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# PHARMACEUTICAL AIDS: A REVIEW

**ABSTRACT**

Pharmaceutical excipients are substances that lack significant pharmacological effects but play a vital role in the preparation of pharmaceutical dosage forms, such as tablets, injections, emulsions, and ointments. Pharmaceutical colorants are incorporated into these dosage forms to enhance their sensory characteristics for patients. These colorants are used in relatively low concentrations to achieve the desired effect and can be either natural or synthetic. Additionally, pharmaceutical colorants undergo toxicological analysis to ensure safety. Flavoring agents also contribute to the overall sensory quality of pharmaceutical dosage forms, providing a combined sensory experience involving taste, touch, smell, sight, and sound. All of these factors are a result of the interplay of physiochemical and physiological actions that influence the perception of these substances. Preservatives are commonly added to pharmaceutical formulations, especially liquid medicines, to prevent microbial growth due to the water content in the formulation. Preservatives serve to safeguard these pharmaceutical products from degradation and alterations.

## INTRODUCTION

Pharmaceutical excipients are materials that lack their own pharmacological actions but are indispensable in the pharmaceutical preparation process. They play a crucial role in the formulation, preservation, and transportation of pharmaceutical products. These excipients do not have specific effects on the human body but are used to mask the bitter taste or odor of the formulations, thus increasing patient compliance. Various pharmaceutical excipients are utilized in the formulation of different dosage forms such as tablets, capsules, emulsions, and suspensions. Examples of these excipients include coloring agents, flavoring agents, sweetening agents, emulsifying agents, suspending agents, diluents, and lubricants.

**A high-quality pharmaceutical excipient should possess the following characteristics:**

- Inert and non-reactive
- Non-toxic
- Cost-effective
- Chemically stable
- Sufficient capacity to mask the bitter taste or odor of the formulation

**Applications of pharmaceutical excipients include:**

- Increasing the shelf life of formulations
- Preventing chemical reactions in the formulation
- Preserving the formulation from microbial contamination
- Masking the bitter taste or odor of the formulation
- Allowing the formulation to have different colors, flavors, and tastes
- Enhancing patient compliance
- Increasing the bioavailability of the formulation or active pharmaceutical ingredients
- Facilitating the manufacturing and long-term preservation of the formulation

**Classification of pharmaceutical excipients:**

**1) Based on their origin**

**a) Animal sources**

i) Lactose

ii) Gelatin

iii) Lanolin

iv) Honey

**b) Vegetable sources**

i) Turmeric

ii) Acacia

iii) Starch

iv) Peppermint

**c) Mineral sources**

i) Silica

ii) Talc

iii) Kaolin

iv) Paraffin

**d) Synthetic sources**

i) Boric acid

ii) Lactic Acid

iii) Polysorbate

iv) Polyethylene glycol

**2) Based on dosage form**

**a) Used in solid dosage form**

i) Colloidal silicon di-oxide

ii) Clay

iii) Silica gel

iv) Castor oil

**b) Used in liquid dosage form**

i) Water

ii) Alcohol

iii) Ethanol

iv) Phosphate buffer

**c) Used in semi-solid dosage form**

i) Sodium benzoate

ii) Cholesterol base

iii) Lanolin

iv) Petroletum

**3) Based on Function**

**a) Anesthetic**

i) Chloroform

ii) Ether

iii) Halothane

iv) Nitrous oxide

**b) Laxative**

i) Xantham gum

ii) Karaya

iii) Bran

**c) pH modifier**

i) Citric acid

ii) Sodium hydroxide

iii) Hydrochloric acid

iv) Sodium phosphate

**d) Astringent**

i) Alum

ii) Cinnamon

iii) Zinc sulphate

iv) Copper sulphate

**e) Carminative**

i) Ginger

ii) Fennel

iii) Coriander

iv) Clove

**f) Nutrient sources**

i) Agar

ii) Lactose

Organoleptic aids: Organoleptic aids are agents used to enhance the appearance of formulations and improve patient compliance. These aids encompass flavoring agents, coloring agents, and sweetening agents.

**Coloring Agents**

Coloring agents serve the purpose of adding color to formulations, enhancing their visual appeal. These agents are not limited to pharmaceutical preparations but are also used in the food and cosmetics industries. For coloring agents to be suitable, they must meet specific criteria:

- Coloring agents must be non-toxic.
- Coloring agents should not possess any pharmacological actions of their own.
- They must be free from harmful impurities.
- Even a small quantity of coloring agents should be adequate to impart the desired color to the formulation.
- Coloring agents should remain stable when exposed to sunlight, microbes, and tropical temperatures.
- The pH of coloring agents should remain stable.
- These coloring agents should be compatible with both the active pharmaceutical ingredient (API) and excipients.

**Classification**

**Coloring agents can be categorized as follows:**

**1. Natural colors**

**a) Colors of mineral origin**

i) Titanium dioxide

ii) Red ferric oxide

iii) Yellow ferric oxide

iv) Carbon black

**b) Colors of plant origin**

i) Indigo

ii) Carrot

iii) Beta carotene

iv) Chlorophyll

v) Annatto seed

vi) Saffron

**c) Colors of animal origin**

i) Tyrian blue

ii) Cochineal

iii) Carmine

**2. Synthetic colors**

a) Caramel

b) Coal tar dyes

c) Lake dyes

1. **Natural Colors**

Natural colors are derived from both plant and animal sources. Let's delve into these categories:

a) Mineral origin colors: These pigments are obtained from minerals and are used in the manufacturing of medicines and cosmetics. They find application both internally and externally in the formulation of these products. For instance, Titanium dioxide is a naturally occurring oxide used in various cosmetics like sunscreen. Red ferric oxide and yellow ferric oxide are other mineral-derived colors. Carbon black is a pigment primarily used in the formulation of drinking preparations, providing protection against sunlight.

b) Plant origin colors: These colors come from plants. Indigo is obtained from the plant Indigo tinctoria and falls within the color spectrum of 420-450. Beta carotene is derived from carrots, spinach, and broccoli and is a rich source of vitamin A. Chlorophyll is a pigment found in the mesosomes of cyanobacteria and in the chloroplasts of algae and plants. Annatto seeds produce an orange-red condiment and food colorant derived from the seeds of the achiote tree. Saffron is obtained from the flower of Crocus sativa, with its vivid crimson stigma and styles collected and dried for use as a colorant.

**Coloring Agents Produce Color:**

Chlorophyll: Green

Annatto seeds: Yellow to orange

Indigo: Blue

Saffron: Yellow

Beta carotene: Red to orange

c) Animal origin colors: These colors are sourced from animals. Tyrian blue is an animal-origin color derived from snails. Cochineal is used to produce red color in medicines and cosmetics and is obtained from insects living in cacti. These insects are dried in the sunlight, ground into a powder, and dissolved in water to obtain red color. Cochineal is widely used in the manufacturing of medicines and cosmetics. Carmine, also known as carmine lake or crimson lake is derived from the aluminum complex of carminic acid and is used to produce a bright red color in pharmaceutical preparations and cosmetics.

2. **Synthetic colors:**

These colors are synthesized using various chemicals in the laboratory and are used in the formulation of medicines and cosmetics. Synthetic colors enhance the appearance of formulations and have no harmful effects on the human body. Caramel, also known as invert sugar, is obtained through the process of caramelization. Coal tar dyes are produced by combining various aromatic hydrocarbons like toluene, xylene, and benzene. Lake pigments are derived by precipitating dyes with metallic salts and are water-soluble.

**According to the Drug and Cosmetic Act, 1940, there are three types of coloring agents:**

a) FD & C colors: Used in the formulation or manufacturing of medicines, food, and cosmetics.

b) D&C colors: These dyes and pigments are used in the manufacturing of medicines and cosmetics that come into contact with mucous membranes.

c) External D&C colors: Utilized in the formulation of medicines and cosmetics that are externally applied to the skin.

**Applications:**

Increases acceptability: By using coloring agents in formulations, patient acceptability for the medicine is increased. Coloring agents also prevent variable appearances of the same formulation in different batches, improving patient compliance.

To identify the formulation: Coloring agents aid in the identification of medicines. The use of different colors in different strengths of the same medicine (API) helps differentiate medicines at various manufacturing stages.

To provide stability of formulation: Some coloring agents possess specific qualities that stabilize the formulation when added in coatings or gelatin shells during tablet or capsule manufacturing.

**Flavoring agents**

Flavoring agents are used in medicines to make them taste better, especially when they have a bitter or unpleasant taste. They play a significant role in masking the medicine's taste and odor, making it easier for patients to take. Flavoring agents are primarily used in medicines that are taken by mouth. When a patient takes a medicine by mouth, they quickly notice its taste. Sometimes, the taste or smell is so unpleasant that patients might even spit out the medicine. That's why it's crucial to add flavoring agents during the manufacturing of medicines.

Typically, about 0.5-0.75 percent of flavoring agents are used in making medicines. It's important to be careful when adding flavoring agents because they can change the nature of the medicine. If a flavoring agent dissolves in water, it's mixed in the liquid part of the medicine. If it doesn't dissolve in water, it's mixed in the non-liquid part of the medicine.

**Classification**

**Flavoring agents can be classified as follows.**

**1) Sweetening agents**

a) Sucrose

b) Invert syrup

c) Sorbitol

d) Treacle

e) Saccharin sodium

**2) Flavored Syrup**

a) Fruit flavored syrup

b) Syrup with weak therapeutic activity

c) Cocoa syrup

**3) Aromatic oils**

a) Ginger

b) Peppermint

c) Clove

d) Cinnamon

e) Lemon

f) Orange

g) Dill

**4) Synthetic flavor**

a) Ketones

b) Lactones

c) Benzaldehyde

d) Vanillin

e) Esters

**Choosing the Right Flavoring Agent**

- The choice of flavoring agent depends on the active ingredient (API) and other ingredients in the medicine. Flavoring agents help cover up the taste and smell of the medicine. People are often more sensitive to the smell than the taste.
- The choice of flavoring agent also depends on the existing taste and smell of the medicine. Different types of flavoring agents are used for different forms of medicine, whether they are solid, liquid, or semi-solid.
- The type of dosage form, whether it's a solid pill, liquid, or semi-solid, also affects the choice of flavoring agent.
- The age of the patient matters when selecting flavoring agents. Medicines for children might require different flavors than those for adults.
- The choice of flavoring agents also depends on how the medicine is used, whether it's applied externally or taken internally.

**Sweetening Agents**

Sweetening agents are like sugar and syrups that make medicines and syrups taste sweet. We use things like sucrose, invert syrup, treacle, sorbitol, and saccharin sodium to add sweetness. Sucrose is used in linctuses, elixirs, syrups, and even in tablet coatings. Invert syrup is even sweeter than simple syrup because it has a mix of glucose and fructose. We make invert syrup by mixing sucrose with acid.

**Flavored Syrups**

- Flavored syrups make medicine taste better.
- For syrups with low therapeutic value, we also add flavors.
- Fruit-flavored syrups are made from citrus fruits like lemons, oranges, and sweet lemons.
- Cocoa syrup hides the bad taste of medicine.

**Aromatic Oils**

Sometimes, we use oils like ginger, cinnamon, clove, and mint to make medicine taste better.

**Synthetic Flavors**

- We make synthetic flavors in labs using different chemicals.
- These flavors help mask the taste or smell of medicine.
- Some examples are ketones, benzaldehyde, esters, and lactones.

**Applications**

- Flavoring agents make medicine taste good and smell nice.

- They also help patients take their medicine regularly.
- We use them in chewable tablets, buccal tablets (for the mouth), and other oral medicines.
- Chocolate flavor is often used in kids' medicine because they like it.
- We can use various flavors for medicines meant for older people.

**Sweetening Agents**

Sweetening agents make medicine taste sweet and thicker.

They, along with flavoring agents, are important for oral medicines.

In simple words, they hide the unpleasant taste of medicine in things like tablets, emulsions, and suspensions.

**When choosing sweetening agents for pharmaceutical preparations, several important criteria should be considered:**

No Interaction: Sweetening agents should not react with the pharmaceutical preparation.

No Interaction with API or Excipients: They should not chemically or physically interact with the active pharmaceutical ingredient (API) or other ingredients in the formulation.

Consideration for Diabetic Patients: For diabetic patients, it's essential to use synthetic sugars as sweetening agents because they have zero calories.

Sweetness in Small Quantity: Sweetening agents should be capable of adding sweetness to the formulation even in small amounts. This is important because we consume a large amount of sugar in our daily routine, such as sugar in tea.

Stability: The sweetening agents must remain stable in the pharmaceutical formulation.

Safety: Sweetening agents should not have any harmful effects on the human body.

**Classification**

**Sweetening agents can be divided into two main categories:**

**Natural Sweetening Agents**

**a) Saccharides**

i) Sucrose

ii) Glucose

iii) Honey

**b) Non-Saccharides**

i) Terpenoids

ii) Steroidal saponins

iii) Proteins

iv) Dihydrochalcones

v) Dihydroisocoumarins

vi) Volatile oil

vii) Polyols

**Synthetic Sweetening Agents**

a) Aspartame

b) Sucralose

c) Saccharin

Sweeteners

**Sucrose**: Sucrose is a type of sugar we get from sugarcane juice. People use it mainly for making sweets like toffees, biscuits, and ice cream.

**Aspartame**: This sweetener is used in food and beverages.

**Lactose**: Lactose is used to cover up the bad taste of some medicines. It also helps keep medicines stable.

**Saccharin**: Saccharin is a man-made sweetener. It's super sweet, about 500 times sweeter than sugar. We use it to make medicines taste sweet.

**Sodium Cyclamate**: This is another artificial sweetener, and it's quite sweet, about 30-50 times sweeter than sugar.

**Sucralose**: Sucralose is an even sweeter artificial sweetener, about 600 times sweeter than sugar. It has no calories. We often use it in food and drinks like candies, coffee, and soft drinks.

**Honey**: Honey comes from bees, and it's the only natural sugar from animals. It's also used as an antioxidant. Honey is incredibly sweet, about 10,000 times sweeter than sugar, and it's safe for people with diabetes.

**Why We Use Sweeteners in Medicines**

We add sweeteners to medicines to make them taste better, so people are more likely to take them. Sweeteners are also used in liquid medicines to make them syrupy, which help control their thickness.

Sugar is sometimes used to coat tablet pills, making them easier to swallow.

Liquid Glucose (Glucose Syrup): This is made by breaking down starch. It's used to make pharmaceutical products soft and sweet.

**Preservatives**

Preservatives are natural or man-made substances used in medicines to stop them from going bad. They prevent harmful germs like bacteria, yeast, and molds from growing in medicines.

**Characteristics:**

- It should not be harmful.
- It should stay the same without changing.
- It should do what it's supposed to.
- It should stop germs from growing in medicines.
- It should not alter the medicine's chemical makeup.
- A little bit should be enough to work well."

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