



A COMPREHENSIVE REVIEW ON PHARMACEUTICAL EXCIPIENTS

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ABSTRACT

Pharmaceutical Excipients play a crucial role in the development and formulation of medicinal products. These inactive substances are used to enhance the stability, bioavailability, and patient acceptability of drugs. Excipients can be classified into various categories, including fillers, binders, disintegrants, lubricants, and coatings. The selection of suitable Excipients is critical to ensure the quality and efficacy of pharmaceutical products. Excipients can interact with drugs, affecting their stability and bioavailability, and can also impact the manufacturing process. This review article aims to provide an overview of pharmaceutical Excipients, their classification, properties, and applications, drug Excipients interaction.

KEYWORDS: Pharmaceutical Excipients, Binders, Disintegrants,

Lubricants, Coatings.

INTRODUCTION^[1]

The Latin excipere, which means "to except" and can be simply translated as "other than," is the root of the English word excipient.

Anything besides the active pharmaceutical ingredient is referred to as a pharmaceutical excipient.

DEFINITION EXCIPIENT^[2]

A substance, other than the active pharmaceutical ingredient (API), that has been appropriately evaluated for safety and is intentionally included in a drug delivery system to aid in the processing of the drug product during its manufacture, protect, support, enhance stability, bioavailability, or patient acceptability, assist in product identification, or enhance any other attribute of the overall safety and effectiveness of the drug product during storage or use.

FUNCTION OF EXCIPIENTS^[3]

- **Changing Solubility and Bioavailability:** Excipients can increase an API's solubility and bioavailability in the body.
- **Preserving Osmolarity and pH:** Excipients help keep liquid formulations compatible with the body's physiological parameters by preserving their osmolarity and pH.
- **Enhancing Patient Acceptability:** They improve patient acceptability and promote compliance, particularly in younger patients, by improving the overall taste and appearance of the medication product.
- **Aiding in Product Identification:** A few excipients make it easier to identify the medication product.
- **Ensuring Safety and Effectiveness:** Excipients are added to drug delivery systems in order to enhance the formulation's overall safety and effectiveness.
- **Increasing Stability:** By helping to maintain the stability of Active Pharmaceutical Ingredients (APIs) in the dosage form, excipients extend the shelf life of pharmaceutical products.

THE FOLLOWING STANDARDS ARE CRUCIAL FOR CHOOSING AND USING EXCIPIENTS^[4]

- Physical and chemical stability.
- Physiological inertness.
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- Compliance with regulatory agency standards.
- Lack of impact on drug bioavailability.

- Absence of harmful microorganisms.
- Economical.

CLASSIFICATION^[5,6]: Excipients can be classified on the basis of their origin, use in dosage form and functions they perform.

- **ON THE BASIS OF THEIR ORIGIN**

SR NO	SOURCE	EXAMPLE
1	Animal source	Lactose, Stearic acid, Bees wax, Honey, Musk, Lanolin, Gelatin.
2	Synthetic	Boric acid, Saccharin, Lactic acid, Polyethylene glycols.
3	Plant origin	Shrubs/tree exudates: gum arabic, gum ghatti, gum karaya, gum tragacanth, and khaya and albiziagums.
4	Microbial origin (bacterial and fungal)	xanthan, dextran, curdian, pullulan, zanflo, emulsion, Baker's yeast glycan, schizophyllan.
5	Vegetable source	Starch, Peppermint, Turmeric, Guar gum, Alginates, Acacia etc.
6	Seed gums	guar gum, locust bean gum, starch, amylose, and cellulose.
7	Tuber and roots	potato starch.
8	Extracts	pectin, larchgum;
9	Mineral source	Calcium phosphate, Silica, Talc.

- **ON THE BASIS OF THEIR USE IN DOSAGES FORM**

SR NO	DOSAGE FORM	EXAMPLE
1	Solid dosage form	Lactose, directly compressible Starches, Crosscarmalose, Crosspovidone, Sodium starch glycolate, activated carbon, Polypropylene glycol, Triacetin, Saccharin.
2	Liquid dosage form	Dichlorodifluoromethane, Erythrosin, Aspartame, Sorbitan esters, Microcrystalline cellulose, Sodium Lauryl Sulphate (SLS).
3	Semi-solid dosage form	Glycerin, mineral oil, gelatin, hydrogenated vegetable oil, polyethylene glycol, Benzyl alcohol, Carbomer934.

- **ON THE BASIS OF FUNCTION, THEY PERFORM**

SR NO	FUNCTION	EXAMPLE
1	Glidants	Colloidal Silicone dioxide, Corn starch.
2	Diluents	Dextrose, Sorbitol, Microcrystalline cellulose.
3	Binders and Adhesives	Acacia, Gelatin, Starch paste, Polyvinyl pyrrolidone, Glucose,
4	Lubricants	Talc, Stearic acid, Magnesium stearate, Calcium stearate, Polyethylene glycol, Surfactants, vegetable oil.
5	Disintegrants Superdisintegrants	Starches, Clays, Cellulose, Cross linked polymers, Modified starches such as Primogel and Explotab, Crosscarmalose, Cross Povidone.
6	Sorbents	Silica gel, activated carbon,
7	coating materials	Hydroxy propyl methyl cellulose (HPMC), Synthetic polymers, Shellac, Corn protein Zein, Polysaccharides.
8	Plasticizers	Castor oil, Diacetylated Monoglycerides, Polyethylene glycol.
9	Buffers	Phosphate buffers, Acetate buffers
10	wetting agents	Sodium Lauryl Sulphate (SLS), Tween 80.
11	thickening agents.	Methyl cellulose, Hydroxyethyl cellulose, Microcrystalline cellulose.
12	chelating agents.	Disodium EDTA, Dihydroxy ethyl glycine, Citric acid and Tartaric acid.
13	sweetening agents	Sucrose, Sorbitol, Saccharin.
14	Antioxidants	Ascorbic acid, Sodium bisulphate.
15	flocculating agents	Starch, Sodium alginate.
16	Flavours	Aromatic waters, Syrup.
17	Preservatives	Benzyl alcohol, propyl paraben, methyl paraben, chlorocresol, imidazolidinyl urea, sodium benzoate
18	Solubilizers	Lanolin, cholesterol or cholesterol esters

TYPES OF EXCIPIENTS^[7,8]

BINDERS

Function and Purpose

Binders are excipients that give cohesion to the granules or hold the drug formulation together. powders in solid dosage forms like capsules and tablets. The compression of the is aided by binders. formulation into a solid dosage form while maintaining its integrity. They assist in making sure that the tablets or granules can be handled and stored securely since

they don't break apart too soon. Binders also assist in the by preserving the integrity of the dosage form until it arrives at the gastrointestinal tract, the API is released in a regulated manner.

Example: starch, gelatine.

DISINTEGRANTS

Function and Purpose

Disintegrants are substances employed in pharmaceutical formulations to encourage quick disintegration of tablets, capsules, or other solid dosage forms disintegrate when they come into contact with liquids in the gastrointestinal tract. A crucial step in guaranteeing correct drug release is disintegration. Disintegrants take up water, which leads the tablet to swell and disintegrate into smaller pieces, which increases the surface area available for dissolution.

Example: Croscarmellose sodium, croscopolvidone.

LUBRICANTS

Function and Purpose

Lubricants are agents utilized in pharmaceutical formulations to minimize friction throughout the manufacturing process, especially during the compression or filling of tablets and capsules. They assist in avoiding adherence to the equipment and guarantee smooth processing of the formulation. Lubricants also contribute to enhancing the flow characteristics of powders and granules. In certain instances, lubricants may also offer a minor coating on the tablet surface, enhancing its swallowing ease.

Example: Magnesium stearate, Calcium stearate.

FILLERS (DILUENTS)

Function and Purpose

Fillers or diluents are excipients employed to increase the volume of a pharmaceutical formulation, especially in tablets and capsules, where the active pharmaceutical ingredient (API) may exist in minimal amounts. Fillers assist in attaining the targeted dosage size and enhance the processing and management of the medication. They also enhance the flow characteristics of powder mixtures and support the consistent dispersion of the API.

Example: Microcrystalline cellulose, Dextrose.

PRESERVATIVES

Function and Purpose

Preservatives are agents utilized to inhibit microbial growth and maintain the stability and safety of pharmaceutical formulations. They hold particular significance in liquid and semi-solid dosage forms, which are more vulnerable to contamination from bacteria, molds, or yeast. Preservatives function by preventing the proliferation of microorganisms, thus prolonging the product's shelf life.

Example: sodium benzoate.

COLORANTS

Function and purpose

Colorants are Excipients incorporated into pharmaceutical formulations to give color to the product, enhancing its visual appeal and recognisability. In certain instances, colorants are utilized to distinguish between various strengths or types of medication. Colorants do not exert a direct therapeutic effect but enhance the overall patient experience and adherence. They also assist in the identification of the product, which is essential for patient safety.

Example: Titanium dioxide.

STABILIZERS

Function and Purpose

Stabilizers are excipients that safeguard the drug formulation against degradation throughout manufacturing, storage, and transport. They assist in preserving the chemical stability and integrity of the API by inhibiting hydrolysis, oxidation, or other chemical reactions that could result in potency loss or the creation of harmful byproducts. Stabilizers are especially crucial in formulations that include biologics, vaccines, and delicate APIs.

Example of Stabilizer: Ascorbic Acid (Vitamin C).

SOLVENTS

Function and Role

Solvents are excipients utilized to dissolve or disperse the API in pharmaceutical formulations, especially in liquid dosage forms such as solutions, suspensions, or injectables. The selection of solvent can influence the solubility, stability, and bioavailability of the drug. Solvents also aid in creating emulsions or suspensions in liquid dosage forms.

Example of Solvent: Water.

SURFACTANTS

Function and Role

Surfactants are additives employed to lower the surface tension between two different phases, like oil and water, enabling the creation of emulsions or suspensions. Surfactants also enhance the solubility and bioavailability of medications that are not easily soluble in water. Besides their emulsifying capabilities, surfactants can act as wetting agents, detergents, or stabilizers in various formulations.

Example of Surfactant: Polysorbate 80.

FLAVOURING AGENTS

Function and Role

Flavouring agents are additives that are included in pharmaceutical formulations, especially in liquid dosage forms, to enhance the flavour and total palatability of the drug. They are especially crucial in paediatric and geriatric groups, where the likability of the medication can greatly influence patient adherence. By concealing undesirable tastes or smells, flavouring agents can assist in ensuring that patients are more inclined to take their medications as directed.

Example of Flavouring Agent: Saccharin.

COATINGS

Function and Role

Coatings are excipients applied onto the surface of tablets, capsules, or other solid dosage forms to offer various benefits, such as safeguarding the drug from degradation, managing the release of the API, enhancing appearance, and making swallowing easier. Coatings can also serve to conceal the taste or smell of the drug and prevent gastrointestinal discomfort. Additionally, coatings can assist in protecting sensitive APIs, like biologics or those susceptible to oxidation, from the harsh environments of the stomach or exposure to the elements. Tablet coatings may be either functional (providing a specific drug release profile, like sustained-release or enteric coating) or non-functional (for aesthetic reasons). The selection of coating material is influenced by the desired outcome of the formulation and the characteristics of the drug.

Example of Coating: Hydroxypropyl Methylcellulose (HPMC).

PH MODIFIERS (BUFFERS)

Function and Role

pH modifiers or buffers are excipients employed to adjust and sustain the pH of a pharmaceutical formulation within a designated range, ensuring the stability, solubility, and bioavailability of the API. Numerous drugs exhibit limited solubility or stability at specific pH levels, and pH modifiers assist in optimizing these conditions. For instance, certain drugs demonstrate greater solubility in acidic surroundings, whereas others necessitate a neutral or slightly basic environment to remain stable.

Buffers are crucial in preserving the ideal pH in oral, injectable, and topical formulations. In oral formulations, they can avert the degradation of sensitive APIs caused by gastric acidity, while in injectables, they help guarantee that the pH is compatible with physiological conditions to prevent irritation or tissue damage.

Example of pH Modifier: Sodium Citrate.

THICKENING AGENTS

Function and Role

Thickening agents are excipients utilized to increase the viscosity of a formulation. They are frequently used in liquid or semi-solid formulations such as syrups, suspensions, creams, ointments, and gels. Thickening agents enhance the consistency and texture of the formulation, ensuring that the API is effectively delivered to the target site. They also inhibit the settling of suspended particles in liquid formulations and enhance the stability and spreadability of topical preparations.

The selection of a thickening agent is based on the desired viscosity, along with the formulation's intended application. In oral formulations, thickening agents can improve the mouthfeel, while in topical formulations, they can assist in regulating the release of the drug through the skin.

Example of Thickening Agent: Carbomer.

CHELATING AGENTS

Function and Role

Chelating agents are excipients that attach to metal ions in pharmaceutical formulations, inhibiting the metal ions from initiating degradation reactions like oxidation. These agents are especially crucial in formulations containing active pharmaceutical ingredients (APIs) that

are prone to degradation induced by metal ions, including certain vitamins, biologics, and antibiotics. By creating stable complexes with metal ions, chelating agents improve the stability and longevity of the drug product.

Chelating agents may also be utilized in the management of metal toxicity, where they attach to surplus metal ions in the body and aid in their elimination.

Example of Chelating Agent: Ethylenediaminetetraacetic Acid (EDTA).

ANTIOXIDANTS

Function and Role

Antioxidants are additives incorporated into pharmaceutical formulations to avert the oxidation of the API. Oxidation can result in the deterioration of the drug, diminishing its effectiveness and possibly producing harmful byproducts.

Antioxidants safeguard the drug by counteracting free radicals and reactive oxygen species that might induce oxidative harm.

These additives are especially crucial for formulations that include APIs susceptible to oxidation, such as vitamins, some biologics, and delicate drugs like statins.

Example of Antioxidant: Ascorbic Acid (Vitamin C).

CLASSIFICATION OF DRUG EXCIPIENT INTERACTIONS^[9]

1) PHYSICAL INTERACTIONS: Physical interactions involve no covalent bond formation but can influence critical properties such as drug solubility, dissolution rate, and bioavailability. Examples include

- **Adsorption:** APIs can adsorb onto Excipients surfaces (e.g., digoxin on magnesium stearate), reducing drug availability.
- **Polymorphic transformation:** Excipients can induce changes in the crystalline form of a drug, affecting solubility.
- **Moisture transfer:** Hygroscopic excipients may alter the moisture content of APIs, impacting their stability.

2) CHEMICAL INTERACTIONS: Chemical interactions involve covalent or ionic bond formation between drug and Excipients, potentially leading to drug degradation.

- **Maillard Reaction:** Reducing sugars like lactose can react with primary or secondary amines in drugs (e.g., atenolol), causing discoloration and degradation.

- **Hydrolysis:** Moisture-sensitive drugs such as aspirin may degrade in the presence of water-retaining excipients.
- **Oxidation:** Excipients containing peroxides or metal ions can promote oxidation of sensitive APIs (e.g., diazepam).
- **pH-dependent reactions:** Excipients that alter microenvironmental pH can destabilize acid- or base-labile drugs.

3) BIOPHARMACEUTICAL INTERACTIONS: These interactions impact the drug's pharmacokinetics.

- **Solubility enhancers:** Surfactants can increase solubility but may also affect absorption.
- **Release modifiers:** Polymers such as HPMC can control drug release but may interact unfavourably under certain conditions.

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