

A review of herbal excipients used in pharmaceutical formulations

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Abstract

Herbal excipients have emerged as a promising alternative to synthetic excipients in pharmaceutical formulations. Derived from natural sources, these excipients offer several advantages, including biodegradability, biocompatibility, and non-toxicity. This review highlights the various types of herbal excipients, their sources, and applications in pharmaceutical formulations. The ideal properties of herbal excipients, such as their ability to improve bioavailability and stability, make them an attractive option for formulators. Examples of commonly used herbal excipients, including gums, mucilages, and polysaccharides, are discussed. The advantages and disadvantages of herbal excipients are also presented, along with their potential applications in various dosage forms. Overall, herbal excipients have the potential to revolutionize the pharmaceutical industry by providing a natural and sustainable alternative to synthetic excipients.

Keywords: Herbal excipients; Pharmaceutical formulations; Biodegradability; Non-toxicity; Bioavailability

1. Introduction

The Latin term "excipients," which means to receive, to gather, and to take out, is where the word "excipient" originates. The active pharmaceutical ingredient (API), manufacturing procedures, and excipients employed all affect a formulation's standard [1]. From an inert and inexpensive vehicle to a crucial component of the formulation, the conventional idea of excipients as any component other than the active ingredient has experienced a significant transformation [2]. "The substance used as a medium for giving a medicament" is the definition of an excipient [3]. Known as solvent blending, this system functions by lowering the interfacial tension between the hydrophobic solute and the mostly aqueous solution. Nowadays, ethanol, propylene glycol, sorbitol, glycerin, and polyethylene glycol 400 (PEG 400) are the water-soluble organic solvents that are utilized [4]. A mixture of excipients and active pharmaceutical ingredients (API) makes up a pharmaceutical dosage form. [5] The global pharmaceutical sector is predicted to increase from \$1.23 trillion in 2020 to \$1.25 trillion in 2021 at a compound annual growth rate (CAGR) of 1.8%, according to Research and Markets' 2021 forecast [6]. Sophisticated compounds that serve multiple purposes in contemporary pharmaceutical dosage forms, such as enhancing patient acceptability, improving the stability and bioavailability of the active ingredient, and carrying out technological tasks that guarantee ease of manufacture, have supplanted conventional excipients [7]. Excipients are the ingredients of a pharmaceutical form other than the active ingredient, according to the European Medicines Agency (EMA) [8]. "Substances other than the active pharmaceutical ingredient (API) that have undergone a suitable safety evaluation and are purposefully incorporated into a drug delivery system are known as pharmaceutical excipients" [9]. Starches, celluloses, gums, and pectins are a few examples of natural excipients that have been investigated as a substitute for synthetic ones [10].

Excipients are components other than the active medication ingredient that are present in a completed pharmaceutical dosage form, according to the International Pharmaceutical Excipients Council (2009) [11]. Excipients are the additions that transform active medicinal compounds into dose forms that patients can receive [12]. Recent modifications to the Food and Drug Administration's (FDA) and European Medicines Agency's (EMA) legal and regulatory standards are

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partly to blame for this (FDA, 2006; EMA, 2008) [13]. The essential components of these changes that enable formulation scientists to accomplish their goals are excipients. According to Parker et al. (2009), excipients are simply "the components of a formulation other than the active ingredient" [14]. Nevertheless, compounds derived from plants also present a number of possible difficulties, including the fact that they are produced in tiny amounts and in combinations that are architecturally complicated, which might vary depending on the plants' location and additional factors like the time of year. This could lead to a costly and drawn-out isolation and purification procedure. The topic of intellectual property rights is another one that has grown in significance [15]. Excipients are also necessary to improve the bioavailability of drugs, especially those with poor solubility. Drugs that are not particularly soluble in water can be made more soluble and dissolve more quickly with the help of surfactants like sodium lauryl sulphate and solubilizers like polyethylene glycol. This increase in bioavailability is crucial to ensuring that the drug reaches therapeutic levels in the bloodstream [16].

Synthetic analogues of naturally occurring minerals make up the majority of crystalline compounds utilized as excipients or active components [17].

Pharmaceutical excipients derived from plants are highly sought after these days and are used by researchers to create a variety of formulations [18]. According to estimates, 277,102,564 tonnes of cassava were produced worldwide in 2016, with Nigeria, Thailand, Brazil, and Indonesia producing the most [19]. Pharmaceutical excipients are substances other than the Active Pharmaceutical Ingredient (API) that have been suitably assessed for safety and purposefully added to a drug delivery system, according to the USP-NF [20]. It is well known that both synthetic and semi-synthetic products have been used for a very long time. They often have special qualities and benefits over naturally occurring compounds, such as a low sensitivity to different ingredients or moisture, which makes pharmaceutical products more effective and efficient [21]. An excipient is a material that is used to administer a drug, that is, solely to act as an inert carrier for the active ingredients [22]. Novel excipients are required to fulfill the multifunctional roles of improving bioavailability and stability, influencing release pattern, and improving patient acceptance as a result of advancements in drug delivery systems. Researchers have investigated both natural and synthetic excipients for these purposes [23]. Its goal is to shape the drug product's manufacturing process, which will ultimately help the drug's physiological absorption [24]. They are an effective and affordable way to deliver active therapeutic ingredients in formulations since they are also easily customizable to meet specific needs. Therefore, this study aims to clarify the potential of natural excipients as a lubricant, disintegrant, binder, and diluent in a range of formulations since they are able to give the generated dosage form more nourishment and are biocompatible [25].

2. Pharmaceutical excipients



Figure 1 Excipients used in the solid dosage form [26]

Nonactive substances that are combined with therapeutically active substances to create medications are known as pharmaceutical excipients. An excipient is an ingredient that isn't an active ingredient. Excipients have a substantial and increasing functional impact on the drug product's efficacy and behavior [26].

2.1. The ideal characteristics of an excipient are as follows:

- Chemically stable
- Non-reactive
- Less equipment and process sensitive Inert to human body
- Nontoxic
- Acceptable with regards to organoleptic characteristics
- Economical
- Having efficiency in regards with the intended use.
- Excipients are considered as inert substance [27].

2.2. Advantages of Pharmaceutical Herbal Excipients:

- All living things make biodegradable polymers, which are compounds found in nature. They don't appear to have any negative consequences on people or the environment.
- They are essentially completely biocompatible and non-toxic because they are primarily composed of repeating monosaccharides derived from carbohydrates. Because of this, they are not toxic.
- They are less costly to produce and more affordable than synthetic materials.
- Because they come from a natural source, they are risk-free and have no negative consequences.
- They are widely produced and available in many countries due to their extensive use in a wide range of sectors [28].
- Biodegradable: All living things naturally make biodegradable polymers. They don't have any negative consequences on people or the environment [29].

2.3. Disadvantages of Pharmaceutical Herbal Excipients:

- Microbial contamination: During production, they are exposed to the external environment, which increases the risk of microbial contamination.
- Variation: Synthetic polymer production is a controlled process with set constituent quantities, in contrast to natural polymer manufacturing, which is dependent on the environment and several physical conditions.
- The uncontrolled rate of hydration Differences in the amount of chemical components present in a certain substance can be caused by variations in the collection of natural resources at different times, as well as variations in species, climate, and geography. Slow Process: It is impossible to change how rapidly things are produced because of the environment and numerous other factors. As a result, spontaneous polymer formation occurs at a slow pace [30].
- The formation of natural polymers depends on the environment and a number of physical parameters, whereas synthetic manufacturing is a regulated process with predetermined quantities of materials [31].

3. Classification of Pharmaceutical Excipients:

Excipients are commonly classified according to their application and function in the drug

3.1. Binders

To transform active pharmaceutical substances into a pharmaceutical dosage form that can be administered appropriately, excipients also referred to as additives are utilized. Binders are the excipients utilized to bind or hold all the substances employed in the formulation of the dosage form, as their name suggests. Binders are added to a formulation to improve the bonding strength between the particles or to impart plasticity [1].

3.2. Diluents

Active Pharmaceutical Ingredients (API) typically exhibit a therapeutic effect in pharmaceutical dose forms, but they are not given directly blends with excipients to create a form that is appropriate for patient compatibility. Diluents and fillers are excipients that are used to dilute liquid formulations or to increase the bulk of solid formulations [1].

3.3. Lubricants

The proper production of pharmaceutical solid dosage forms depends on lubrication; lubricants are necessary components in sturdy formulations to achieve this. Despite the fact that lubricating issues lead to numerous failures in pharmaceutical manufacturing processes, lubricants do not receive enough attention in the formulation of

pharmaceuticals. An emphasis on magnesium stearate, the application of lubricant in the manufacturing of pharmaceutical products and production procedures is investigated [32].

3.4. Disintegrants

The most popular way to provide patients active pharmaceutical ingredients (APIs) is through pharmaceutical solid dosage forms, such as tablets or capsules. In addition to the API, tablets are frequently powder compacts containing a number of excipients. Materials known as excipients are included in a formulation in to improve processability, affect how a drug releases in the body, or reach the necessary fill weight of a dosage form. These intricate porous networks travel via a number of paths when they come into contact with physiological fluids. The powder compact's dissolution and disintegration characteristics have the biggest impact on a drug's effectiveness [32].

3.5. Preservatives

Preservatives are excipients that keep pharmaceutical formulations stable and safe by inhibiting microbial growth. Since liquid and semi-solid dosage forms are more prone to bacterial, mold, or yeast contamination, they are especially crucial. Preservatives prolong the product's shelf life by preventing the growth of germs [33].

3.6. Glidants

To help with particle rearrangement within the die during the initial phases of compression and to enhance the flow characteristics of the material to be fed into the die cavity, glideants are added to the formulation. Glidants are useless if the flow characteristics are really bad, and force-free processes might need to be taken into account. Glidants impact on granule flow is contingent upon the size and shape of both the glidant and granule particles. Examples of common glidants include calcium phosphate, stearates, colloidal silica silicates, talcum, and starch [34].

3.7. Flavouring agents

The senses of taste, touch, smell, and sight combine to form flavors. Today, the flavoring industry uses technology to create a lot of artificial flavors. A wide range of pharmaceutical formulations, such as cough syrups, sedatives, antibiotics, and antimalarials, contain flavors. Flavors are also frequently used in the food business. Organoleptic agents include flavoring agents. To obscure an unpleasant taste or dose form order, flavors are used as taste masking agents.

3.8. Sweeteners

Sweeteners are food additives that are used or intended to be used as tablet sweeteners or to enhance sweetness to meals. Table top weeteners, are sweeteners made of or containing any of the authorized sweeteners and are meant to be sold to the final customer. They are typically used as a sugar substitute. Government laws do not apply to sweetening agents like sugar and honey since they are not regarded as additives. Sweeteners come in two varieties: high intensity and bulk [22].

4. Types of herbal excipients

4.1. Gums

Gums are amorphous, translucent substances produced by plants. Gums are typically pathological byproducts that show up when a plant is injured or developing under unfavorable conditions. Plants contain gums, which are anionic or nonionic polysaccharides. Gums create sugar and uronic acid salts when hydrolysed [25].

4.2. Guar gum

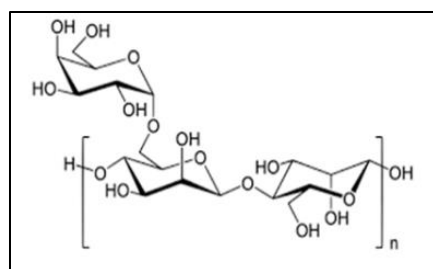


Figure 2 Chemical structure of gum acacia [36].

This naturally occurring, liquid-soluble polymer is derived from the berries of the guar crop, *Cyamopsis tetragonoloba*. It is used in many different industries, such as food, medicine, cosmetics, and textiles, due to its thickening and stabilizing properties. Guar gum is also used as a dietary supplement to treat a variety of diseases [36].

4.3. Gum acacia

Acacia senegal (Linne) Willdenow and other similar species of acacia (Family Leguminosae) produce gum acacia, often known as gum Arabic, which is a dried gummy exudate. It has been established that the gum is an acidic polymer composed of D-galactose, L-arabinose, L-rhamnose, and D-glucuronic acid. Acacia is primarily employed as an emulsifying and suspending ingredient in oral and topical medicinal formulations, frequently in conjunction with tragacanth. It is also utilized as a tablet binder and in the manufacturing of pastilles and lozenges [37].

4.4. Karaya gum

Sterculia urens (Family Sterculiaceae) is the source of Karaya gum, a partly acetylated polymer of glucuronic acid, galactose, and rhamnose. When creating directly compressed matrices, release-controlling agents such as xanthan gum and karaya gum both of which are swelling, hydrophilic natural gums were employed [38].

4.5. Xanthan gum

The gram-negative bacterium *Xanthomonas campestris* ferments to create xanthan gum, a high molecular weight extracellular polysaccharide. This naturally occurring cellulose derivative's main structure is made up of a cellulosic backbone called beta-D-glucose residues and a beta-D-mannose-beta-D-glucuronic acid-alpha-D-mannose trisaccharide side chain joined to the main chain's alternating glucose residues [16]. Compared to synthetic hydroxypropylmethylcellulose, xanthan gum shown a greater capacity to delay the release of the medication [39].

4.6. Alginates

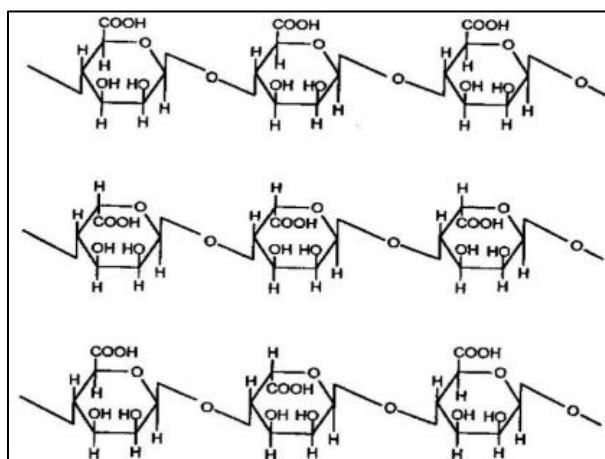


Figure 3 Structure of Alginates [35]

Alginates are naturally occurring polysaccharide polymers that have been separated from *Phaeophyceae*, or brown seaweed. It is possible to convert alginic acid into its salts, with sodium alginate being the most widely utilized form at the moment. A linear polymer made up of blocks of alternating or random units of mannuronic and guluronic acids separates homogenous blocks (made up of either acid residue alone) of D-mannuronic acid and L-guluronic acid residues organized in blocks in the polymer chain. Alginates can be used in a variety of drug delivery applications, including liposomes, matrix type alginate gel beads, local applications, gastrointestinal transit time modulation, and the delivery of biomolecules for tissue engineering [35].

4.7. Tamarind gum

The endosperm of the seed of the tamarind tree, *Tamarindus indica*, an evergreen, contains tamarind xyloglucan. The seeds are used to extract tamarind gum, often referred to as tamarind kernel powder (TKP). Seed selection, seed coat removal, separation, hammer milling, grinding, and sifting are the steps used to turn the seeds into gum. Tamarind gum is a polysaccharide made up of galactosyl, xylosyl, and glucosyl in a 3:2:1 ratio. One important structural polysaccharide found in higher plants main cell walls is xyloglucan. *Tamarindus indica*, a member of the leguminacy family, yields

tamarind seed polysaccharide (TSP) from its seed kernel. Plants naturally contain xyloglucans (XGs), sometimes known as amyloids [40].

4.8. Neem gum

Azadirachta indica trees, which are members of the Meliaceae family, are the source of neem gum. Mannose, glucosamine, arabinose, galactose, fucose, xylose, and glucose are all found in neem gum. It is utilized as a binding agent in pharmaceuticals in Nimesulide sustained release matrix tablets made from *Azadirachta indica* fruit mucilage was investigated [41].

4.9. Dikamali gum

A gum resin extracted from the leaf buds of a shrubby plant by cutting the stem or branches, this plant (*Gardenia gummifera*) is a member of the Rubiaceae family. Geographically, it can be found in every district of South India, but especially in the Western Ghat region of Karnataka, Tamil Nadu, Andhra Pradesh state, Kerala, the Malabar coast, Burma, Bangladesh, and Karnataka state (North Canara district, Karwar, Mangalore). Dikamali, Gandharaj, Hingunadika, Nadihingu, Pindava, and so on are more names. In the past, several flavonoids, including gardenin A, B, C, D, and E, were separated from Dikamali. It is produced in India in quantities of 10 to 15 tons per year and comprises 89.9% resin, 0.1% oil, and gardenin, a coloring ingredient [42].

5. Physicochemical Properties

Because chitosan has a main amino group in its structure, it is a very basic polymer. The primary variables that could impact the characteristics of CS are its degree of deacetylation (DD) and molecular weight. The molecular weight and degree of deacetylation are the main differences between the many grades of CS that the researcher can create thanks to these parameters.

6. Biological Properties

It has been utilized in surgery, orthopedics, ophthalmology, and dentistry because of its bioadhesive ability to stick to both soft and hard tissues. It also has anticancer, anticholesteremic, and fungistatic or bacteriostatic properties [43].

7. Physical Interaction

It occurs often yet is very difficult to observe. A physical interaction does not result in any chemical changes. In the manufacturing of dosage forms, for example, physical interactions are frequently used to change the solubility of medications. However, problems usually arise because many physical interactions are impromptu. The performance of a product may be enhanced or degraded by physical contact. An example of an API and excipient is the physical interaction between microcrystalline cellulose and primary amine medications.

Following water-based dissolution, a very little amount of the drug might remain on the microcrystalline cellulose. For high-dose pharmaceuticals, this might not be a big deal, but for low-dose drugs, it can cause dissolving failures. This has been a problem in the past, but it can be resolved by using a weak electrolyte solution as the dissolving media (0.05 M HCl, for example). Under these revised dissolution test conditions, adsorption onto the microcrystalline cellulose is significantly reduced, and even low-dose APIs can dissolve 100% of the way [44].

8. Conclusion

Herbal excipients have demonstrated significant potential in pharmaceutical formulations, offering a natural and sustainable alternative to synthetic excipients. Their biodegradability, biocompatibility, and non-toxicity make them an attractive option for formulators. The use of herbal excipients can also contribute to sustainable development and environmental conservation. However, further research is needed to fully explore the potential of herbal excipients and to address the challenges associated with their use, such as variability in quality and standardization. Regulatory frameworks should also be established to ensure the safe and effective use of herbal excipients in pharmaceutical formulations. Ultimately, the integration of herbal excipients into pharmaceutical formulations has the potential to revolutionize the industry and improve public health.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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