masking taste of bitter drugs; citrus flavour is used to combat sour or acid taste of drugs; and cinnamon, orange and raspberry flavour for saline taste drugs.
- The chewable or effervescent tablets need flavours as well as sweetening agents to improve patient acceptance.
- As the flavouring agents are often thermolabile and volatile, the time of incorporating them in formulations is critical.
- They cannot be added to formulation when hot.
- In case of liquid dosage forms these agents are added to the solvent or vehicle of the formulation in which it is most soluble or miscible.
- **Water-soluble flavouring agents:** are added to the aqueous component of the formulation and poorly soluble flavouring agents are added to the alcoholic or other non - aqueous solvent of the formulation.
- **In multi - component systems:** the appropriate solvent level of the flavouring agent is essential to keep them in solution.

**Examples:** Volatile oils such as cocoa, citrus, cinnamon, orange and raspberry, clove, fennel, orange, wintergreen oil, and rose, jasmine, and lavender are used as flavours.

**Note:** Usual strength at which these agents used is 0.5 to 0.75 %.

They are usually stored at 15-30°C with relative humidity of 45 %.

## Sweetening agents

- Sweetening agents are used to impart sweet taste to the bitter pharmaceutical formulation.
- These agents need to be dissolved either when taken as solution or dissolved in saliva.
- It is used to impart acceptable taste to the oral formulation because all drugs for oral use may not have pleasant taste and often unpleasant taste is to be masked.

### A. Natural Sweetening Agent

#### 1. Sucrose:

- Sucrose is soluble in water and is easily available in highly purified form.
- It is physico - chemically stable at pH 4-8.
- It is frequently used in conjugation with sorbitol, glycerin and other polyols which reduce the tendency of sucrose to crystalline.

#### 2. Liquid glucose:

- Liquid glucose, also known as glucose syrup or confectioner's glucose, is syrup made from the hydrolysis of starch.
- It can also be made from potatoes and wheat, and less often from barley, rice and cassava.
- Glucose syrup contains varying amounts of glucose, maltose and higher oligosaccharides, depending on the grade, and can typically contain 10 % to 43 % glucose.
- Glucose syrup is used to sweeten, soften texture and add volume.

### B. Synthetic Sweetening Agent

#### 1. Saccharin:

- It is an artificial (synthetic) sweetening agent which is almost 500 times sweet as sugar but gives a bitter taste aftertaste.
- It is available as saccharin sodium and saccharin calcium.
- Its main limitation is its carcinogenic property which makes it a secondary choice.

#### 2. Cyclamates:

- Sodium cyclamate is an artificial sweetener, 30-50 times sweeter than sucrose.
- It is often used with saccharin in a ratio of 10 : 1 to mask the off - tastes of both sweeteners .
- It is cheaper than most sweeteners, including sucralose, and is stable under heating. Now, being a carcinogenic, it has been banned.

#### 3. Aspartame:

- It is the methyl ester of aspartic acid and phenyl alanine.
- It is hygroscopic in nature and thus has less stability in presence of moisture.

#### 4. Sucralose:

- It is a non - nutritive non - caloric sweetener.
- It is about 320 1,000 times sweeter than sucrose, twice sweeter than saccharin, and three times sweeter than aspartame.

- It is stable under heat and over a broad range of pH conditions and thus it is used for products that require a longer shelf life.
- It is a sweetener of choice due to its favorable low calorie , higher degree of sweetness , stability and safety properties .