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Natural Excipients

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ABSTRACT

The use of natural excipients to deliver the bioactive agents has been hampered by the synthetic materials. However advantages offered by these natural excipients are their being non-toxic, less expensive and freely available. The performance of the excipients partly determines the quality of the medicines. The traditional concept of the excipients as any component other than the active substance has undergone a substantial evolution from an inert and cheap vehicle to an essential constituent of the formulation. Excipients are any component other than the active substance intentionally added to formulation of a dosage form. The traditional view that excipients are inert and do not exert any therapeutic or biological action or modify the biological action of the drug substance has changed and it is now recognized that excipients can potentially influence the rate and/or extent of absorption of a drug. As herbal excipients are non toxic and compatible, they have a major role to play in pharmaceutical formulation. Excipients are also sometimes used to bulk up formulations that contain very potent active ingredients, to allow for convenient and accurate dosage. Depending on the route of administration, and form of medication, different excipients may be used.

Keywords: Natural, excipients, functional activities, recent advances

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INTRODUCTION

Excipients were defined as ‘the substance used as a medium for giving a medicament’, that is to say with simply the functions of an inert support of the active principle or principles. [1]

Types of excipients are binders, disintegrants, glidands, lubricants, flouring & coloring agents, sweeteners, fillers, etc.

The advantages of natural excipients over the synthetic one can be listed as: biodegradable, non-toxic, having low cost, environmental friendly, local availability, better patient acceptance, mostly they are from edible sources. On the other hand there are some disadvantages like microbial contamination, batch to batch variation. [2,3]

NATURAL EXCIPIENTS CAN BE CLASSIFIED ON THE BASIS OF SOURCE OF ORIGIN AS FOLLOWS:

<u>Form Animal</u>	<u>From Vegetable</u>	<u>From Mineral</u>
<u>Beeswax</u>	<u>Kokum butter</u>	<u>Bentonite</u>
<u>Gelatin</u>	<u>Starch</u>	<u>Kaolin</u>
<u>Honey</u>	<u>Pectin</u>	<u>Paraffins</u>
<u>Lactose</u>	<u>Peppermint</u>	<u>Talc</u>
<u>Cochineal</u>	<u>Tumeric</u>	<u>Calamine</u>
<u>Lanoline</u>	<u>Cardamon</u>	<u>Fuller's earth</u>
<u>Spermaciti</u>	<u>Saffron</u>	<u>Asbestos</u>

ACACIA:



Biological source of acacia is *Acacia arabica*. Family *Leguminosae*.

1. Functional Category: Emulsifying agent; stabilizing agent; suspending agent; tablet binder; viscosity-increasing agent [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances: Acacia is mainly used in oral and topical pharmaceutical formulations as a suspending and emulsifying agent, often in combination with tragacanth. It is also used in the preparation of pastilles and lozenges, and as a tablet binder, although if used incautiously it can produce tablets with a prolonged disintegration time. Acacia has also been evaluated as a bioadhesive; and has been

used in novel tablet formulations, and modified release tablets. [4] In Anti asthmatic theophylline tablet lozenges instead of sucrose based compressed lozenges for patient suffering from asthma. [5]

Sustained release matrix tablets of diclofenac sodium using natural polymers as release modifier. [6]

ALGINIC ACID:



It is a polyuronic acid composed of reduced mannuronic and glucuronic acids, which are obtained from algal growth of species of family *Phaeophyceae*.

1. Functional Category: Stabilizing agent; suspending agent; sustained release adjuvant; tablet binder; tablet disintegrant; viscosity-increasing agent.[4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

1. In tablet and capsule formulations, alginic acid is used as both a binder and disintegrating agent at concentrations of 1–5% w/w.
2. Alginic acid is widely used as a thickening and suspending agent in a variety of pastes, creams, and gels; and as a stabilizing agent for oil-in-water emulsions. Alginic acid has also been investigated for use in an ocular formulation of carteolol.
3. In combination with an H₂-receptor antagonist, it has also been utilized for the management of gastroesophageal reflux.e.g. cimetidine tablets.
4. In the area of controlled release, the preparation of indomethacin sustained-release microparticles from alginic acid (alginate)–gelatin hydrocolloid coacervate systems has been investigated.
5. In addition, as controlled-release systems for liposome-associated macromolecules, microspheres have been produced encapsulating liposomes coated with alginic acid and poly-L-lysine membranes.
6. Alginate gel beads capable of floating in the gastric cavity have been prepared, the release properties of which were reported to be applicable for sustained release of drugs, and for targeting the gastric mucosa.
7. Alginic acid has also been used to improve the stability of levosimendan.
8. In addition, sodium alginate has been incorporated into an ophthalmic drug delivery system for pilocarpine nitrate. [4, 7]

DEXTRIN:

It is produced by incomplete hydrolysis of starch with dilute acid or by heating dry starch.

1. Functional Category: Stiffening agent; suspending agent; tablet binder; tablet and capsule diluent. [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

Dextrin is a dextrose polymer used as an adhesive and stiffening agent for surgical dressings.

It is also used as a tablet and capsule diluent; as a binder for tablet granulation; as a sugarcoating ingredient that serves as a plasticizer and adhesive; and as a thickening agent for suspensions.

Additionally, dextrin has been used as a source of carbohydrate by people with special dietary requirements because it has low electrolyte content and is free of lactose and sucrose. Dextrin is also used in cosmetics.

Recent advance of dextrin is the colon specific delivery system of dextrin matrix tablet of ibuprofen. [8]

CASTOR OIL:

It is obtained from plant *Ricinus communis* family Euphorbiaceae.

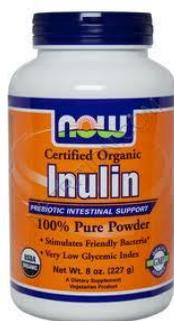
1. Functional Category

Emollient; oleaginous vehicle; solvent [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

Castor oil is widely used in cosmetics, food products, and pharmaceutical formulations. In pharmaceutical formulations, castor oil is most commonly used in topical creams and ointments at concentrations of 5–12.5%. However, it is also used in oral tablet and capsule formulations and as a solvent in intramuscular injections. Therapeutically, castor oil has been administered orally for its laxative action, but such use is now obsolete [9]. Also can be used as solvent for intramuscular injection.

INULIN



It is polysaccharide from bulbs of plant *Inula helenium* family *Compositae*.

1. Functional Category

Diagnostic aid; sweetening agent; tablet binder. [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

Inulin has many potential uses in pharmaceutical applications, as a filler–binder in tablet Formulations;

1. To stabilize therapeutic proteins.
2. To enhance the dissolution of lipophilic drugs e.g. stabilizes delta-(9)-tetrahydrocannabinol (THC). Dextrin helps to dissolve 80% within 3 minutes. Therefore can be administer as sublingual dosage form.
3. Methacrylated inulin hydrogels have been investigated for the development of colon specific drug delivery systems.
4. Inulin is used as a diagnostic agent to measure the glomerular filtration rate.

5. It is used in the food industry as a sweetener and stabilizer; and also as a pro-biotic, where it has been shown to provide protection against inflammatory and malignant colonic diseases in animals.
6. It is also used as a noncaloric dietary fiber supplement. [10-12]

KAOLIN:

Kaolin is a purified native hydrated aluminium silicate free from gritty particles.

1. Functional Category Adsorbent; suspending agent; tablet and capsule diluent. [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

Kaolin is a naturally occurring mineral used in oral and topical pharmaceutical formulations.

In oral medicines, kaolin has been used as a diluent in tablet and capsule formulations; it has also been used as a suspending vehicle. In topical preparations, sterilized kaolin has been used in poultices and as a dusting powder. Therapeutically, kaolin has been used in oral antidiarrheal preparations. [4]

Recent advance related to kaolin, it can be used as suspending agent in injections like ampicillin, cloxacillin. [13]

XANTHAN GUM:

It is produced by pure fermentation of glucose using the bacterium named as *Xanthomonus compestris*.

1. Functional Category

Stabilizing agent; suspending agent; viscosity-increasing agent. [4]

2. Applications in Pharmaceutical Formulation or Technology & Recent Advances:

Xanthan gum can be used as a binder in colon specific drug delivery system. It can be also used as suspending agent for synergistic rheological effect, also used in sustained release tablet e.g. diltiazem HCl & in ophthalmic liquid preparations to prolong retention in precorneal area. [14]

STARCH:



Starch consists of polysaccharide granules obtained from the grains of maize (*Zea mays*), rice (*Oryza sativa*), or wheat (*Triticum aestivum*); belonging to family *Gramineae* or from tubers of potato (*Solanum tuberosum*); family *Solanaceae*. [4]

Recent Advances:

1. Starch treated with nitric acid in addition of dicalcium phosphate used to increase the flow property of starch by increasing crystallinity.[15]
2. Starch citrate is used for developing rapidly dissolving tablet formulation of aceclofenac which is an anti-inflammatory analgesic of BCS class II with poor solubility, dissolution rate & low bioavailability.[16]
3. Acetylation of potato starch with acetic anhydride forming starch acetate can be used for formation of matrix tablet of nifedipine with controlled release over more than 24 hrs. [78]
4. Starch obtained from Moth bean (*Phaseolus acontifolius*) can be used as binder in paracetamol tablets. Compared to potato starch it shows more binding ability in less concentration (2.5-10% w/w). [17]
5. Rajgira starch and carboxymethyl starch (CMS) were evaluated for their efficacy as tablet disintegrant in comparison with rice starch. The highest swelling power of rajgira starch has a marked effect on the tablet disintegration. CMS showed higher swelling power and more



viscous gel. It could also be used as a tablet disintegrant. With this special property, CMS had a potential to be used in drug controlled release dosage forms. [18]

6. Sodium starch glycolate along with kollidon Cl, crosscamellose sodium can be used as superdisintegrant in paracetamol immediate release tablets. [19]

CONCLUSION

The objective of this project was to compile information about various pharmaceutical excipients obtained from natural sources such as plant, animal, and mineral. From the collected information about various natural excipients the advantages of these can be summarized as they are biodegradable, biocompatible, non-toxic, having low cost, better local availability, better patient acceptance.

As these excipients are obtained from natural sources the processes during their manufacturing are environmental friendly and show better tolerance in patients as most of them are obtained from edible sources. Starch is the most widely used natural excipient used in formulation of tablets. Modifications in such can be used to formulate novel delivery system formulations.

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