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Review Article

AN OVERVIEW ON NATURAL POLYMERS AS PHARMACEUTICAL EXCIPIENT

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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. Excipients are any component other than the active substances intentionally added to formulation of a dosage form Research in natural polymers has witnessed growing interest and attention. This is attributable to a number of factors which include their relative abundance, low cost, and biodegrable and eco-firendly profiles. Natural polymers are basically polysaccharides so they are biocompatible and without any side effects. This review discusses various natural polymers.

KEY WORDS: Non-toxic, Less expensive, Eco-Friendly.

INTRODUCTION

A polymer is a large molecule (macromolecules) composed of repeating structural units. These subunits are typically connected by covalent chemical bonds. Both synthetic and natural polymers are available but the use of natural polymers for pharmaceutical applications is attractive because they are economica, readily available and non-toxic. They are capable of chemical modifications, potentially biodegradable and with few exceptions, also biocompatible.1 Substances of plant origin pose several potential challenges such as being synthesized in small quantities and in mixtures that are structurally complex, which may differ according to the location of the plants as well as other variables such as the season. This may result in a slow and expensive isolation and purification process. Another issue that has become increasingly important is that of intellectual property rights.[1] today we have several pharmaceutical excipients of plant origin, like starch, agar, alginates, carrageenan, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose. These natural excipients find applications in the pharmaceutical industry as binding agents, disintegrates, sustaining agents, protective's, colloids, thickening agents, gelling agents, bases in suppositories, stabilizers, and coating materials. Classification of excipients is based on their role in

the pharmaceutical formulation, their interactions influencing drug delivery, or their chemical and physico-chemical properties. 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. To stabilize the active ingredient, excipients are added, ensuring that the active ingredient stays "active", and, just as importantly, stable for a sufficiently long period of time that the shelf-life of the product makes it competitive with other products.

CLASSIFICATION OF NATURAL POLYMERS[2]

Plant origin - Cellulose, Hemicellulose, Glucomannan, Agar, Starch, Pectin, Inulin, Rosin, Guar gum, Locust bean Gum, Gum Acacia, Karaya gum, GumTragacanth, Aloe Vera gel.

Animal origin - Chitin, Alginates, Carageenans, Psyllium, Xanthum gum.

ISOLATION AND PURIFICATION OF GUMS

Gums can be extracted from plant parts by various methods like heating, solvent precipitation, and microwave assisted extraction. The easiest method is solvent precipitation. In this method the part of the plant containing gum/mucilage is selected followed by drying, grinding, and sieving of that plant part. This is then stirred in distilled water and heated for complete dispersion in distilled water and kept for 6–8 heat room temperatures. The supernatant is obtained by centrifugation. The residue is then washed with water and the washings are added to the separated supernatant. Solvent for precipitation is selected and, finally, the supernatant is mixed with twice the volume of precipitating solvent by continuous stirring. The precipitated material is washed with distilled water and dried at 50–60^{0}C under vacuum. Plant material must be treated with petroleum ether and chloroform (to remove pigments and chlorophyll) and then with distilled water.

CHARACTERIZATION OF GUMS[3]

Preliminary confirmatory tests for dried gums are summarized in Table 1 for characterization; analytical techniques can be classified according to the type of information generated.

Table no 1. Preliminary tests for dried gums and mucilages

Test	Observation	Inferences
Molisch's test: (100 mg dried mucilage powder + Molisch's reagent + conc. H_2SO_4 on the side of a test tube)	Violet green colour observed at the junction of the two layers	Carbohydrate present
Ruthenium test: Take a small quantity of dried mucilage powder, mount it on a slide with ruthenium red solution, and observe it under microscope.	Pink colour develops	Mucilage present
Iodine test: 100 mg dried mucilage powder + 1 mL 0.2 N iodine soln.	No colour observed in solution	Polysaccharides present (starch is absent)

STRUCTURAL

Gums and mucilages are polysaccharides and they contain sugars. So, confirmation of different sugars present can be done by chromatography (TLC/HPLC) and structure elucidation can be carried out by FTIR, mass, and NMR spectroscopy.

PURITY

To determine the purity of the selected gums, tests for alkaloids, glycosides, steroids, carbohydrates, flavonoids, terpenes, amino acids, saponins, oils and fats, and tannins and phenols are carried out.

IMPURITY PROFILE

Suitable analytical techniques can be used for testing of impurities.

PHYSICOCHEMICAL PROPERTIES

Color, odour, taste, shape, texture, touch, solubility, pH, swelling index, loss on drying, hygroscopic nature, angle of repose, bulk and true densities, porosity, and surface tension can be estimated.Themicrobial load and presence of specific pathogens are also determined. Gums are highly

viscous in nature. So, the rheological properties of excipients are important criteria for deciding their commercial use.

TOXICITY

The acute toxicity of gums are determined by fixed-dose method as per OECD guideline no. 425.

NATURAL POLYMERS FROM PLANT ORIGIN[4]

XANTHAN GUM

This gum is produced by a pure-culture fermentation of a carbohydrate with Xanthomonas campestris and purified. It is also known as Corn sugar gum. It is the sodium, potassium or calcium salt of a high molecular weight polysaccharide containing D-glucose, D-mannose and D-glucuronic acid. It also contains not less that 1.5% of pyruvic acid. It is a cream coloured powder, soluble in hot and cold water and neutral to litmus. A 1% solution has viscosity of about 1000 centipoises. Solutions of xanthan gum demonstrate maximum stability at pH value between 4 and 10. Compared with tragacanth, xanthan gum was found to be easier to use and capable of preparing suspensions of better quality and improved consistency. Xanthan gum is used as a stabilizer, thickener and emulsifier extensively in pharmaceutical, cosmetic industries and in food industry for dairy products. The pseudo plastic properties of this gum enable toothpastes and ointments both to hold their shape and to spread readily. The stability was generally good and only a small number of drugs had been found to be incompatible (Amitriptyline, Tamoxifen and Verapamil). For extemporaneous dispensing, a 1% solution of xanthan gum with hydroxy benzoate, prepared in advance, was diluted to 0.5% with water when preparing the suspension. Xanthan gum was found to be suitable suspending vehicle for delivering antispasmodics topically along the length of the oesophagus in patients with oesophageal spasm. Coagulation of the gum had been observed when it was used for suspension of certain film coated tablets. In a recent study the sedimentation volume of suspension with carboxy methyl cellulose and xanthan gum for period of 45 days. Results indicated that xanthan gum in a concentration of 0.2% is superior to carboxy methyl cellulose.

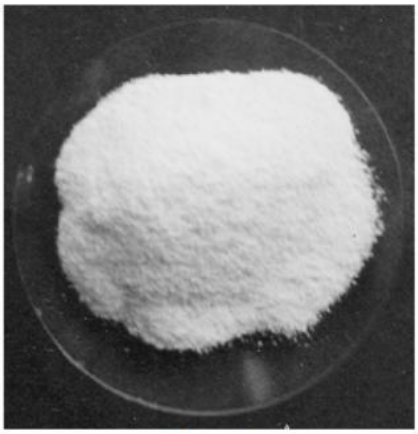
ACACIA

The air dried gummy exudates from the stem and branches of Acacia senegal Willd. (Family Mimosaceae) and other species of Acacia of African origin. It also known as Senegal gum. The tree is known in Kordofan as ‘Hashab’ and in Senegambia as ‘Verek’. The gum, produced in kordofan from tapped trees is considered to be good. The Senegal and Nigerian gum is also of good quality. The Senegal gum is available in the desert areas of India like Rajasthan, Gujarat and Haryana. It is soluble in water leaving only a very small residue of vegetable particles, whereas practically insoluble in alcohol and ether. Acacia is used as a suspending and emulsifying agent and as a tablet binder. Its demulcent properties are employed in various cough, diarrhoea and throat preparations. The principal use of gum Arabic is in confectionery as an emulsifier, for preserving flavours of soft drinks and also in the manufacture of chewing gums. It is used in the pharmaceutical industry as binding agent in the manufacture of cough pastilles and other medical preparations or as a coating for pills. The gum is also used for hair set and as a suspending agent.

Acacia gum

AGAR[5]

Agar (or) Agar-Agar, also known as Japanese Isinglass, Chinese-Isinglass or Vegetable Gelatin. It is the dried, hydrophilic and phycocolloidal concentrate from a decoction of various marine red algae, particularly species of Gelidium (Gelidaceae), Pterocladi (Gelidaceae), order Gelidiales and Gracilaria (Gracilariaceae). The dried Agar-Agar usually occurs in bundles comprising thin, membranous, agglutinated strips; or in cut, flaked or granulated forms. It may be week yellowish orange, yellowish grey to pale yellow or colourless. It is tough when damp, brittle when dry, odourless or with a slight odour and has mucilaginous taste. The Agar-Agar is insoluble in cold water, but soluble in boiling water. Agar contains two different polysaccharides named as agarose and agaropectin. Agarose is responsible for gel strength of agar and composed of D-galactose and 3,6-anhydro- L-galactose units. It contains about 3.5% cellulose and 6% of nitrogen containing substance. Agaropectin is responsible for the viscosity of agar solutions. It is believed to be a sulphonated polysaccharide in which galactose and uronic acid units are partly esterified with sulphuric acid. Agar is used as emulsifying, suspending, stabilizing, thickening or gelling agent and bulk laxative. It is also used in the preparation of jellies, confectionery items, tissue culture studies and in microbiology.



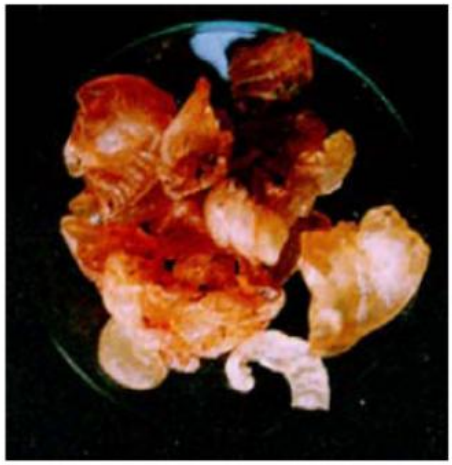
Agar-Agar

CARRAGENAN

Carrageenan is the hydrocolloid obtained from red seaweeds by extraction with water or aqueous alkali and recovered by alcoholic precipitation, drum drying or freezing (Class Rhodophyceae). It consists of a mixture of the ammonium, calcium, magnesium, potassium and sodium sulphate esters of galactose and 3,6-anhydro-galactose copolymers. About 30ml water is required to dissolve 1g of it at temperature 80°C. It is widely used as dissolution rate retarding polymer in sustained release dosage form in many pharmaceutical industries. Solution of carrageenan (1%) was also used to induce inflammation (Paw oedema) for screening of anti-inflammatory activity.6 Carrageenan is used in pharmacy and food industry as a suspending and gelling agent. Tooth paste, creams, lotions and other cosmetic products are also prepared by using carrageenan. In food industry, it is utilized in milk products, ice creams, chocolate, jams and gels in the concentration of 0.5-1%.

STERCULIA GUM

It is the dried gummy exudate obtained from the tree Sterculia urens Roxb. (Family − Sterculiaceae). It is also known as Sterculia, Karaya, Indian Tragacanth or Bassora Tragacanth gum. It is produced in India, Pakistan and to a small extent in Africa. Karaya also differs from tragacanth in that it contains no starch and stains pink with solution of ruthenium red. It has low water solubility but swells to many times its original volume. Acetylated, branched heteropolysaccharide with a high component of D-galacturonic acid and D-glucuronic acid residues. The granular grades are used as a bulk laxative, being only next to psyllium seed in use for this purpose. The powdered gum is used in lozenges, pastes and dental fixative powders and it has proved particularly useful as an adhesive for stoma appliances. It also acts as stimulant. It is available, with frangula, as granules. The cross linked Tragacanth (Epichlorhydrin) exhibits superior wicking and swelling action and hence can be used as a potential disintegrant.8



Sterculia gum

GELATIN

Gelatin is a product obtained by partial hydrolysis of collagen derived from skin, white connective tissue and bones of animals. The process converts insoluble collagens into soluble gelatin, the solution of which is then purified and concentrated to a solid form. It is soluble in a hot mixture of glycerol and water and in 6N acetic acid, whereas it is practically insoluble in alcohol, chloroform, fixed oils, volatile oils and ether. Gelatin is used in the preparation of pastes, pastilles, suppositories, coating of tablets and manufacturing of hard and soft capsule shells. It is also used for the microencapsulation of drugs and other industrial materials. Specially purified and pyrogen free gelatins are available for intravenous injection and a grade with big 'Bloom strength' is used for making

gelatin capsules and for bacteriological culture media.

Gelatin

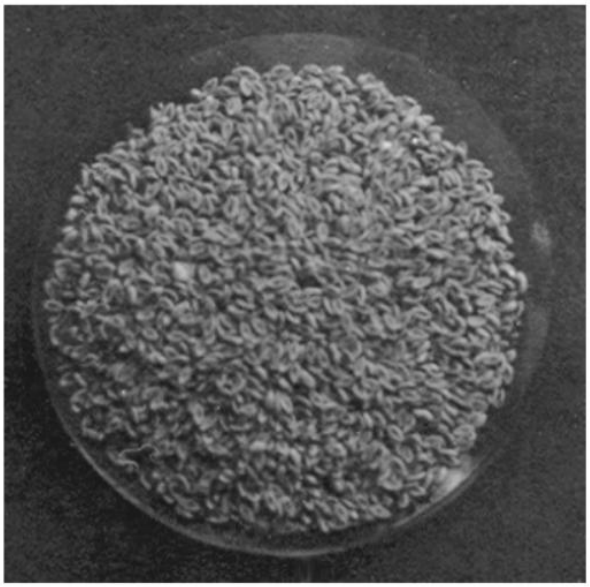
CHITOSAN

Chitosan is a natural polymer obtained by deacetylation of chitin. It is present in shell fish. Chitosan is a linear polymer of β(1-4) linked 2-amino-2-deoxy-D-glucopyranose. Chitin is isolated from the exoskeleton of crustaceans such as crabs, krill and shrimps. It gives no reactions for cellulose or lignin. When heated with 50% potash at 160-170° C for one hour, it is converted into chitosan, C H O N , ammonia and acids such as acetic and oxalic. Chitosan with a concentration of 1.25% in dilute acetic acid has very high viscosity, i.e., 120 cps. Its molecular weight is 1,43,000 to 2,10,000. It is a cationic polysaccharide and contains approximately 6.5% of nitrogen. Chitosan is a novel drug carrier material and it improves the dissolution rate of controlled release matrix tablets. The additional uses of chitosan are as coating agent, gel former, and to induce desirable properties such as mucoadhesion and permeation enhancement to improve oral bioavailability of a drug. Microcapsules were prepared from Gum Karaya and Chitosan using the principle of complex coacervation for the first time with a continuous oil-phase and they were also evaluated for their in vivo performance.9

Chitosan

ISPAGHULA

Ispaghula husk consist of dried seeds of the plant Plantago ovata Forsk. (Family − Plantaginaceae) commonly known as Isabgol or Ispaghula or Spogel seeds. It contains mucilage, which is present in the epidermis of seeds. It contains no toxic principles and when taken with water or milk most of it pass out of gastro-intestinal tract in 6 to 12 hours. Larger doses are essential as their action is produced partly by lubricating action of mucilage and partly by the increase in bulk of intestinal contents, which mechanically stimulates the intestinal peristalsis. Mucilage is used as binding agent in the granulation of material for preparation of compressed tablets. It is used as a suspending and thickening agent due to its high swelling factor and ability to give a uniform viscous solution. It is much sought in pharmaceutical industry as enteric coating material, tablet disintegrator and also used in sustained release drug formulations.



Ispaghula

ALMOND GUM

Almond gum is obtained from the tree *Prunus amygdalus* (family: *Rosaceae*). It is a water soluble gum extrudes from wounds on almond tree. Gum contains aldobionic acid, L-arabinose, L-galactose, D-mannose, etc. Almond gum contains different components which have emulsifying, thickening, suspending, adhesive, glazing, and stabilizing properties. Gum obtained from almond tree was studied for its binding property in tablet formulations. The drug release increased with almond gum when compared to synthetic gum concentration and the release mechanism was found to be non-Fickian diffusion. The almond gum was found to be useful for the preparation of uncoated tablet dosage .[10]

CASHEW GUM

Cashew gum is the exudate from the stembark of*Anacardiumoccidentale* (family:*Anacardiaceae*). The gum contains galactose, arabinose, rhamnose, glucose, glucuronic acid, and other sugar residues, while hydrolysis of the gumyields L-arabinose, L-rhamnose, D-galactose, and glucuronic acid Studies were performed on cashew gum for its gelling property. The gels prepared with 5.0% of mucilage were found to be ideal and comparable with a commercial preparation. The prepared gels did not produce any dermatological reactions. The gels were found to be stable with respect to viscosity, drug content, and physical appearance at all temperature conditions for 3 months. Cashew gum was also studied for its binding property. In this study binding property of cashew gum was compared with acacia. It was observed that the disintegration time of the tablet increased with increase in concentration of cashew gum and controlled release property wherein study showed that increase in the polymer ratio retarded the drug release to a greater extent.

NEEM GUM

Neem gum is obtained from the trees of *Azadirachta indica* (family: *Meliaceae*). Gum contains mannose, glucosamine, arabinose, galactose, fucose, xylose, and glucose Studies were performed on neem gum for its binding property and sustained release property. Results show that as the proportion of *Azadirachta indica* fruitmucilage increases, the overall time of release of the drug from the matrix tablet also increases.

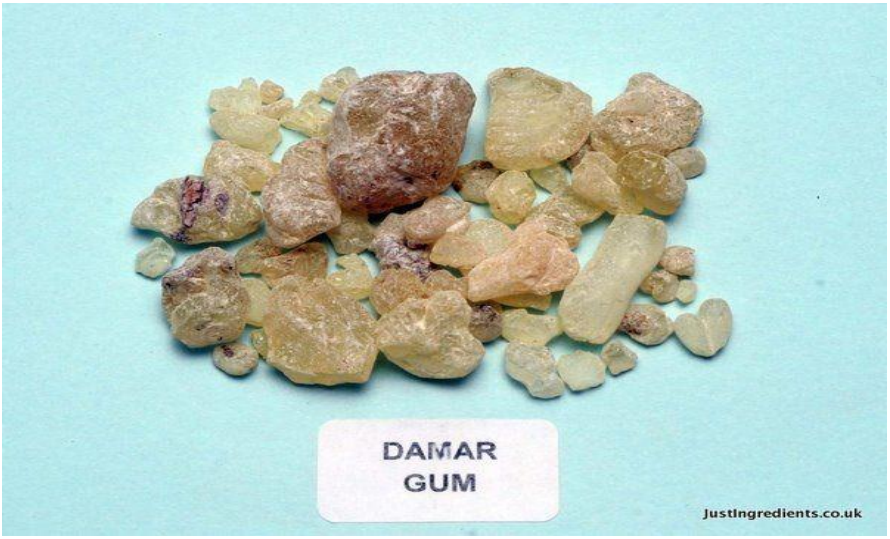
MORINGA OLEIFERA GUM

Gum is obtained from exudes of stem of *Moringa oleifera* (family: *Moringaceae*). The gum is a polyuronide constituting of arabinose, galactose, and glucuronic acid in the preparation of 10 : 7 : 2, rhamnose present in traces Studies were performed on this gum for its gelling property. The gelling concentration of the gum was found to lie between 7 and 8.5% w/v. The gels exhibited pseudoplastic flow and viscosity were found to be ideal for topical application binding property and release retardant property. Different batches of tablet were prepared and evaluated for drug release.[11] It was observed that drug release increased with increasing proportions of the excipient and decreased proportion of the gum. Release mechanism was found to be Fickian. Gum was also studied for its disintegrating property. Different batches of tablets were formulated varying them by quantity of the gum. It was observed that wetting time decreased with the increase in concentration of gum in formulation; thus disintegration time of tablet formulation prepared from gum was found lesser as compared to tablet formulation prepared from synthetic disintegrant like starch, sodium glycolate (SSG), and croscarmellose sodium (CCS).

GUM DAMAR[12]

Gum damar is a whitish to yellowish natural gum produced by tapping trees of *Shorea wiesneri* (Family: *Dipterocarpaceae*). It contains about 40% alpharesin (resin that dissolves in alcohol), 22% beta-resin, 23% dammarol acid, and 2.5% water. Studies were performed on gumdamar for its sustained releasematrix forming property. Drug release from thematrix showed sustained drug delivery beyond 10 hour. Microencapsulating property of the gum was also evaluated. The increase in gum: drug ratio showed an increase in particle size, encapsulation efficiency and decrease in drug release rate. It has been used also for water-resistant coating and in

pharmaceutical and dental industries for its strong binding properties.



GUM COPAL

Gum copal is a natural resinous material of plant *Bursera bipinnata* (family: *Burseraceae*). Copal resin contains agathic acid along with ciscommunic acid, transcommunic acid, polycommunic acid, sandaracopimaric acid, agathalic acid, monomethyl ester of agathalic acid, agatholic acid, and acetoxy agatholic acid .Copal gum has been evaluated as matrix-forming material for sustaining the drug delivery. In an independent study copal resin was used as a film forming agent. Films showed good swelling property. It was concluded that it can be used as a coating material for sustained release and colon targeted drug delivery. Film was prepared using gum copal and its swelling studies were performed in different phosphate buffer (pH 4.5, pH 6.0, and pH 7.4); significant swelling was found in pH 7.4 so colon can be targeted [15]

MOI GUM

Moi gum is obtained from leaves, stems, fruits, and bark of the stem *Lannea coromandelica* (family: *Anacardiaceae*). This gum is yellowish white colour in fresh and on drying becomes dark. Gum ducts are present in leaves, stems, and fruits and aremost abundant in the bark of the stem. The roots contain cluytyl ferulate; heartwood gives lanosterol; bark, dlepi-catechin, and (+)-leucocyanidin; flowers and leaves, ellagic acid, quercetin, and quercetin-3

arabinoside. Flowers also contain isoquercetin and morin. Leaves in addition contain beta-sitosterol, leucocyanidin, and leucodelphinidin. Moi gum was evaluated as microencapsulating agent and release rate controlling material. Microspheres were prepared by solvent evaporation technique. Moi gum produced microspheres having acceptable size and morphology. Microspheres formulated using moi gum showed sustained release beyond 10 hours in comparison to guar gum but when used in 1 : 1 ratio microspheres showed more sustained release.

KONDAGOGU GUM

Kondagogu gum or hupu gum is a naturally occurring polysaccharide derived as an exudate from the tree *Cochlospermum religiosum* (family: *Bixaceae*). Gum contains rhamnose, galacturonic acid, glucuronic acid, b-D galactopyranose, a-D-glucose, b-D-glucose, galactose, arabinose, mannose, and fructose. Studies were performed on kondagogu gum for its gastric floating property. The polymer concentration, concentration of sodium bicarbonate, and that of pharmatose to the weight of drug and polymer were selected as independent variables. Cumulative percent drug released at 12 hrs was selected as dependent variable. The release rate decreased as the proportion of hupu gum increased .Hupu gum was also evaluated for its mucoadhesive microcapsule forming property. All microspheres showed good mucoadhesive property in *in vitro* wash of test. *In vitro* drug release studies showed that the guar gum had more potentiality to retard the drug release compared to other gums and concentrations. Drug release from the microspheres was found to be slow and following zero order release kinetics with non-Fickian release mechanism, stating that release is depended on the coat: core ratio and the method employed.

MIMOSA SCABRELLA GUM

Gum is obtained from seeds of *Mimosa scabrella* (family: *Mimosaceae*). Gum is highly hydrophilic galactomannan that provides 20–30% of galactomannan (G) with a mannose: galactose ratio of 1.1: 1. Studies were performed on *Mimosa scabrella* gum for its controlled release matrix forming property. In this study it was observed that drug release decreased with the increase of polymer concentration and 25%w/w of gum showed excessive sustained release effect.The release mechanism was a combination of diffusion and relaxation .[20]

BHARA GUM

Bhara gum is a yellowish natural gum extracted fromthe bark of *Terminalia bellerica* (family: *Combretaceae*). Main chemical constituents are tannins which mainly include ß-sitosterol, gallic acid, ellagic acid, ethyl gallate, galloyl glucose, and chebulaginic acid. A new sustained release microencapsulated drug delivery system employing bhara gum has been proposed. The microcapsules were formulated by ionic gelation technique using famotidine as the model drug.The effect of different drug: bhara gum ratio drug release profile was examined and compared with guar gum. Microcapsules employing bhara gum exhibited slow release of famotidine over 10 hours.

HAKEA GUM

Hakea gum is a dried exudate from the plant *Hakea gibbosa* (family: *Proteaceae*). Gum contains glucuronic acid, galactose, arabinose,mannose, xylose which is 12 : 43 : 32 : 5 : 8. The exuded gum is only partly soluble in water. Gum was investigated as a sustained release andmucoadhesive component in buccal tablets. These results demonstrate that *Hakea gibbosa*, not only may be used to sustain the release but also can act as bioadhesive polymer. In this study, time required for 90% of the drug was used as basis for comparison. It was observed that formulation which did not contain hakea gum showed 90% release of the drug in about 14 minutes. While when hakea gum was used inconcentration of 32mg per tablet, it was seen that 90%release of the drug took place in around 165 minutes. Also when tablets were directly compressed using hakea gum, for 32mg gum per tablet, 90% release took place in 405 minutes.

GREWIA GUM

Grewia gum is a polysaccharide derived from the inner bark of the edible plant *Grewia mollis* (family: *Tiliaceae*). The gum consists of glucose and rhamnose as the main monosaccharide components and galacturonic acid as the main sugar acid. Studies were performed on grewia gum for its binding property, compressional property. In this study it was found that formulations containing grewia gum exhibited higher degree of packing than those containing PVP. Grewia gum was also found to improve fluidity granules than PVP. Studies were also carried out on matrix forming property of this gum. In this study tablets containing different concentrations of grewia gum were compressed by direct compression technique and were evaluated. *In vitro* drug release studies reveal that grewia gum can control the release of cimetidine from tablets for up to 12 hours. Therewas synergy between grewia gum and HPMC in delaying the release of cimetidine from tablets and film forming property [22]

MANGO GUM

Mango gum is a dried gummy exudate polysaccharide obtained from the bark of *Mangifera indica* (family: *Anacardiaceae*). Studies were performed on mango gum for its binding sustained release disintegrating property of this gum was also studied. Tablets containing this gum showed good appearance and better drug release. The study further revealed a poor relation between the swelling index and disintegrating efficiency. Mouth dissolving tablets were prepared using this gum.

OLIBANUMGUM

Olibanumgum is a dried, gummy exudation obtained from *Boswellia serrate* (family: *Burseraceae*). Gum olibanum is used as an anti-inflammatory remedy and recent studies have found positive influence of olibanum on rheumatism. Its composition and chemical characteristics depend on its three principal origins: Aden/Somalia, Eritrea, and India which contains approximately 5–9% oil content, 13–17% resin acids, 20–30% polysaccharides, 40–60% boswellic acid. Studies were performed on olibanum gum for its sustained release matrix forming, bindin. Olibanum resin coated microcapsules were formulated by emulsification solvent evaporation method. It was observed that drug release from the resin-coated microcapsules was slow over 24 hours and depended on core: coat ratio, wall thickness, and size of the microcapsules.

TERMINALIA GUM

Terminalia gum exudates are from the incised trunk of the tree *Terminalia randii* (family: *Combretaceae*). Extracts of the stemand bark of *Terminalia randii* are used in the treatment of dysentery, diarrhea, hemorrhoids, and wounds. Gum exudates obtained from *Terminalia randii* have been evaluated as binding agent. The results showed that the crushing strength and crushing strength friability ratio increased with increase in polymer concentration while friability decreased.

CONCLUSION

Polymers play a vital role in the drug delivery. So, the selection of polymer plays an important role in drug manufacturing. But, while selecting polymers care has to be taken regarding its toxicity, drug compatibility and degradation pattern. By this review, we can say that natural polymers can be good substitute for the synthetic polymers and many of the side effects of the synthetic polymers can be overcome by using natural polymers.

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