WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Review On: Excipients Used in Herbal Drug Technology

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ABSTRACT :

The formation of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for the production and manufacturing of herbal medications requires standardization. Various traditional methods as well as modern improvements are presented in this review article.DNA fingerprinting, metabolomics, differential pulse polarography, chemometrics, and X-ray diffraction are examples of recent advances.Herbal or natural excipients have a significant benefit over their synthetic analogues in terms of safety, cost, and availability.As a result, the goal of this study is to shed light on the potential of natural excipients as a diluent, binder, disintegrant, and lubricant in a variety of formulations because they are biocompatible and capable of providing additional nutrition to the produced dosage form.The traditional definition of excipients as any component other than the active ingredient has evolved from an inert and inexpensive vehicle to an essential component of the formulation. Excipients are any ingredients included in the formulation of a dosage form that aren't the active ingredient(s). The purpose of this article is to provide an overview of herbal excipients that are employed in both traditional and new medication delivery methods.

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Keywords: Polysaccharides, volatile oils, controlled delivery, Standardization, herbal drug, DNA fingerprinting, chromatographic techniques

Introduction :

Excipients are defined as "the substance employed as a vehicle for administering a medication" [1.] Natural polysaccharide polymers are used in pharmaceutical formulations to aid in the processing of the drug delivery system during its manufacture, to protect, support, or enhance stability, bioavailability, or patient acceptability, to aid in product identification, or to improve any other aspect of the drug's overall safety, effectiveness, or delivery during storage or use [2]. Several plant-derived pharmaceutical excipients, such as starch, agar, alginates, carrageenan, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose, are used as binding agents, disintegrants, sustaining agents, protective, colloids, thickening agents, gelling agents, bases in suppositories, stabilizers, and coating materials in the pharmaceutical industry[3]

An excipient is a material that is employed as a vehicle for administering a medicament, with the sole purpose of providing inert support for the active principle or principles. The word excipient comes from the Latin word excipients, which means to receive, collectively, to the outside. The product's quality is determined by the manufacturing procedures, active pharmaceutical ingredient (API), and excipients used in the formulation. These excipients contribute significantly to the API's performance, ensuring the product's safety efficacy. Excipient has traditionally been employed to supply the bulk of a formulation because it includes a potent medicine that cannot be taken alone and to ensure consistency of the drug in a dose form. In a dosage form, a variety of excipients are utilized, each of which corresponds to a different route of administration, formulation condition, and formulation strength. Excipients are attached in various concentrations. Excipients are used as a stabilizing agent for API in the formulation, ensuring that the active compound remains active and stable for the duration of the product's shelf life. They are also used to mask unpleasant tasks and ensure that the required amount of the active ingredient reaches the right place in the body at the expected time. [4]

Herbal or natural excipients have a significant benefit over their synthetic analogues in terms of safety, cost, and availability. As the pharmaceutical industry becomes more aware of these herbal excipients, which are mainly polymers of natural origin, it is becoming more inclined to use them in formulation development. Plant-derived gums and mucilages from natural sources such as carrageenan, thaumatin, lard, storax, agar, gum acacia, tragacanth, and others meet a variety of pharmaceutical excipient requirements. When opposed to their synthetic counterparts, they can be favored for formulation development because they are more stable and have less regulatory concerns. They can also be easily customized to fit unique requirements, making them a powerful and cost-effective vehicle for delivering active medicinal components in formulation. As a result, the goal of this study is to shed light on the potential of natural excipients as a diluent, binder, disintegrant, and lubricant in a variety of formulations because they are biocompatible and capable of providing additional nutrition to the produced dosage form.

In traditional dosage forms such as tablets and capsules, excipients are typically utilized as diluents, binders, disintegrants, adhesives, glidants, and sweeteners1. Due to the difficulty in determining toxicity and obtaining regulatory permission for synthetic excipients, researchers have recently been more interested in herbal excipients. When compared to synthetic competitors, the disadvantage of heavy metal contamination commonly associated

with herbal excipients is outweighed by their lack of toxicity, ease of availability, and cost considerations in the pharmaceutical sector. Natural components are increasingly sought after in food, pharmaceuticals, and cosmetics by modern customers, who assume that anything natural will be safer and free of adverse effects. [5]

Objectives :

- The utilization of natural excipients for the delivery of bioactive substances has been impeded by synthetic materials. Natural excipients, on the other hand, have the advantages of being non-toxic, less expensive, and readily available.
- Because the establishment of toxicity and approval from regulatory bodies is a difficulty with synthetic excipients, researchers have recently showed an increased interest in herbal excipients. [6]

Advantages of Herbal Excipients :

- Biodegradable - All living organisms manufacture naturally occurring polymers. They have no negative consequences on the environment or people.
- Nearly all of these plant components are carbohydrates in origin and are made up of repeating monosaccharide units, making them biocompatible and non-toxic. As a result, they are non-toxic.
- Economic - They are less expensive to buy and produce than synthetic materials.
- Safe and without side effects - Because they come from a natural source, they are both safe and free of side effects.
- They are produced in numerous nations due to their application in a variety of industries.7

Disadvantages of Herbal Excipients :

- Microbial contamination - Because herbal excipients are exposed to the external environment during manufacture, they are susceptible to microbial contamination.
- Variation - Synthetic manufacturing is a controlled method with fixed amounts of chemicals, whereas natural polymer creation is influenced by the environment and other physical factors.
- The unregulated rate of hydration - The percentage of chemical constituents present in a given substance may vary due to differences in the collection of natural materials at different times, as well as differences in geography, species, and climate conditions.
- Slow process - Because the rate of production is determined by the environment and a variety of other factors, it cannot be altered. As a result, natural polymers are produced at a slow rate.
- Heavy metal contamination - Heavy metal contamination is frequently linked to herbal excipients.8,

Classification of Excipients :

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

- Binders, Diluents
- Lubricants, Glidants, Disintegrants.
- Polishing Film formers and coatings agents
- Plasticizers, Colorings
- Suspending agents Preservatives, antioxidants
- Flavorings, Sweeteners, Taste improving agents.
- Printing inks, Dispersing agents Gums .[9]

Binder :

Fig.1 : Binder

Binder excipients are designed to function as an adhesive, literally "binding together powders, granules, and other dry materials to add mechanical strength to the finished product." Binders are used to make a more effective and predictable granule formulation, and they can also lend volume to low active dosage, tablets often employed in wet granulation. Solution binders, for example, are dissolved in a solvent such as gelatin cellulose derivatives, and are categorised according to their application. Sucrose and polyethylene glycol are added to polyvinyl pyrrolidone starch. [10]

Diluents and fillers :

- **Diluents :**

fig.2 : Diluents

A diluting agent is a diluent (also known as a filler, diluent, or thinner). Certain fluids are either too viscous to be easily pumped or too thick to flow from one point to another. This can be troublesome since transporting such fluids in this form may not be economically viable. Diluents are used to help with the restricted movement. This reduces the viscosity of the fluids, as well as the expenses of pumping and shipping. [11]

- **Fillers :**

Filler excipients are used to increase the volume of the substance so that the components may be processed more easily and it can be made into a size that is suitable for consumption. They can also help with product stabilization and manufacturing.Tablets, pills, pellets, paste, solution, suspension, and emulsion are examples of dosage forms in which filler and diluent are used.[12]

Fig.3 : Fillers

Lubricants, Glidants, Disintigrants :-

- **Lubricants :**

Lubricants are excipients that are used to lubricate a process, which entails applying chemicals to make the process run smoothly. Lubricants are used to avoid the clumping of materials used in formulations during the manufacturing process. Lubricants reduce friction between particles and processing equipment and keep the formulation sticky. Lubricants are added to formulations in minute amounts, much like solid dosage forms. [13]

Fig 4 : Lubricants

Examples of dosage form in which lubricants are used as follow:- Tablet , capsules, pills , pastes , suppositories, pellets etc

- **Glidants :**

Glidants are added to the formulation to improve the flow of the tablet-core mix material. Glidants are incorporated into the particle arrangement of the tablet powder blend during the early stages of compression to increase flowability and uniformity within the die cavity of tablet presses.

Fig.5 : Glidant

Although talc is thought to be a better glidant than starch, it has a concentration limit due to its retardant effect on the dissolution–disintegration profile. Glidants reduce friction between particles, allowing tablet granulation to flow more freely. [14]

- **Disintigrants :**

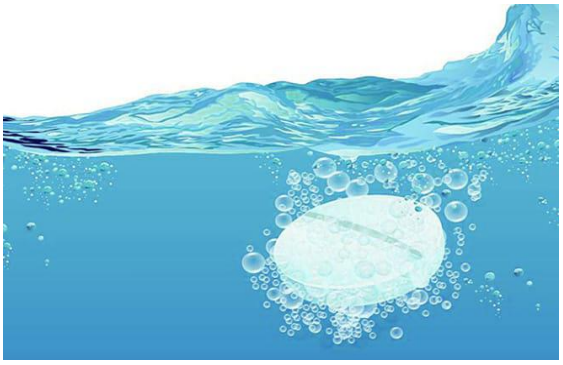

Fig.6 : Disintigrants.

To aid in the de-aggregation of oral solid dose forms, disintegrants are included. When solid dosage forms come into touch with moisture, disintegrants are designed to break them up quickly. [15]

Polishing film formers and coating agent's :

- **Polishing film formers :**

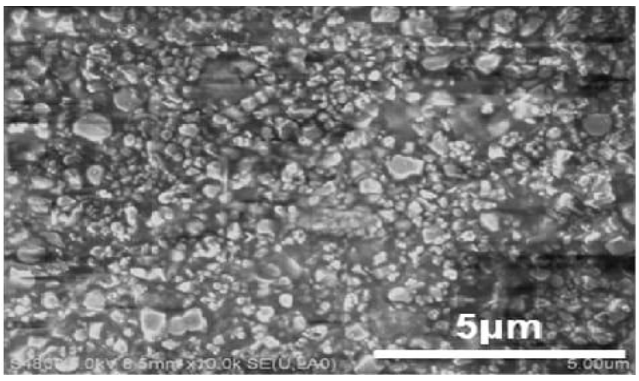

fig.7 : Polishing film formers

Film formers are used as a surface applicant on steel surfaces and can be found in paints. They operate as corrosion inhibitors and are low-cost chemical products that seek to keep steel looking pristine. In addition, film formers protect the steel surface from rust, corrosion, and other pollutants. [16]

- **Coating agent :**

Fig.8 : Coating agent

Coating agents have a variety of uses in pharmaceutical solid dosage forms, and they're just as useful in people. Coating agents are applied to the dosage form to coat or produce a film. These coating methods improve drug protection while simultaneously altering medication release. Coating agents are employed to avoid the stomach and absorb the medication from the intestines, depending on the exact site of drug release; coating agents play a significant function. Coating agents improve the appeal of a formulation. [17] and [18]
Examples of dosage form in which coating agents are used: Tablets, Pills, Capsules etc.

Plasticizers , coloring :

- **Plasticizers :**

Fig.9 : Plasticizers

Plasticizers are chemicals that are applied to materials to make them softer and more flexible; certain plasticizers are better than others at this [19] .There are two types of plasticizers for elastomers: ester and petroleum oils. In general, ester plasticizers benefit polar elastomers in terms of processing, whereas petroleum oils benefit nonpolar elastomers. [20]

- **Coloring Agent's :**

Fig.10 : Coloring Agent

There are two types of plasticizers for elastomers: ester and petroleum oils. In general, ester plasticizers benefit polar elastomers in terms of processing, whereas petroleum oils benefit nonpolar elastomers. [20]
Example of dosage forms in which coloring agents are used:-
Tablets, Pills, Pallets, Capsules, Pastes, Ointments, Syrups, Emulsions, Suspensions etc.

Classification :
• Natural dyes derived from plants, such as berries, flowers, bark, leaves, seeds, and so on (e.g. Catechu, Indigofera, Myrobalan and Pomegranate).
• Insect-derived natural colors, such as cochineal and lac.
• Animal-derived natural dyes, such as mollusk, murex snail, cuttlefish, and shellfish.
• Mineral-based natural colours such as clay, ochre, and malachite[22]

Suspending agents, preservatives, antioxidants :

Aqueous Suspending Agents

Fig.11 : Aqueous suspending agents

Aqueous biological polymers such as methylcellulose (MC), sodium carboxymethylcellulose (CMC), and hydroxypropylmethylcellulose are the most popular suspending agents (HPMC). Suspending agents are available in a variety of viscosities and molecular weights.[23]

- **Preservatives :**

Fig.12 : Preservatives

Preservatives are chemical compounds found in the pharmaceutical, cosmetics, and food sectors. They are introduced in formulation to avoid the degradation of products by microbial development. They also prevent the unfavorable chemical changes from occurring. Antimicrobial preservatives and anti-oxidants are the two types of preservatives that are commonly used. [24]

- **Antioxidants :**

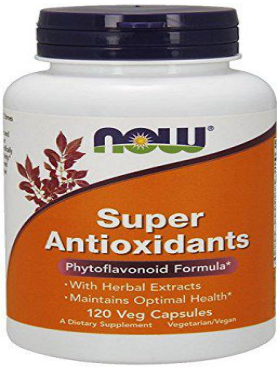

Fig.13 : Antioxidants

An antioxidant is a substrate that keeps molecules inside a cell from oxidizing. It is a well-known chemical reaction that permits electrons or hydrogen to be removed from a material. Antioxidants are routinely used as food supplements and have been studied for their ability to prevent diseases including heart disease and cancer. Flavouring agents, sweeteners, and taste enhancers are all examples of flavoring agents..[25]

- **Flavouring agents:**

Fig.14 : Flavoring agent

Flavors are a combination of the senses of taste, touch, smell, and sight. Many artificial flavors are now made with the use of technology in the flavoring industry. Flavors are used in a variety of medicinal formulations, including cough syrups, sedatives, antimalarials, and antibiotics. Flavors are commonly employed in the food industry as well. Flavoring agents are classified as organoleptic agents. Flavors are utilized as taste masking agents, obfuscating a disagreeable taste or dosage form order. [26]

- **Sweeteners :**

Sweeteners are described as food additives that are used or intended to be used as a tabletop sweetener or to lend a sweet flavor to meals. Tabletop sweeteners are sweeteners that are made up of or contain any of the authorized sweeteners.

Fig.15 : Sweeteners

are meant for sale to the final customer, and are typically used as a sugar substitute. Sweetening foods, such as sugar and honey, are not additives and are therefore exempt from government requirements. Sweeteners are divided into two categories: high intensity and bulk. 27

Taste improving agents:

Fig.16 : Test improving agent

Many dietary components have been labeled as "taste enhancers," such as monosodium glutamate (MSG), sodium chloride (NaCl), and sweeteners, yet their principal impact is to simply add more molecules that cause more taste or smell sensations. MSG, salt, and sweeteners, for example, do not truly augment other chemosensory traits; instead, they give additional meaty/savory, salty, or sweet properties.[28]

Printing inks , Dispersing agent Gums :

- **Printing inks :**

Fig.17 : Printing inks

Unlike paints and varnish coats, printing inks are applied to the surface as a very thin layer, with a thickness ranging from 2 to 30 m depending on the printing technique.Inks are liquid materials that are used for writing and printing. Their primary use is to stain a surface in order to create a text, image, or pattern[.29]

- **Dispersing agent :**

Fig.18 : Dispersing agent

Solutions for aqueous, solvent-based, high solids, 100 percent solids systems, and universal pigment concentrates are among the dispersion agents for coatings and ink formulations. These polymeric, oligomeric, and surfactant-based technologies are well-known for their excellent color development, viscosity reduction, improved gloss, and stability, as well as their applicability for low-VOC and APEO-free systems. [30]

- **Gums :**

Fig.19 : Gums

Plants create gums, which are transparent and amorphous compounds. Gums are usually pathological products that appear when a plant is developing in poor conditions or when it is wounded. Gums are anionic or nonionic polysaccharides that are found in plants. Gums produce sugar and uronic acid salts when hydrolyzed. 31

Applications of natural excipients :

Natural excipients are used in a variety of sectors to express biological active agents that have been hampered by synthetic components. Natural excipients have the advantages of being non-toxic, less priced (economic), and readily available. The quality of the prepared product is directly related to the functions of the excipients. Excipients are chemicals that are not medically active but are inner in nature and help active molecules work better. Natural excipients, on the other hand, are any component derived from natural resources that is purposely incorporated with the formulation of a dosage form. This article provides an overview of natural excipients used in both traditional and new medication delivery systems. [32,34]
Since ancient times, natural substances have been employed. Ayurveda is an Indian traditional medicine system in which direct plant parts and extracts from various medicinal plants are utilized to cure a variety of ailments. Herbal treatments such as churn, baati, and bhasma are utilized before synthetic substances are introduced. Synthetic chemicals are utilized in a limited range under special guidelines due to their high toxicity or negative effects. To increase the effectiveness of substances, scientists now prefer to use natural excipients whenever possible or semi-synthetic molecules. The majority of medicinally active chemicals are found in nature or are produced from naturally occurring active compounds in the form of derivatives. Natural or herbal goods are also used increasingly by consumers because they are less or non-toxic. [35,36]

Conclusion :

Today, the emphasis is on patient compliance, and NDDS research is accelerating to meet this goal. Herbal excipients can be chemically compatible with excipients in drug delivery systems because they are potentially biodegradable compounds. In addition, when compared to their synthetic counterparts, herbal excipients are non-toxic, readily available, and less expensive. They play a significant role in the pharmaceutical sector. As a result, there will be continuous interest in natural excipients in the coming years in order to develop better materials for drug delivery systems.

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