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Herbal excipients: An overview

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Abstract
Due to huge achievements in drug delivery system, excipients are presently included in novel drug delivery system to serve particular roles and in some cases; they directly or indirectly affect the extent and rate of drug release and drug absorption. Excipients are used from artificial resources in the up-to-date era, causing undesirable pharmaceutical and therapeutic impact. Natural excipients are plant or plant-based substances, obtained from many components of the plant. Thus, companies and customers are therefore looking at natural resources as they believe that anything natural will be safer and without side effects and can be used to solve toxicity and chemical compatibility issue of synthetic excipient's in different drug delivery systems. This article is an effort to review natural excipients in existing dosage forms as well as new drug delivery systems to serve humanity by ensuring safe, effective, quality and price-effective medical superiority worldwide.

Keywords: natural excipients, solid dosage form, low cost, active ingredient

Introduction

The World Health Organization (WHO) describes excipient as non-active ingredients that have been competently analysed for safety and included in a drug delivery system to [1]

1. Processing assistance during development of drug delivery system.
2. Protect aid and improve stability, bioavailability and acceptability of patients.
3. Helps in the identification of substance
4. Strengthen any other feature of the drug's overall safety and effectiveness during processing or use.

Excipient is the substance or compound other than the active pharmaceutical component and packaging elements, often influencing the quality of the final product, sometimes forming almost complete formulation. Nature has provided us with a variety of products that contribute directly or indirectly, to improving and sustaining the safety of all human beings used as natural excipients [2]. The excipients make an excellent contribution to API efficiency and ensure product safety and efficacy [3]. Several pharmaceutical herbal excipients, such as starch, agar, alginates, carrageen an, guar gum, xanthan gum, gelatin, pectin, tragacanth, and cellulose, which are used in the pharmaceutical industry as binding agents, disintegrants, sustaining agents, protective colloids, thickening agents, gelling agents. Because plant supplies are renewable and can be sustainably grown or collected, it can provide steady fresh resource availability. As a raw material for extracting herbal excipients, waste from the food industry can be used. These are other factors for increased demand as excipients for herbal products [4]. Excipients are also obtained from organic sources, chemically produced or semi-synthesized from organic products. Excipients maintain drugs safe from micro-organisms and suitable for long-term consumption, in addition to creating them delicious and therefore favour compliance with treatment. To stabilize the active ingredient added excipients ensure that the active ingredients shall remain "active" and also stable until the product's expiry time or shelf life is adequate to improve the active ingredient competition with other products, but also help to treat human disease. Most excipients are used at specific levels, so adverse reactions are rare [5]. The following review offers an brief details on herbs that are categorised as medicinal aids into several categories based on distinct roles.

Role of excipient in development of dosage form

Natural-origin excipients are of particular interest to us for reasons of reliability and avoid reliance on fossil-derived materials. Excipients are mainly classified according to their application and function in the drug products: -

- Binders
- Fillers and Diluents.
- Lubricants, Glidants, Disintegrants.
- Polishing Film formers and coatings agents
- Plasticizers, Colouring agents
- Suspending agents Preservatives, antioxidants.
- Flavorings, Sweeteners, Taste improving agents.
- Printing inks, dispersing agents Gums

Advantages of herbal excipients [6]

- Natural excipients are all derived from the natural resources and are therefore safe and environmentally friendly.
- All these natural / herbal excipients are chemically carbohydrates in nature and therefore these excipients are non-toxic substances.
- Natural excipients are cheaper and their manufacturing cost is less than synthetic excipients
- Herbal excipients are obtained from a natural source, thereby having no adverse effects or side effects on humans.
- Natural excipients are easily available from different natural resources.

Disadvantages of Herbal Excipients [6]

- There are several possibilities of microbial contamination during the manufacture of natural excipients in contact with the external environment.
- The production of natural excipients depends on environmental, regional and climatic conditions. As a result, the number of different natural excipients also depends on different factors that cannot be changed; natural excipients therefore have a slow process rate for the production of excipients.
- Natural excipients have a very slow rate of manufacturing.

1. Binders

Binders, as their name suggests, are the excipient used to bind or hold all the components used in the dosage formulation. Binders are used in the mixture to express plasticity or to increase the potential of binding between the formulated particles. Natural binders such as starch gums the mucilage of dried fruit have binding properties and some other characteristics

Such as filler, disintegrants. Natural polymers are safe and economical than synthetic polymers. Some plant derived binders are mentioned in the table no. 1

Table 1: List of some excipients used as binder

Sr. no.	Name of excipient	Source	Family
1	Tamarind seed	Tamarindus indica	*Leguminosae*
2	Fenugreek mucilage	Trigonella foenum graecum	*Leguminosae*
3	Mangifera indica gum	Mangifera indica	*anacardiaceae*
4	Gum acacia	Acacia Arabica	*Combretaceae*
5	Mucilage of Artocarpus Heterophyllus	Artocarpus Heterophyllus	*Moraceae*

1.1. Tamarind seeds

Tamarind xyloglucan is derived from *Tamarindus indica (family Fabaceae)* tamarind seed endosperm. This is essential for viscosity, adhesivity. Tamarind seeds have several uses; they are a by-product of commercially used tamarind fruits. Tamarind gum is a polysaccharide made up of glucosyl: xylosyl: galactosyl ratio 3: 2: 1. The polysaccharide derived from tamarind seeds were used by wet granulation method to formulate matrix tablets and analysed for its effects on drug release. Tablets have been manufactured using varying polymer ratios with decreased drug release showing an increase in polymer content. Tamarind seed polysaccharide has been investigated as a biodegradable carrier for colon-specific drug delivery system. The matrix tablets prepared using tamarind gum was seen to be capable of allowing most of the drug into the colon and limiting the release in upper GIT [7]. The purified polysaccharide tamarind seed has relative chemical similarity for MUC-1 and Epsialin mucin. Tamarind seed polysaccharide (TSP) is used as solubilizer in 1:3 as the capsule of high-dispersal Aceclofenac, Atorvastatin and Irbesartan; improves solubility and dissolution properties compared to the drug itself, without affecting stability of the material being formulated [8].

1.2 Fenugreek seeds [9]

The crop *Trigonella foenum graecum Linn.* is an annually aromatic herb of the leguminous family, known also in English as fenugreek. For their medicinal values, these plants have long been used. Because of their biocompatibility, Fenugreek plant provides natural polysaccharides for food and pharmaceutical use. Because of its biocompatibility, biodegradability, easy accessibility and low cost, Fenugreek plant provides natural polysaccharides used as food and pharmaceutical excipients. low concentration level of fenugreek seeds develop high viscosity mucilage. Colic flatulence, dysentery, diarrhoea, decrease of appetite dyspepsia, chronic cough, dropsy, swollen kidney, spleen enlargement and diabetes has been treated with fenugreek. This can be used as antiurolithic, diuretic, antidandruff, anti-inflammatory and antioxidant agent. There is a huge proportion of mucilage in fenugreek seeds.

2. Fillers and Diluents

Diluents or fillers are pharmaceutical components which do not have any pharmacological effect but are necessary for pharmaceutical preparations. Diluents are chemically ineffective excipients, most of which are used in the formulation up to 80 percent to build up the necessary bulk of the dosage form. [10]

Some plant derived binders are mentioned in the table no. 2

Table 1: List of some natural excipients used as Fillers and diluents

Sr no.	Name of Excipients	Sources
1	Microcrystalline cellulose	Plants
2	Lactose	Milk
3	Sucrose	Cane
4	Glucose	Various Fruits
5	Gelatin	Animals

2.1. Cellulose

Microcrystalline cellulose (MCC)

With an average production of 50 billion tons of biomass, cellulose is the most widespread natural polymer on earth. Cellulose comprises of 1, 4 d linear groups of anhydro glucopyranosyl units. Microcrystalline cellulose is partly depolymerized purified cellulose that exists as a smooth white, odourless hygroscopic crystalline powder consists of poor flowing non fibrous materials. It is prepared by processing with alpha cellulose (type Iβ), which is produced as a pulp from fibrous plant material, with mineral acids. The most prevalent origin of pharmaceutical MCC is wood, in which cellulose chains are packed in layers held together by a cross-linking polymer (lignin) and strong hydrogen bonds. Cotton had also been documented as an important source of MCC. It is commonly considered the best binding diluent and is one of the recommended direct compression binder [11]. It is most frequently used as a filler, binder and disintegrant in concentrations of 10-30 percent. Microcrystalline cellulose is sold under the brands of Avicel (FMC Corporation, USA), Emcocel and Vivapur (JRS Pharma GmbH & Co. KG, Germany), Vivacel etc and it is available in various particle sizes and humidity levels.

2.2. Lactose

Lactose is one of the most frequently used diluents in many pharmaceutical formulations (including tablets, capsules and inhalers) due to its low price and biological acceptability. A disaccharide of lactose consisting of d galactose and glucose fragments connected by a 1,4 glyosidic bond is typically isolated from aqueous emulsions (e.g.milk)[12]. Lactose is often used in colour enhancing and flavour producing sugar in food and confectionary. Other beneficial lactose characteristics include elevated physical and chemical strength, low hygroscopicity, excellent compaction characteristics, high water solubility and high compatibility with many active components. The amorphous form of lactose is highly compatible with many active components in direct compression tablets.

3. Disintegrants

Desintegrating agents constitute substances in tablet and certain formulations of rigid capsules used to make it easier for dissolution fluid to penetrate moisture and disperse dosage form. An oral solid form of dosage should ideally be dispersed into the core particles from which it was made of. [13]

Table 3: List of some natural excipients used as disintegrants

Sr no.	Excipients	Sources	Family
1	Gum Karaya	trees of the genus *Sterculia*.	*Sterculiaceae*
2	Guar gum	*Cyamopsis tetragonaloba (L)*	*Leguminosae*
3	Plantago ovata seed mucilage	Plant genus *Plantago*	*Plantaginaceae*
4	Lepidium sativum mucilage	*Lepidium sativum*	*Brassicaceae*
5	Chitin and chitosan	*crab and shrimp shells*.	*Polysaccharide*

3.1. Gum karaya

A dry exudate of *sterculia genus* known as gum karaya is the lowest soluble gums used
in many sectors such as oil and gas, fabrics, paper and pulp, pharmaceuticals, medicine and
Several other goods. Gum karaya is an acid polysaccharide. It is a chemical consisting of galactose sugars, rhamnosis and galactic acid. The high viscosity form of gum reduces its application in the development of conventional dosage form as a binder and disintegrants. Gum karaya was analyzed for its potential as various findings from a tablet disintegration show that a modified gum karaya disintegrated quickly in the tablets. Gum karaya can be used as an alternative super-disintegrant with frequently available artificial and organic super-disintegrants, due to its low price, bio-compatibility and easy availability [14]

3.2. Guar gum

Guar gum is extracted from the seeds of the drought tolerant plant *tetragonoloba cyamopsis*, a member of the *Leguminosae* family. Guar gum is similar to the locust bean gum mainly composed of the complex polymer of galactose and mannose, but the proportions are different. Guar gum is used as a colloid, a binding agent and a disintegrating agent in formulations of pills, in bulk laxatives as a depressing appetite, used in peptic ulcer therapy, reduces blood sugar concentrations in diabetic and serum levels in hyperlipidemia patients. This is a useful emulsion stabilizer [15]. It is not susceptible to tablet matrix pH, moisture content, or solubility. It is not always pristine white and sometimes differs in colour from off-white to tan and tends to discolour in alkaline tablets with time.

4. Lubricants

Lubricants avoid clumping together of components and the adherence to the filling tablet or capsule machine. Lubricants maintain a low friction between the solid and the die necessary to form and eject the tablet. Lubricants improve product flow through reduction of inter-particle friction. There are usually two kinds of lubricants, the first being hydrophilic in nature. Generally, hydrophilic lubricants have limited lubrication characteristics and do not demonstrate characteristics as anti-adherents. The second is hydrophobic in nature. Hydrophobic lubricants are most commonly used in the pharmaceutical industry. They have a good lubrication property; they are also used in small quantities, as anti-adhesives and gliders. some plant derived lubricants are mentioned in table no.4

Table 4: List of some excipients used as natural Lubricants

Sr no.	Name of excipients	Sources
1	Stearic acid	Animals
2	Sodium Stearyl Fumarate	Plants and animal
3	Castor oils	Seeds of castor
4	Sodium chloride	Minerals (sea)
5	Paraffin oil	Paraffin plant

4.1. Stearic acid

Stearic acid is a saturated, waxy, fatty acid obtained from fats and oils from animals or vegetables. Stearic acid generally occurs in nature as a mixed triglyceride, or fat, with other long-chain acids and as a fatty alcohol ester (i.e. coconut oil and cocoa butter). It is much more abundant in fat from animals than in fat, lard and tallow from vegetables. The use of stearic acid and its derivatives, such as magnesium stearate and sodium stearyl fumarates, as lubricants of choice in the production of solid dosage forms is generally considered safe (GRAS) and is used for pharmaceuticals in small amounts (usually less than 5 percent).They enhance the density, adhesivity and flow to powdered mixtures of excipients. Stearic acid has the highest lubrication efficiency, as the surface area rise can provide more covering on the surface. Stearic acid is usually added at around 2.5 % by weight.

4.2. Sodium stearyl fumarate [16]

Sodium stearyl fumarate is an alternative lubricant used in solid-dosage form in contrast to stearic acid. Because sodium stearyl fumarate is often given in a pure form, it can be chosen to avoid chemical incompatibility due to less pure stearate lubricants (stearic acid and magnesium stearate), due to the fact that stearic acid is often supplied as a solid-dose substitute lubricant. In formulations of various APIs, sodium stearyl fumarate is used as a lubricant. It is less hydrophobic and is less retardant in tablet dissolution than magnesium stearate. The lubricant properties of sodium

stearyl fumarate in comparison to magnesium stearate are nearly the same and affect tablet strength and disintegration. Nevertheless, the prolonged mixing increased its lubricating ability and had no effects on the disintegration of the tablets because of the nature of the sodium stearyl fumarate particle size.

5. Preservatives

Preservatives are usually used to maximize the shelf life of several food products and pharmaceuticals. Preservatives are vital to avoid the alteration and degradation of microorganisms during storage, particularly in those with greater water content. Some plant derived preservatives are mentioned in table no.5

Table 5: List of some excipients used as natural preservatives

Sr no.	Name of excipient	Source	Family
1	Clove oil	Buds of Myrtaceae Syzygium	Myrataceae
2	Neem oil	Fruits of Azadira chtaindica	Meliaceae
3	Cumin seeds	Seeds of Cuminum cyminum	Apiaceae
4	Cayenne pepper	Fruits of Piper nigrum	Pipera ceae
5	Turmeric	Roots of Curcuma longa	Zingiberaceae
6	cinnamon	Bark of Cinnamomum verum	Lauraceae

5.1. Clove oil

This plant is contains highest amount of phenolic compounds such as eugenol, eugenol acetate and gallic acid, while ß-pinene, limonene, farnesol, benzaldehydes, 2-Heptanone and ethylhexanoate are other volatile compounds that occur in lower levels in clove oil. Clove is particularly attracted because of the strong antioxidant and antimicrobial activities among the others. Clove essential oil is generally accepted as a safe substance at levels below 1500 mg / kg. The world health organization defined that the appropriate intake of clove per day is 25mg/kg of weight in individuals. Eugenol is easily consumed by oral route that reaches quickly plasma and blood with average half-lives of 14.0 h and 18.3 h, respectively.

5.2. Neem oil

This herb is outstanding because all parts of this plant are medicinal. The seeds, leaves, flowers and bark are all very essential and are used to make herbal medicines. Some popular terms are Nim, Vepa, Margosa plant, Nimbay, Yepa, Indian lilac and Pichumarda and it belongs to the *Meliaceae* family. This medicinal herb is used globally and is widely used to cure colds, chest pain as well as diabetes in some countries such as Jamaica.

6. Conclusion

The objective of this review was to collect knowledge and information about various natural pharmaceutical excipients from natural sources such as plants, microbes, marines, animals, and minerals. In the pharmaceutical, cosmetic and food industries, natural excipients have an significant role to play. They are becoming the best drug delivery systems materials. Natural excipients can also be altered to have modified drug delivery technologies and thus can be able to compete with the artificial excipients commercially available in the market. There is considerable scope for research of new plant-based excipients and could be utilized as a new natural polymer for the growth of different drug delivery system in pharma industry.

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