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AN OVERVIEW ON NATURAL POLYMERS AS EXCIPIENTS IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Natural polymers are generally polysaccharides which are polymeric in nature and are obtained from woody and non woody plant parts such as bark, seeds, sap, roots, rhizomes, fruits, leaves and plant gums. The natural polymers are having wide applications with fewer side effects, biodegradable, enhance bioavailability, economic, easily available and have been used in various dosage forms. The review focuses in the overview of natural polymers, properties, chemical constituents of polymer and their uses in dosage forms as excipients.

KEYWORDS

Biodegradable and Non-biodegradable, Natural, Excipients, Diluents and Disintegrants.

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INTRODUCTION

Polymers

Word polymer is derived from the Greek word 'Poly' means many and Meros means parts which mean "many parts". The polymers are defined as macromolecules composed of one or more chemical units (monomers) they are divided into Natural, semi synthetic and Synthetic basing on their origin.

Natural polymer

Natural polymers or herbal polymers obtained from nature mean they are obtained from plants and animals. Example: starch, protein, cellulose.

Semi synthetic polymer

As the name suggests these are chemically prepared from natural polymers as raw materials Example: silicones, cellulose derivatives, synthetic rubbers, nylon, etc.

Advantages of natural polymer excipients

- These are inexpensive
- Readily and easily available
- Biodegradable and bio compatible
- Inert and Nontoxic
- Free from side effects
- Environment friendly
- Better Patient acceptability
- Local availability

Disadvantages of synthetic polymers as excipients

- Expensive
- Produces toxic and side effects
- Poor bioacceptability and bio compatibility
- Not easy to process
- Not environment friendly
- Release of degradation products
- Loses its mechanical strength on aging
- Skin, Eye irritation and mild inflammatory reactions during handling.

Most of the pharmaceutical excipients used in pharmaceutical industry as binding agents, glidants, lubricants, polishing agents, film formers, coating agents, plasticizers, colouring and suspending agents, preservatives, antioxidants, flavorings, sweeteners, dispersing agents, gums, disintegrants, sustaining agents, protective colloids, thickening agents, gelling agents, bases in suppositories, stabilizer sand coating material.

These excipients contribute to the performance of the API and maintain safety, efficacy of the product. Pharmaceutical excipients are obtained from natural sources or prepared synthetically or manufactured semi synthetically from plant based substances. Pharmaceutical excipients are classified depending on their physicochemical characteristics or their role in the formulation of pharmaceutical dosage forms Excipients are added to ensure that drug should remain as such without any degradation and drug should remain stable till the expiry date of the product[4,5].

The natural substances used as excipients have been derived from various sources.

The polymers used as excipients are majorly of carbohydrate sources.

Proteins and Polypeptides[12,13]

Proteins form the basic part of all the living beings. They are versatile in nature. They can also be used as catalysts. Some proteins act as enzymes and are responsible for various chemical reactions in the human body. Hemoglobin which is a polymer carries the oxygen from lungs to the cells of a human body. Protein polymers have biomaterial applications. Insulin is a polypeptide. Polypeptides are amino acid polymers. Linear polymers and polymeric micelles have been used pharmaceutically. Viva Gel® is an example of a polymeric drug based on a multivalent lysine-dendrimer.

Starch[14]

Starch is prepared from condensation method and is a polymer of glucose monomers .Starch is porous in nature and absorbs moisture. Starch comes under class of carbohydrates and it is found in the cereal potatoes and grains. It is made up of amylopectin and amylose which are the main component of starch in most of the plants. Starch has a larger molecular weight. In different concentrations starch is used as a diluents and a disintegrant. Starch as diluents is sold in the brand name Emdex and Celutab (hydrolysed starch). As a disintegrant it is sold under the name Primogel and Explotab. Directly compressible starch is available as StaRx 100.

Alginates (Sodium Alginate)[15]

Alginates made of alginic acid. It is linear, unbranched and anionic polysaccharide. It is obtained from brown seaweed and marine algae such *as Laminaria hyperborea, Ascophyllum nodosum and Macrocystispyrifera*. Alginic acid is converted into its salts. It consists of two monomers, namely D-mannuronic acid and L-guluronic acid with 1, 4 glycosidic bonds as blocks of homopolymers, heteropolymeric blocks. They have high molecular weights of 20 to 600 kDa.

Alginates serve in drug de-livery, by formulating into alginic gel beads, in liposome formulation, it also modulates GI transit time and in tissue engineering applications. It mainly has an application as a carrier.

Collagen[14]

Collagen is a polymer protein. The connective tissue present in the skin of human beings is made of collagen. From collagen gelatin is prepared by hydrolysis that is used in the formulation of capsule shells in which the medicaments are enclosed. Each strand of collagen has a molecular weight of 10000.

Chitin AndChitosan[16-8]

Chitin is a polysaccharides is obtained from the shells of crawfish, shrimp, lobsters and other crustaceans. It is, insoluble and flexible but hard. Chitin has become an area of research in reusing of waste cloth and plastics. The derivatives of Chitosan are N-trimethyl chitosan, mono-N-carboxymethyl chitosan. The Chitosan derivatives used as absorption enhancers for mucosal drug delivery systems. Water treatment for separating organic compounds and heavy metals, for sewage treatment. Chitin is a combination of sugar and protein. Chitosan is a natural biopolymer prepared by hydrolysing the polysaccharide chitin.

Nucleic acids[5]

Nucleic acids made of various nucleotides. RNA and DNA are common nucleotides.

Guargum[15]

The biological source: endosperm of the seed of *Cyamopsis tetragonolobus.*

Family: Leguminosae. Guar gum is a polysaccharide. It is composed of the sugars galactose and mannose. A linear chain of 1, 4-linked mannose residues consists of the back bone of the polymer to which galactose residues are 1, 6-linked at every second mannose, forming short side branches. Due to its greater solubility it serves as a better emulsifier. It is stable in solution form over pH range 5-7.

Pectin[6]

Pectin is the purified carbohydrate. It is obtained by acid hydrolysis of the rind of citrus peels i.e. *Citrus Simon* or *Citrus Aurantium,* belong s to the family *Rutaceae*. The backbone of this polymer is formed by 1, 4-linked Dgalacturonic acid residues and hundreds of 1,2- linked L-Rhamnose residues building blocks per molecule, It has an average molecular weight of 50,000 to about 1,80,000. The galacturonic acid polysaccharides are rich in neutral sugars such as rhamnose, glucose, arabinose, galactose and xylose

Latex[17]

Latex is a natural polymer obtained from the plant *Ficus elastica belonging to family Moraceae.* It is prepared synthetically or naturally. It can also be prepared by the process of building up long chains of molecules of styrene. Untreated latex is an irritant to the eyes and skin. It is toxic. Different types of rubber like hard and soft rubber, prepared by vulcanization process. Rubber is used as a packing material in pharmaceutical industry for vials and in preparing machinery parts to reduce friction.

Cellulose[6]

Cellulose is easily found natural polymer. It can be obtained from cotton and other plant parts. Modified celluloses are used in osmotic and enteric coated delivery systems. It is used in paper manufacturing using woods of trees. Cellulose forms the supporting structures of the plant. Cellulose is made of monomers of glucose. Ether and ester derivatives of cellulose are excipients that frequently used in pharmaceutical industrialized products. They are most widely used as suspending agents in oral liquid and other extemporaneous preparation, viscosity increasing agents in topical formulations.

Tragacath[18]

Tragacanth is obtained from the branches of Astragalus gummifer belonging to Family *Leguminosae.* Its chemical compositon is 60% - 70% bassor in which is water insoluble. It also contains Tragacanthic acid which is made of D-galacturonic acid, L-fructose, D-galactose, D-xylose and other sugars. Tragacanthin is composed of arabinose and uronic acid which dissolves in water to form a viscous colloidal solution whereas Bassorin component swells to form a thick gel. It is used in the formulation of suspensions and

emulsions. It is also combined with acaia in certain ration in preparing some formulations.

Acacia[10,17,18]

The air dried gummy exudates from the stem and branches of Acacia Senegal Wild. Belongs to Family *Leguminosae*, Sub family *Mimosaceae* and its other species are of African origin. It is also called as Senegal gum. The gum, is produced from tapped trees. The Senegal and Nigerian gums are also of good quality. It is soluble in water leaving and practically insoluble in alcohol and ether. It is also known as Indian gum and it consists of arabin, enzyme oxidase. It is administered intravenously in case of hemolysis. Acaia is used in the pharmaceutical industry as an emulsifier, suspending agent, demulcent, stabilizing agent and viscosity-increasing agent and tablet binder. Used in the preparation of pastilles and lozenges aliong with gelatin used in microencapsulation.

Okrogum

It is used as a binder for pharmaceutical tablet formulation[17,18].

Dextran[19]

Dextran is a carbohydrate and a polysaccharide with the formula $(C6H10O6)_n$ and has a positive optical rotation. It has a molecular weights ≥1,000 Dalton, It has a α-linked d-glucopyranosyl repeating units. It is used in the injection formulations. Dextran used as isotonicity adjusting agents along with salt solutions. Dextran is a biodegradable neutral bacterial exopolysaccharide

Ghatti[17]

It is a gummy exudates obtained from *Anogessius latifolia Wallich (bark)*, family *Combretaceae*. Gum ghatti is very good emulsifier, thickener and stabilizer used in pharmaceutical, industry. It is an efficient binder for the compressing tablets when compared with acacia gum and starch paste. Because of its stability in oil in water emulsion it is used in oil soluble vitamin formulations. Gum is edible and used in calico printing and in confectionery. It is good stabilizer for ice cream in 0.5% concentration. It forms as table oil in water emulsion hence used in the formulation of oil soluble vitamin preparations.

Carrageenan[6]

It is composed of a sulphated polysccharide. It is obtained from the Irish moss (seaweed), the red algae *Chondrus crispus Linn.* Belonging to family *Gigartinaceae,* class *Rhodophyceae*.

Carrageenan is used as

- Stabilizing agent,
- Solubilizing agent,
- Emulsifying agent and
- Viscosity builder in food products.
- Tooth paste,
- In cosmetic products like creams, lotions
- It is utilized in milk products, ice creams and gels in the concentration (0.5-1%).
- Carrageenan is used as a phlogistic agent for inducing inflammation in the rat paw oedema model for the study of anti-inflammatory activity.

Laminarin[20,21]

The molecule of laminar in consists of storage glucan which is a polysaccharide of glucose obtained from brown algae. It is used to enhance its biological activity and in cancer therapies, tissue engineering, antioxidant drug, gene delivery and anti-inflammatory functions.

Examples

S.No	Animal	Vegetable	Mineral
1	Beeswax	Agar	Asbestos
2	Cantheride	Cardamom	Bentonite
3	Cochineal	Guargum	Calamine
4	Gelatin	Kokum butter	Chalk
5	Honey	Orange oil	Fullers earth
6	Lactose	Pectin	Kaolin
7	Lanolin	Saffron	Keisulghur
8	Lard	vanilla	Paraffins
9	Musk	Starch	Shilajit
10	Shellac	Turmeric	Talc

The source of excipients and their uses are as follows[6-11]

S.No	Plant sources	Uses as excipients	Animal sources	Uses as excepients
1	Acacia	Binder, Diluent	Carrageen an	suspending and gelling agent Diluent, Thickening properties Stabilizing properties Binding property
2	Aloe mucilage	Stimulating Purgatives Emollient, Stimulant, Stomachic, Tonic	Chitosan	used as a filler
3	Amylose	Stabilizer and Thickener	laminar in	Non-ionic emulsionable wax
4	Arabinogalactose	Stabilizer, Binder and Sweetener	Gelatin	Carrier, coating, separating agent, Binder, diluent
5	Cellulose	Diluent, Thickening Properties Stabilizing Properties	Honey	Sweetner, antiaging, antiseptic
7	Dextrin	Removable Adhesives, Adhesives	Alginates	Diluent, thickening, stabilizers in emulsions, suspending agents, tablet binders and tablet disintegrants
8	Ghatti	Emulsifier, Stabilizer	Collagen	Preparation of sutures, as a gel in food casings and in photographic emulsions.
9	Guargum	Thickening, Stabilizing	Agar	Suspending agent, emulsifying agent, gelling agent tablet disintegrant medium for bacterial culture Thickener, laxative, appetite suppressant
10	Inulin	Stabilizing and Adjuvant	Chitin	Bacteriostatic, immunologic, antitumoral, hemostatic and anticoagulant
11	Karaya gum	Bulk Laxative, Adhesive for Dental Fixtures and Ostomy Equipment and as a Base for Salicylic Acid Patches. Lozenges to Relieve Sore Throat. Carrier For Drugs, In Pharma Industry, Emulsifier,	Laminar in	Abortificient

		Thickener and Stabilizer. Paper and Textile Industries.		
12	Latex from rubber tree	Packaging Material	Wool	filtering aid and straining medium
13	Okra	Binder		
14	Pectin	Hydrophilic Polymeric Material in CR Products, Binder, Diluents, Thickening, Stabilizing		
15	Starch	Binder, Diluent		
16	Tamarind gum	Gentle Laxative due To Osmosis, Acid Refrigerant		
17	Tragacath	Binder Diluents, Suspending Agent, Thickening Agent and Emulsifier		
18	Xanthan	Stabilizer and Suspending Agent, Viscosity Controller In Abrasives And Adhesives, Gelling Agent In Explosives.		
19	locust gum	Super Disintegrant		

CONCLUSION

Herbal formulations include extracts, tinctures, expressed juices and exudates. Since, these are used as excipients they are natural in origin hence possess less side effects and are compatible with other excipients as they are inert and nontoxic. Gelatinized starches, microcrystalline cellulose, modified celluloses are used as disintegrants whereas Fenugreek mucilage, locust beans, Isapghula husk are used as super disintegrants. Natural polymers like Acaia, tragacanth, pre gelatinized starch which are polysaccharide in nature are used as binders. These natural polymers are used in food and pharmaceutical industry as excipients have low toxicity and are biodegradable and highly available at low cost. They can also be used as vehicles and able to show precision and accuracy of dosage and also improve organoleptic properties.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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