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Natural Polymer: An Approach for the Formulations Used as Pharmaceutical Excipient

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Research Article

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ABSTRACT

Nature is blessed with numerous varieties of polymers. When two or more than two small molecule combines together they form large molecule. The process that is called as polymer synthesis is the process in which large molecule is composed of small molecule that are attached together in a monomeric unit to form the larger forms. The common example of this synthesis includes the formation of starch molecules by the combination of various glucose units. Cellulose is the most abundant organic compound. Its natural form is cotton and is obtain from the woolly parts of trees. Polysaccharide chitin is similar to cellulose. It is present in the cell walls of fungi and is the fundamental substance in the exoskeletons of crustaceans, insects and spiders. Gums are used as a pathological product. They are formed by injuring plant parts or under the un favorable condition such as drought, by break down of cell walls.

INTRODUCTION

Gums readily dissolve in water. Mucilage is generally normal products formed by the metabolism (Physiological product) within the cell (intracellular formation). Mucilage dissolve in water formed slimy masses. Both gums and mucilage's are plant hydrocolloids yielding mixture of sugars [1-3]. Hydrogels are used as a polymer. Hydrogel absorb or retain large amount of water.

Pectin is one of the major constituents of citrus by products and has good gelling properties. Pectin is an excellent carbohydrate polymer derived from mainly natural resources and it is the structural component of plant cell wall.

Pectin has unique gel forming ability in presence of divalent cation which makes it an ideal carrier for delivering bioactive agents [4].

MATERIALS AND METHODS

Formulations based on natural polymers

Microsphere: Microspheres are mainly free flowing powders. These consist of proteins or synthetic polymers, which are biodegradable in nature having the particle size is less than 200 µm. These are used for drug targeting. They play an important role in sustained and controlled release of drug [5]. Different natural polymers used in the formulation of microsphere.

Nanoparticles: Nanoparticles are the solid particles having the size range of 10-1000 nm. Polymer used in the nanoparticles formation must be biocompatible or biodegradable. Nanoparticles are used as a carrier system for novel drug delivery. Nanoparticles are used as a particular drug delivery system. Nanoparticles have been used to improve the pharmacokinetic or pharmacodynamic properties of various types of drug molecules. Carrier nanoparticles show desirable pharmaceutical or medical field result. Nanoparticles are used for controlled and sustained release drug delivery system. Nanoparticles surface is playing a key role in drug targeting. Hydrophobic polymer is mainly used for surface modification of the nanoparticles this is done by coating it with a polymer such as Poly Ethylene glycol PEG or biodegradable polymer poly (Lactic acid) and poly (Lactic-co-glycolic acid) thus hydrophilic PEG chains allows to control the protein and peptide absorption, in addition it will allows the regulation of cell behaviour on the polymer surface[6].

Pharmaceutical application: Mucilages are most commonly used as adjuvant in Pharmaceutical preparations. Mucilages and gum are mainly used in formulation of suspensions and emulsions. Plant mucilages and gums are Pharmaceutically important polysaccharide with wide range of applications such as thickening, binding, disintegrating, suspending, emulsifying, stabilizing, and gelling agents. Gums may be used as sustained and controlled release formulations.

Binding agent: Different mucilages have been used as binding agent in pharmaceutical formulations. Mucilage has good binding properties as compared to many synthetic compounds. Binding property of mucilage was used to determine the ability of mucilage as pharmaceutical excipient in different research papers. Generally binding and granulating properties are determined with each other in single step. Mucilages from *Aspargus recemosus* and *Cassia sophera* were evaluated as binding agents in tablet formulations and these mucilages were found to be suitable binders for uncoated tablets as compared to starch [6]. Evaluation of *Chlorophytum borivilianum* mucilage as pharmaceutical excipient shows that it can be used as suspending agent as compared to tragacanth and also found to be effective binder [7-10]. *Plantago ovata* and *Trigonella foenum graecum mucilages* have evaluated for binding property in tablet formulation and they show comparable disintegration, hardness and release data as starch. Evaluation of *Delonix regia* endospermic mucilage as tablet binder using calcium carbonate tablets for general appearance, hardness, friability and disintegration shows that this mucilage can be used as a good binder. Seed mucilage of *Vigna mungo* (L.) have been evaluated as a binder in tablet formulations and showed good binding properties. Gum mucilages of *Cissus populnea* and *Acassia senegal* were evaluated for their binding properties using paracetamol tablets and show good binding properties. The seed mucilage of *Caesalpinia*

pulcherrima has been successfully evaluated for their granulating and binding properties in tablets, using diclofenac sodium as model drug. The mucilage which was isolated from mice would be non-toxic when it was evaluated for acute toxicity (LD50>5 gm/kg body weight) [11].

Evaluation of *Cassia angustifolia* seed mucilage using Diltiazem HCl as model drug showed that it has good granulating and binding properties. Mucilage isolated from *Zizyphus jujuba lamk* seed have been used to prepare tablet formulation and further evaluated for their binding properties [12]. In one study mucilage was isolated from seeds of *Prosopis juliflora (Mimosaceae)* and further used to evaluate its binding properties in tablet formulation using diclofenac sodium as model drug. The result determined that the granules prepared using mucilage having excellent flow property and tablets prepared using 8% and 10% of mucilage shows drug release over a period of 5h. Mucilage extracted from *Plantago psyllium* seeds has been evaluated for its inertness and safety parameters; further binding properties of tablets were assessed using paracetamol as model drug. In one study mucilage was isolated from the seeds of *Caesalpinia pulcherrima (Euphorbiaceae)* and further evaluated for their granulating and binding properties in tablets, using diclofenac sodium as model drug. Results showed that *Caesalpinia pulcherrima* mucilage has excellent binding property and could be used as a binder in conventional tablet formulation. Mucilage extracted from seeds of *Cassia auriculata* have been successfully evaluated for their binding properties. Seed mucilage extracted from *Cassia fistula Linn* has been evaluated for their binding properties in tablet formulation using diltiazem HCl as model drug. It was observed that increasing the concentration of mucilage increases hardness and decreases the disintegration time in tablets formulation [13].

Gelling agent

Gels are specific Pharmaceutical formulation, which are generally applied externally. They are used either topically on the external skin for the control of pain. But when they are applied to body cavity, have specific purpose such as improvement of bioavailability, control of side effects and drug targeting. The nasal route of administration, has received a great deal of attention in recent years as a convenient and reliable method not only for local but also for systemic administration of drugs. The nasal cavity offers a number of unique advantages such as easy accessibility, good permeability especially for lipophilic, low molecular weight drugs, and avoidance of harsh environmental conditions and hepatic first pass metabolism. It has a potential for direct delivery to the brain, and it provides direct contact of vaccines with lymphatic tissue and act as inducer as well as effectors of the mucosal immune system. Highly swellable mucoadhesive gels exhibiting mucoadhesive behaviour could be extremely useful in nasal delivery applications. Mucoadhesive agents in their molecular form make intimate contact with mucin of mucosa and then make adhesion with the nasal membrane and finally the mucoadhesive carriers allow the release of drug through nasal membrane in a continuous fashion. Many plants contain mucilages, which provide high concentration of complex sugars. When solutions of polysaccharides (hydrophilic polymer) are mixed, they interact with each other; this can result in an increase in viscosity, which becomes greater than the viscosity of each solution individually. Under certain conditions, they may even form a gel. Such a phenomenon is often called as rheology synergism. When these mucilage are mixed with water, a protective and soothing preparation results, which can be applied externally. Mucilage of various plants has been used as gelling agent due to its non-toxicity, low cost, free availability, emollient and non-irritating nature. The mucoadhesive strength and viscosity of mucilages are generally found to be higher in comparison to the synthetic polymers, namely Hydroxy Propyl Methyl Cellulose (HPMC) and

carbopol, which are conventionally used for a similar purpose. A revolutionized formulation of oxytocin nasal gel using natural mucoadhesive agent obtained from the fruits of *Dellinia indica. L.* has been already prepared [14,15]. *Trigonella foenum graceum L*. has been used to prepare intra nasal gel using diazepam as model drug. *In vitro* release of ketoprofen from proprietary and extemporaneously manufactured gels has been studied at Rhodes University, Grahamstown. A water soluble chitosan gel was also prepared for skin hydration and it was characterized and evaluated at Sains University, Malaysia. In the same context Shah and Donovan, at University of Iowa studied bio adhesive gels for extended intranasal residence time and optimization of formulation was carried out. *Sesbania* seed mucilage has been evaluated for its gelling properties. *Anacardium occidentale* mucilage may be used as gelling agent for topical delivery of non-steroidal anti-inflammatory drugs [16].

So different studies are able to demonstrate that mucilage can be a good substitute of synthetic gelling agents; due to their good release profile, water-soluble nature, physical stability and spreadibility.

In one study mucilage extracted from *Alyssum homolocarpum* seed was evaluated for rheological properties. Results obtained showed that extracted mucilage can be used as thickening agent in different formulations. Mucilage obtained from leaf of *Cocculus hirsutus* has been used to prepare gel of flurbiprofen. Study showed that leaf mucilage can be used as base for gel preparation [17].

RESULTS AND DISCUSSION

Suspending agent

Suspensions have a number of applications in Pharmaceuticals. They are used to supply drugs to the patients in liquid dosage form. If drug is insoluble or poorly soluble, a suspension may be the most suitable dosage form. To improve the stability of this type of formulations, different types of suspending agents are used. Suspending agents may be natural, semi-synthetic and synthetic in nature. Mucilages are used primarily to aid in suspending insoluble substances in liquid formulations; their colloidal character and viscous nature prevent immediate sedimentation. This should be considered that all mucilages are prone to decomposition, showing appreciable decrease in viscosity on storage. Mucilages are cheap and effective natural excipients that can be used as an effective alternative for the formulation of pharmaceutical suspensions. Due to their higher viscosity, mucilages can be a stabilizer of choice in a suspension. Suspending property of mucilages are comparable to different gums, which have been already used in pharmaceutical preparations. *Cassia tora* mucilage have been evaluated for its suspending properties and showed better result than compound tragancth gum, *acacia* gum and gelatin [18-20]. Evaluation of *Chlorophytum borivilianum* mucilage using zinc oxide suspension showed good suspending properties has and can be used to prepare pharmaceutical suspension [21]. *Abelmoschus esculentus* mucilage also showed good suspending properties when evaluated in paracetamol suspension.

Disintegrant

Disintegrant are substances or group of substances added to the formulations that facilitate the disintegration of tablets into smaller particles that dissolve more rapidly than in the absence of disintegrants. Disintegrant have the major function to oppose the efficiency of tablet binder and physical forces that act under compression to form the tablets. Tablet disintegration has been considered as the rate limiting step in faster drug release. Disintegrants are

substances that are added to formulations to dissolve more rapidly in aqueous environment. Mucilages have been used as disintegrants due to their swelling properties. They can display good binding property; both of these properties depend upon the concentration of mucilage in formulation. Generally in the 1 to 10% concentration of total tablet weight mucilages can act as binder and above it they act as disintegrant. This is an important parameter to determine the application of mucilage in particular formulation. Mucilages are used as disintegrant in solid pharmaceutical formulations. Many of them are already evaluated for its disintegrant properties and others are in process. *Plantago ovata* mucilage has been evaluated for their disintegrant and superdisintegrant properties Seed mucilage of *Ocimum gratissimum, Ocimum americanum* and *Salicornia fruticosa* have been used as disintegrant in solid formulations. Studies showed that mucilage obtained from leaves of *Hibusccus rosasinensis* can be successfully used as superdisintegrant in tablet formulation. It was also found that the mucilage extracted is devoid of toxicity.

Seed mucilage of *Lepidium sativum (Cruciferae)* was used to prepare fast disintegrating tablets and formulated tablets were compared with tablets prepared using synthetic disintegrant such as sodium starch glycolate, kyron-T314 and acdisol. The results showed that disintegration and mean dissolution time for batch containing 10% mucilage was better than other tablets prepared using different synthetic disintegrating agent [22].

Sustained release polymer

Among various dosage forms, matrix tablets are widely accepted for oral sustained release as they are simple and easy to formulate. Matrix system is the specific type of release system, which prolongs and controls the release of drug that is dissolved or dispersed. Making drug-embedded matrix tablets through the direct compression of a blend of drug, retardant material, and additives is one of the simplest formulation approaches. The inclusion of polymeric materials in a matrix system is a common method of modulating drug release. Various natural gums and mucilages have been examined as polymer for sustained release formulations. The use of natural polymers and their semi-synthetic derivative in drug delivery continues to be an area of active research. Drug-release retarding polymers are the key performers in matrix systems. Various polymers have been investigated as drug retarding agents, each presenting a different approach to the matrix system. Based on the features of the retarding polymer, matrix systems are usually classified into three main groups: hydrophilic, hydrophobic, and plastic. Hydrophilic polymers are the most suitable for retarding drug release, and there is growing interest in using these polymers in sustained drug delivery [23]. Mucilage from *Aloe barbadensis* Miller have been used as a pharmaceutical excipient for sustained release matrix tablets. Results showed that the dried *Abelmoschus esculentus* fruit mucilage can be used as a matrix forming material for controlled release matrix tablets. Cactus mucilage has been used to prepare an edible coating in Pharmaceutical formulation.

In one study buccal discs of fluconazole were prepared using *Mimosa pudica* seed mucilage as bucoadhesive polymer. Results easily predict the fact that mucilage has sufficient bucoadhesive strength and have characteristics to be used as bucoadhesive polymer. Matrix moderated transdermal systems of diltiazem HCl have been prepared using various proportions of *Ficus reticulata* fruit mucilage. Results easily predict the fact that this fruit mucilage has sufficient properties to prepare transdermal system [24].

In recent years, plant derived polymers have evoked tremendous interest due to their diverse Pharmaceutical applications such as diluent, binder, disintegrant in tablets, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels and bases in suppository. These polymers are biocompatible, cheap and easily available. Natural gums and mucilage are well known for their medicinal use. They are widely used in the

pharmaceutical industry as thickeners, water-retention agents, emulsion stabilizers, gelling agents, suspending agents, binders, film formers, and sustained-release agents. They are also used in cosmetics, textiles, paints, and paper-making. Demand for these substances is increasing, and new sources are being developed. India, because of its geographical and environmental position, has traditionally been a good source for such products among the Asian countries. Still, large quantities are imported from Europe to meet increasing demand. Natural gums and mucilage are preferred to semi synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action, and nonirritant nature (Table 1) [25-28].

Table 1. Natural polymers used in formulation of microsphere.

S. No.	Drug	Polymer	Formulation	Referene
1	Ofloxacin	Natural gelatin	Microsphere	[9]
2	Ornidazole	Chitosan	Microsphere	[10]
3	Indomethacin	Egg albumin, ethyl cellulose	Microsphere	[11]
4	Famotidine, Aspirin,Zidovudine, Diclofenac potassium	Ethyl cellulose	Microsphere	[12]
5	Phenobarbitone	Casein-chitosan	Microsphere	[13]
6	Azido dioxithymidine	Olibanum gum	Microsphere	[14]
7	Losartan potassium , Theophylline	Sodium alginate	Microsphere	[15]
8	Ofoxacin	Sodium alginate, gelatine, chitosan	Microsphere	[16]
9	Lamivudine	Moi gum	Microsphere	[17]
10	Indomethacin	Polyacrylamide-grafted-chitosan	Microsphere	[18]
11	Dexamethasone	Albumin	Microsphere	[19]
12	Diflunisal	Eudragit-100	Microsphere	[20]
13	Meclofenamate	Cellulose propionate	Microsphere	[21]
14	Naproxen	Albumin, PGA	Microsphere	[22]
15	Mesobuthus eupeus, Trimidazone	Chitosan	Microsphere	[23,24]
16	Curcumin	Guar gum, xanthan gum	Microsphere	[25]
17	Indomethacin	Egg albumin, Eudragit	Microsphere	[26]
18	Metformin	Hydroxypropyl methylcellulose, Chitosan	Microsphere	[27]
19	Norfloxacin	Carbopol	Microsphere	[28]

CONCLUSION

Natural polymers play a vital role in the preparation of pharmaceutical formulation .Gums and mucilage's have proved to be promising biodegradable polymeric materials .In food industry, pharmaceuticals ,cosmetic products many studies have been conducted which proves them to be advantageous, less toxic and economical in comparison with the synthetic materials. Microspheres, nanoparticles, ocular insert, transdermal, implants and

other drug delivery system prepared by natural polymers. Now a day's natural polymer are mostly used in the novel drug delivery systems.

CONFLICT OF INTEREST

Author has no Conflict of interest.

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