REVIEW ARTICLE

Gums and Mucilages: Excipients for modified Drug Delivery System

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ABSTRACT

Natural gums and mucilages are available in nature freely. These natural gums and mucilages were successfully used in various dosage forms. These gums posses various advantages over synthetic polymers as they biodegradable, low cost etc. In recent years researches have been carried in formulation of modified dosage form using various gums and mucilage and they found to compete the synthetic polymers available in market. In this review we describe the development in natural gums and mucilages for use in modified drug delivery system and the interaction of API with some synthetic and also natural excipients used in pharmaceutical formulations.

Keywords: Natural polymers, Natural gums and mucilage, Pharmaceutical excipients, pharmaceutical application, modified gums, incompatibility

INTRODUCTION

Nature has provided us a wide verity of materials to improve and sustain the health of all living things either directly or indirectly. Natural gums are promising biodegradable polymeric materials. Many studies has been carried out in the fields including food technology and pharmaceuticals using gums and mucilages [1] .The traditional use of excipients in drug formulations was to act as inert vehicles to provided necessary weight, consistency and volume for the correct administration of the active ingredient, but in modern pharmaceutical dosage forms they often fulfill multi-functional roles such as modifying release, improvement of the stability and bioavailability of the active ingredient, enhancement of patient acceptability and ensure ease of manufacture. A large number of plant-based pharmaceutical excipients are available today. Many researchers have explored the usefulness of plant-based materials as pharmaceutical excipients. Ability to produce a wide range of material based on their properties and molecular weight, natural polymers became a thrust area in majority of investigations in drug delivery systems [2]. Natural gums can also be modified to meet the requirements of drug delivery systems and thus can compete with the synthetic excipients available in the market [3].

Gums are naturally occurring components in plants, which are essentially cheap and plentiful. Natural gums are polysaccharides consisting of multiple sugar units linked together to create large molecules. Gums are considered to be pathologic products formed following injury to the plant or owing to unfavorable condition such as drought, by breakdown of cell walls (extra cellular formation, gummosis)[4]. Acacia, Tragacanth, guar gum are examples of gum [5]. They are heterogeneous in composition. Upon hydrolysis they yield simple sugar units such as arabinose, galactose, glucose, mannose, xylose or uronic acids, etc.

Polymers have been successfully employed in the formulation of solid, liquid and semi-solid dosage forms and are specifically useful in the design of modified release drug delivery systems. Both synthetic and natural polymers have been investigated extensively for this purpose, but the use of natural polymers for pharmaceutical applications is attractive because they are economical, readily available, non-toxic, capable of chemical modifications, potentially biodegradable and with few exceptions, also biocompatible. Increasing importance

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is the fact that plant resources are renewable and if cultivated or harvested in a sustainable manner, they can provide a constant supply of raw material [6].

The plant based polymers have been studied for their application in different pharmaceutical dosage forms like matrix controlled system, film coating agents, buccal films, microsphere, nanoparticals, viscous solutions like ophthalmic solutions, suspensions, implants and their applicability and efficiency has been proven [7,8].

Classification of Gums and Mucilages

Gums and mucilages are present in high quantities in a verities of plants, animals, seaweeds, fungi and other microbial sources, where they perform a number of structural and metabolic functions; plant sources provide the largest amounts. The different available gums and mucilages can be classified as follows [9-14].

According to the Charge

Non-ionic seed gums: guar, locust bean, tamarind, xanthan, amylose, arabinans, cellulose, galactomannans. Anionic gums: arabic, karaya, tragacant, gellan, agar, algin, carrageenans, pectic acid.

According to the Source

A) Marine Origin/Algal (Seaweed) Gums: agar, carrageenans, alginic acid, laminarin.

B) Plant Origin: (1) shrubs/tree exudates—gum arabica, gum ghatti, gum karaya, gum tragacanth, khaya and albizia gums; (2) seed gums—guar gum, locust bean gum, starch, amylose, cellulose; (3) extracts- pectin, larch gum; (4) tuber and roots—potato starch.

C) Animal Origin: chitin and chitosan, chondroitin sulfate, hyaluronic acid.

D) Microbial Origin (bacterial and fungal): xanthan, dextran, curdian, pullulan, zanflo, emulsan, Baker's yeast glycan, schizophyllan, lentinan, krestin,scleroglucan.

Semi-Synthetic

Starch derivatives—hetastarch, starch acetate, starch phosphates.

Cellulose derivatives— carboxy methyl cellulose (CMC), hydroxy ethylcellulose, hydroxypropyl methylcellulose (HPMC), methyl-cellulose (MC), microcrystalline, cellulose (MCC). -

According to Shape

Linear: algins, amylose, cellulose, pectins.

Branched: (1) short branches—xanthan, xylan, galactomanan; (2) branch-on-branch-amylopectin, gum arabic, tragacanth.

According to Manomeric Units in Chemical Structure

Homoglycans—amylose, arabinanas, cellulose; diheteroglycans-algins, carragennans, galactomannans;

Advantages of Natural Polymers

The following are a number of the advantages of natural plant–based materials[1].

- Biodegradable—Naturally available biodegradable polymers are produced by all living organisms. They represent truly renewable source and they have no adverse impact on humans or environmental health.
- Biocompatible and non-toxic—Chemically, nearly all of these plant materials are carbohydrates composed of repeating sugar (monosaccharides) units. Hence, they are non- toxic.
- Low cost—it is always cheaper to use natural sources. The production cost is also much lower compared with that for synthetic material. India and many developing countries are dependent on agriculture.
- Environmental-friendly processing—Gums and mucilages from different sources are easily collected in different seasons in large quantities due to the simple production processes involved.
- Local availability (especially in developing countries). In developing countries, governments promote the production of plant like guar gum and tragacanth because of the wide applications in various industries.

Disadvantages of Synthetic Polymers

- The synthetic polymers have certain disadvantages such as high cost, toxicity, environmental pollution

during synthesis, non-renewable sources, side effects, and poor patient compliance.

- Acute and chronic adverse effects (skin and eye irritation) have been observed in workers handling the related substances methyl methacrylate and poly-(methyl methacrylate) (PMMA) [15].
- Reports of adverse reactions to povidone primarily concern the formation of subcutaneous granulomas at the injection site produced by povidone. There is also evidence that povidone may accumulate in organs following intramuscular injections [16].
- Acute oral toxicity studies in animals have indicated that carbomer-934P has a low oral toxicity at a dose of up to 8 g/kg. Carbomer dust is irritating to the eyes, mucous membranes and respiratory tract. So, gloves, eye protection and dust respirator are recommended during handling [17].
- Studies in rats have shown that 5% polyvinyl alcohol aqueous solution injected subcutaneously can cause anemia and can infiltrate various organs and tissues [18].

For a number of reasons there has been an increase in interest in the development of new excipients/diluents. Some drugs show incompatibilities with many of the current range of excipients. For example, atenolol-PVP, atenolol-mg-stearate [19]. One of the more common drug-excipient incompatibilities is the reaction between aldehydic sugars, such as lactose and primary and secondary amines, leading to the formation of Schiff bases. These complex series of reactions lead to browning and discoloration of the dosage form. Despite being a carrier of choice for dry powder aerosol formulations, lactose may need to be replaced with a different carrier, such as mannitol or sucrose, when formulating primary and secondary amines. Magnesium stearate is incompatible with aspirin, some vitamins and most alkaloidal salts [20].

There are several examples of formulation instability resulting from solid–solid interactions [21,22]. Certain classes of compounds are known to be incompatible with particular excipients [23]. Knowledge of the chemistry of the drug substance and excipients can often minimize formulation surprises. Heat and water are the primary catalysts for drug excipient interactions and play a critical role in the degradation of a drug substance [24]. The majority of 'small molecule' API instability reactions occur via hydrolysis, oxidation and Maillard reaction. The moisture content of the drug and excipients plays a critical role in their incompatibility. The incompatibility between a drug and an excipient and that which occurs between a drug and moisture/water activity due to the ability of the excipient to absorb moisture, represents two different kinds of incompatibilities. Excipients such as starch and povidone may possess a high water content (the equilibrium moisture content of povidone is about 28% at 75% relative humidity), which can increase drug degradation. The moisture level will affect the stability depending on how strongly it is bound and whether it can come into contact with the drug [25]. It is generally recognized that aspirin is incompatible with magnesium salts. Higher moisture contents and humidity accelerate the degradation [25]. Many different moisture mediated degradation mechanisms exist, but those mediated by surface moisture appear [26]. Consequently it is important that stress methods incorporate water to encourage the formation of all possible impurities. The way in which water facilitates degradation is not fully understood, but work carried out by Kontny et. al. has confirmed its importance [26]. Degradation problems can, therefore, be difficult to avoid because water often cannot be entirely excluded from drug product formulations. Many excipients are hygroscopic [27,28] and absorb water during manufacturing. Depending on the degree of hydrolytic susceptibility, different approaches to tablet granulation can be used to minimize hydrolysis. For compounds such as acetylsalicylic acid that are readily

hydrolysable, direct compression or dry granulation is preferable, to wet granulation. However drug-excipient incompatibility may still occur.

Chemical interaction between the drug and excipients may lead to increased decomposition. Stearate salts (e.g. magnesium stearate, sodium stearate) should be avoided as tablet lubricants if the API is subject to hydrolysis via ion-catalyzed degradation. Excipients generally contain more free moisture than the drug substance [27] , and in an attempt to obtain the most thermodynamically stable state, water is able to equilibrate between the various components[29]. Common solid-state incompatibilities [30] as shown in Table No.1.

Table 1: List of Common Solid-State Incompatibilities

Functional Group (Example of API)	Incompatible with	Type of Reaction
Primary amine (e.g.Acyclovir)	Mono and disaccharides (e.g. lactose)	Maillard reaction
Esters (e.g.Moexipril)	Basic components (e.g.magnesium hydroxide)	Ester hydrolysis
Lactone (e.g.Irinotecan HCl)	Basic components (e.g.magnesium hydroxide)	Ring opening (hydrolysis)
Carboxyl	Bases	Salt formation
Alcohol (e.g.Morphine)	Oxygen	Oxidation to aldehydes and ketones
Sulfhydryl (e.g.Captopril)	Oxygen	Dimerization
Phenol	Metals polyplasdone	Complexation
Gelatin	Cationic surfactants	Denaturation

Incompatibilities of APIs with different pharmaceutical excipients are summarized in Table No.2 [30]

Table 2: Incompatibilities of APIs with Pharmaceutical Excipients

Excipient	API and its Therapeutic Class
Saccharides	
Lactose	Acyclovir - Antiviral; Aceclofenac and Ketoprofen - Anti-inflammatory; Metformin -Antidiabetic; Amlodipine , Ceronapril , Lisinopril and Oxprenolol - Antihypertensive; Fluconazole - Antifungal; Primaquine - Antimalarial; Promethazine - Antiemetic; Fluoxetine and Seproxetine Maleate – Antidepressant; Picotamide – Anticoagulant; Etamsylate - Antihemorrhagic; Aminophylline and Clenbuterol – Bronchodialator; Baclofen - CNS Drug; Ranitidine - GI Agent; Doxylamine – Antihistaminic; Thiaminechloride HCL – Vitamin
Lactose/meglumine/ Tris Buffer Blend	Glipizide – Antidiabetic
Mannitol, Pearlitol (80% Mannitol +20% Maize Starch)	Quinapril – Antihypertensive; Primaquine - Antimalarial; R-omeprazole – GI Agent; Promethazine –Antiemetic
Starch	Seproxetine Maleate– Antidepressant; Clenbuterol – Bronchodialator
Sodium Starch Glicollate	Seproxetine Maleate – Antidepressant; Clenbuterol – Bronchodialator
Dextrose	Pefloxacin– Antibiotic
Stearates	
Magnesium Stearate	Acyclovir – Antiviral; Aspirin , Ibuproxam , Indomethacin and Ketoprofen - Antiinflammatory; Glipizide, Chlorpropamide, Glimepiride and Glibenclamide - Antidiabetic; Captopril , Fosinopril , Moexipril , Oxprenolol and Quinapril - Antihypertensive; Cephalexin , Erythromycin, Nalidixic Acid , Oxacillin and Penicillin G - Antibiotic; Primaquine - Antimalarial; Promethazine - Antiemetic; Albendazole - Antiamoebic; â-lapachone - Anticancer; Clopidogrel- Anticoagulant; Doxylamine – Antihistaminic; Temazepam – Hypnotic
Stearic Acid	Doxylamine – Antihistaminic
Polyvinyl Pyrolidone (PVP)	Indomethacin , Ibuproxam and Ketoprofen – Anti-inflammatory; Atenolol and Oxprenolol- Antihypertensive; Sulfathiazole – Antibiotic; Haloperidol - Antipsychotic; Ranitidine - GI Agent; Doxylamine - Antihistaminic; Temazepam - Hypnotic; Clenbuterol – Bronchodialator
Dicalcium Phosphate Dihydrate	Ceronapril , Oxprenolol and Quinapril - Antihypertensive; Metronidazole – Antiamoebic; âlapachone and Parthenolide - Anticancer; Famotidine - GI Agent; Temazepam – Hypnotic
Eudragit Polymers	
Eudragit RS and Rl	Diflunisal , Flurbiprofen and Piroxicam – Anti-inflammatory
Eudragit RL100	Ibuprofen – Anti-inflammatory
Eudragit E100	Ranitidine– GI Agent
Celluloses	
Microcrystalline Cellulose (MCC), Avicel PH 101	Enalapril - Antihypertensive; Isosorbide Mononitrate – Antiangina; Clenbuterol – Bronchodialator
Cellulose Acetate	Isosorbide Mononitrate – Antiangina
Hypromellose Acetate Succinate (HPMCAS)	Dyphylline – Bronchodialator
Hydroxypropyl Cellulose	Trichlormethiazide – Diuretic
PEG	Ibuprofen , Ibuproxam and Ketoprofen -Anti inflammatory ; Phosphomycin - Antibiotic; Clopidogrel – Anticoagulant
Polysorbate 80	Ibuprofen – Anti-inflammatory
Sodium Lauryl Sulfate	Chlorpropamide – Antidiabetic; Clopidogrel – Anticoagulant; Chlordiazepoxide – Hypnotic
Chitosan	Diclofenac and Piroxicam– Anti-inflammatory
Magnesium Oxide	Ibuprofen – Anti-inflammatory
Silicon Dioxide	Enalapril – Antihypertensive
Carbonates	
Sodium Carbonate	Adefovir , Dipivoxil – Antiviral
Sodium Bicarbonate	Ibuprofen – Anti-inflammatory
Miscellaneous	
Plasdone	Glimepiride – antidiabetic
Ascorbic acid	Atenolol – antihypertensive
Citric acid	Atenolol – antihypertensive
Butylated hydroxyanisole	Atenolol – antihypertensive
Succinic acid	Phosphomycin – antibiotic
Na dioctylsulfocuccinate	Phosphomycin – antibiotic
Ca and Mg salts	Tetracyclins – Antibiotic
Talc	Seproxetine maleate – antidepressant
Precirol ATO 5	Temazepam – hypnotic

Natural polysaccharides and their derivatives represent a group of polymers widely used in pharmaceutical dosage forms. Various kinds of natural gums are used in the food industry and are regarded as safe for human consumption. These polysaccharides are obtained usually as plant exudates containing various sugars other than glucose and having significant quantities of oxidized groups in adjunct to their normal polyhydroxy format. In many cases, water-soluble polysaccharides generally similar to the exudates are components of land and marine plants and their seeds. These materials result from normal metabolic processes, and many times, they represent the reserve carbohydrate in that system [31].

Gums have a variety of applications in pharmacy. They are used in medicine for their demulcent properties for cough suppression. They are ingredients of dental and other adhesives and can be used as bulk laxatives. The hydrophilic polymers are useful as tablet binders, disintegrant, emulsifiers, suspending agents, gelling agents, stabilizing agents, thickening agents, film forming agents in transdermal and periodontal films, buccal tablets as well as sustaining agents in matrix tablets and coating agents in microcapsules including those used for protein delivery. Various gums with their common names, biological sources, family and its pharmaceutical applications are listed in Table No.3.

Table 3: Applications of Gums and Mucilages in Novel Drug Delivery Systems

Common Name	Botanical Name	Family	Pharmaceutical Applications	Reference
Acacia	*Acacia Senegal*	Leguminosae	Osmotic drug delivery	[6,32]
Bhara gum	*Terminalia bellerica* roxb	Combretaceae	Microencapsulation	[33]
Chitosan			Colon specific drug delivery,microspheres, carrier for protein as nanoparticles	[34, 35].
Cordia gum	*Cordia obliqua* willed	Boraginaecae	Novel oral sustained release matrix forming agent in tablets	[36]
Cactus mucilage	*Opuntia ficus-indica*		Gelling agent in sustained drug delivery	[37]
Guar gum	*Cyamompsis tetraganolobus*	Leguminoseae	Colon targeted drug delivery, cross-linked microspheres	[38-41]
Hakea	*Hakea gibbosa*		Sustained release and peptide Mucoadhesive for buccal delivery	[42]
Ispagol	*Plantago psyllium Plantago ovate*		Hydrogels,colon drug delivery, gastroretentive drug delivery	[43-45]
Karaya gum	*Sterculia urens*	Sterculiaceae	Mucoadhesive and buccoadhesive	[46]
Locust bean gum	*Ceratania siliqua*	Leguminoseae	Controlled release agent	[47]
Mucuna gum	*Mucuna flagillepes*	Papillionaceae	Microspheres	[48]
Okra	*Hibiscus esculentus*	Malvaceae	Hydrophilic matrix for controlled release drug delivery	[49]
Tamarind	*Tamarindus indica*	Leguminoseae	Hydrogels, mucoadhesive drug delivery for ocular purposes, spheroids, nasal drug delivery	[50, 51]
Xanthan gum	*Xanthomonas lempestris*		Pellets, controlled drug delivery System	[52, 53]
Gellan gum	*Pseudomonas elodea*		Ophthalmic drug delivery, sustaining agent,beads,	[54-59]
Pectin	*Citrus aurantium*	Rutaceae	Beads, floating beads, colon drug delivery, pelletization by extrusion/spheronization, microparticulate delivery, transdermal delivery, Iontophoresis, hydrogels	[60-67]

It is established that the hydrophilic polymers release freely soluble drugs at a fairly constant rate [68]. Various synthetic polymers (e.g., cellulose ethers, polyalkyl-methacrylates, etc.) used for various pharmaceutical purpose have been reviewed [69-71]. These polymers, when come in contact with water, are hydrated and form a gel. Natural gums (like agar

in the form of beads and konjac in the form of cylinders) have also been examined as matrices for the sustained release of drugs [72].When natural gums in the form of compressed tablets are placed in water, they are expected to absorb water from the medium and form a gel before they dissolve in the medium. If a drug is contained in the tablet, it is expected to be released through the gel layer, and sustained release may be achieved. It should be noted that many ‘‘old’’ materials compete successfully today after almost a century of efforts to replace them. It is the usual balance of economics and performance that determines the commercial realities. Natural gums have been modified to overcome certain drawbacks, like uncontrolled rate of hydration, thickening, drop in viscosity on storage, microbial contamination [73]. Chemical modification of gums not only minimizes these drawbacks but also enables their use for specific drug delivery purposes. Various modifications made on gums to make them suitable for modified drug delivery applications [74].

CONCLUSION

Gums are abundantly found in nature. They are cheaper than the synthetic polymers available for various purposes. In addition natural gums are promising biodegradable polymeric materials. It is clear that gums and mucilages have many advantages over synthetic materials. Various applications of gums and mucilages have been established in the field of pharmaceuticals. There is a need to develop other natural sources as well as with modifying existing natural materials for the formulation of novel drug delivery systems. The abundance of gums, their economic cost and biodegradability have compelled formulation scientists to design approaches for making them suitable for modifying the drug release of dosage forms.

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