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Natural Excipients: Uses of Pharmaceutical Formulations

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Abstract: With the increasing interest in polymers of natural origin, the pharmaceutical world has compliance to use most of them in their formulations. Pharmaceutical formulation development involves various components in addition to the active pharmaceutical ingredients. Nature has provided us a wide variety of materials to help improve and sustain the health of all living things either directly or indirectly. In recent years there has been an important development in different dosage forms for existing and newly designed drugs and natural products, and semi-synthetic as well as synthetic excipients often need to be used for a variety of purposes. Gum and mucilages are widely used natural materials for conventional and novel dosage forms. This article gives an overview of natural excipients which are used in controlled drug delivery systems. Mainly the natural excipient used is biocompatible, cost effective and provides as nutrition supplements.
Key Words:-Natural polymers, Gum, Mucilages, Pharmaceutical application.

INTRODUCTION

Today, the whole world is increasingly interested in natural drugs and excipients. In recent years, plant derived polymers have evoked tremendous interest due to their diverse pharmaceutical applications such as diluent, binder, disintegrants in tablets, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels and bases in suppository , they are also used in cosmetics, textiles, paints and paper-making . These polymers such as natural gums and mucilage are biocompatible, cheap and easily available and are preferred to semi synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action and non-irritant nature[1]. A large number of plant-based pharmaceutical excipients are available today. 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. muscle fibers, polysaccharides, enzymes and gummy exudates are the natural polymers beings used effectively in formulating the variety of pharmaceutical products. chitosan, carrageenan, acacia, agar, Ispaghula, karaya this are natural polymers most widely used in pharmaceutical and cosmetics product development[2].

The plant based polymers have been studied for their application in different pharmaceutical doses forms such as osmotic drug delivery, microencapsulation, ophthalmic drug delivery, film coting agents, buccal films, implant and their applicability and efficacy. They have been utilized as viscosity enhancers, stabilizers, disintegrants, solubilisers, emulsifiers, suspending agents, gelling agents, bioadhesives, binders in the above mentioned dosage forms[3].

This review gives an insight of plant based novel drug release-retarding materials which have been recently studied as carriers not only in the conventional sustained release dosage forms but also in buccal drug delivery systems, gastro retentive systems and microcapsules. Present day consumers look for natural ingredients in food, drugs, and cosmetics as they believe that anything natural will be more safe and devoid of side effects. Furthermore, they can be modified to obtain tailor made materials for drug delivery systems allowing them to compete with the synthetic products that are commercially available. Many kinds of natural gums are used in the food industry and are regarded as safe for human consumption. It should be noted that many 'old' materials are still popular today after almost a century of efforts to replace them. It is usual to strike a balance between economics and performance in the face of commercial realities[4].

There are various number of natural polymers which have been investigated as pharmaceutical formulation such as-

TAMARIND GUM

Tamarind xyloglucan is obtained from endosperm of the seed of the tamarind tree, Tamarindus indica, a member of evergreen family. Tamarind gum, also known as Tamarind Kernel Powder (TKP) is extracted from the seeds. The seeds are processed in to gum by seed selection, seed coat removal, separation, hammer milling, grinding and sieving. Tamarind gum is polysaccharide composed of glucosyl : xylosyl : galactosyl in the ratio of 3:2:1 xyloglucan is a major structural polysaccharide in the primary cell walls of higher plants5. Tamarind seed polysaccharide (TSP) which is obtained from the seed kernel of Tamarindus indica, Tamarindus indica belonging to family leguminacy , Xyloglucans (XGs), also called amyloids, are widespread in nature in plants[5]. Xyloglucan is a highly substituted, food grade, starch-like polysaccharide and is present in the primary cell walls of dicotyledons and non-graminaceousmonocotyledons.The glucose backbone of XG is abundantly substituted with a (1,6)-linked xylopyranose branches that in turn may be further derivatised by b (1,2)-linked galactopyranosyl residues. A high degree of substitution of the glucan chain produces a stiff, extended conformation for this polysaccharide molecule, with large volume occupancy in solution. About 80% of the glucose residues are substituted by a (1,6)-linked xylose units, which themselves are partially substituted by b (1,2)-galactose residues. Xyloglucans synthesized by all plants examined to date have at least one of the following structural features: side chains terminated by fucosyl residues; side chains terminated by arabinosyl residues; a XXGGG-type repeating core consisting of a cellopentaose backbone with two side chains. Fucosyl residues aretypically absent from seed xyloglucans but present on the xyloglucans in the vegatative portions of the same plant. XG is a polymer with an average molecular weight of more than 50000[6].

Tamarind gum is non Newtonian and yield higher viscosities than most starches at equivalent concentration. This has led to its application as stabilizer, thickener, gelling agent and binder in food and pharmaceutical industries.

Tamarind seeds consist of :-

Polysaccharide (35 - 55%),Proteins (18-20%)Tamarind bean – raw,Lipids (6-10%),Fiber (7 - 18%),Fat (3 - 7.10%),Inorganic salts,Freesugars,Moisture (4 – 10%),Ash (1 - 3%).

The white kernel obtained of tamarind seeds are utilized for producing Tamarind Kernel Powder. Tamarind kernel is rich in Protein, Carbohydrates, Fibers and Oils.Tamarind Kernel Powder is the combination of Galactoxyloglucan polysaccharide (55-65%).

The white kernel obtained of tamarind seeds are utilized for producing tamarind kernel powder. Tamarind kernel is rich in protein, carbohydrates, fibers and oils[7].

In a study the tamarind seed polysaccharide (TSP) was isolated from tamarind kernel powder and this polysaccharide was utilized in the formulation of matrix tablet containing Diclofenac sodium by wet granulation technique and evaluated for its drug release characteristics[8].

FENUGREEK MUCILAGE

Fenugreek, being botanically called as Trigonellafoenum-graecum is also known as "Methi" in Hindi. Fenugreek, is an herbaceous plant of the leguminous family. Fenugreek is an edible seed and hence its isolated gum is the latest addition to the list of galactomannan gums. Fenugreek is an annual crop, mainly cultivated in India. Fenugreek gums was not used in industries till 1990 but after that fenugreek had dual use by removing. Fenugreek seeds contain a high percentage of mucilage (a natural gummy substances present in the coating in the many seeds). Although it does not dissolve in water, mucilage forms a viscous tacky mass when exposed to fluids. Like other mucilage containing substances, fenugreek seeds well up and become slick when they are exposed to fluids. The husk from the seeds is isolated by first reducing the size, and then separated by suspending the size reduces seeds in chloroform for some time and then decanting. Successive extraction with chloroform removes the oily portion which is their air dried. A different extraction procedure also reported to isolate the mucilage from the husk. The powder seeds are extracted with the hexane then boiled in ethanol. The treated powder is then soaked in water and mechanically stirred and filtered. Filtrate is centrifuged, concentrated in vacuum and mixed with 96% ethanol. This is then stored in refrigerator for 4 hrs to precipitate the mucilage[9].

The spice and other components and separate the unique galactomannan which is also known as fenugreek gum powder to be used in the industries. Currently fenugreek gum is having high demand as it is having considerable amount of applications in industries. Fenugreek being an annual legume plant, is native to the Mediterranean region but is also grown in Middle East, Asia and Africa. India is an important exporter of Fenugreek seeds. Moreover, in India fenugreek is used as a spice as well as in medicines also.

In a study the mucilage derived from the seed of fenugreek, was investigated for use in matrix formulation containing propranolol hydrochloride[10].

Application of fenugreek gum powder

Due to the presence of galactomannan in high proportion as the major component, in fenugreek gum powder, it has the quality of controlling blood sugar and blood lipid. So, it is considered very good for obesity and diabetic patients. Fenugreek gum powder also helps in reducing cholesterol, hypertension and chance of heart attack. Fenugreek gum powder also has the distinctive properties due to which the level of sugar in the blood can be lowered. Due to so many medicinal properties, fenugreek gum powder is used in tablet and capsules. It is also used in weight control formulation and other diet food[11].

DELONIX REGIA

The plant Delonix regia (family: leguminosae, sub family: fabaceae) also known as royal Poinciana Planted as avenues in garden and and on roads throughout India. It is commonly known as 'Gulmohar' in Hindi and Marathi. may flower plant or Flamboyant, many branched, broad, spreading, flat crowned deciduous tree and well known for its brilliant display of red-orange bloom, literally covering the tree from May to June. The Delonix regia will provide fullest flowering and best growth when planted in full sun location. Delonix regia bark contain β-sitosterol,saponins, alkaloids, carotene, hydrocarbons phytotoxins and flavonoids. Flowers of Delonix regia also contain carotenoide, tannins, saponins, flavonoids, steroids, alkaloids and β-sitosterol seed consists of saponins, galactomannon. The leaves of the plant contain rich content of lupeol and β- sitosterol. The carotenoids and perhaps non-nutrients like dietary fibers and other phenolic components (falvonoids, tannins and terpenoids) can influence the enzyme involved in the activation and detoxification of xenobiotics including carcinogens. Quantification of the total phenolic and flavonoidal has not been undertaken as on today[12]. The decoction of the leaves is traditionally used in treating gastric problems, body pain, and rheumatic pains of joints. Traditionally Delonix regia plant is used as anthelmintic, antimicrobial, anticancer, antirheumatic, antimalarial, antioxidant, hepatoprotective activity, antiulcer effect and anti-diabetic activity[13].

Traditional medicines play an important role in health services around the globe. About three-quarters of the world population relies on plants and plant extracts for thousands of year in healthcare. Nowaday's person prefers plant based medicines over synthetic medication for the treatment of different disease because of their safety as well as economy. The rational design of novel drugs from traditional medicine offers new prospects in modern healthcare. Herbal medicines are particularly used by the traditional practitioners since the ancient time

but they do not have scientific data[14]. Delonix regia is a flamboyant tree native to Madagascar, its seeds have traveled the world and the species is now common through the tropical cities[15].

It is widely cultivated and may be seen adorning avenues, parks and estates in tropical cities throughout the world. Planted as avenues in garden and and on roads throughout India. Delonix regia belongs to the same type containing the pod type fruits. It usually grows to a modest height (typically around 5 m, though it can reach as high as 12 m) but spreads widely, and its dense foliage provides full shade. Seed pods are dark brown and can be up to 60 cm long and 5 cm wide; the individual seeds, however, are small, weighing around 0.4 g on average[16].

In a study the delonix regia polysaccharide was isolated from delonix regia seeds and this polysaccharide was utilized in the formulation of sustained release antipsychotic tablets using novel polysaccharide isolated from delonix regia seeds and its pharmacokinetic studies.

OCIMUM SANCTUM LINN

Ocimum sanctum Linn (known as Tulsi in Hindi), a small herb seen throughout India.Ocimum sanctum (Family Labiatae) is a many branched, erect, stout and aromatic herb about 75 cms high. This small herb is found throughout India and is cultivated, worshiped in temples and houses of Hindus. The leaves, seeds and root of this plant have been used in indigenous Ayurvedic medicine. The chemical composition of Tulsi is highly complex, containing many nutrients and other biological active compounds. These constituents significantly vary with time, cultivation process and storage. The nutritional and pharmacological properties of the whole herb in natural form, as it has been traditionally used, result from synergistic interaction of many different active phytochemicals, consequently, the overall effects of Tulsi cannot be fully duplicated with isolated compound or extracts. Due to its inherent botanical and biochemical complexity, standardization of the active components of Tulsi so far is very complex. However, best known of many active components that have been identified and extracted are eugenol (an essential oil) and ursolic acid[17].

Eugenol (l-hydroxy-2-methoxy-4-allylbenzene), the active constituent present in Ocimum sanctum L., has been found to be largely responsible for the therapeutic potentials of Tulsi. Although because of its great therapeutic potentials and wide occurrence in India the practitioners of traditional systems of medicine have been using Ocimum sanctum L. for curing various ailments, a rational approach to this traditional medical practice with modern system of medicine is, however, not much available[18]. In Ayurveda Tulsi (Ocimum sanctum L.) has been well documented for its therapeutic potentials and described as Dashemani Shwasaharni (antiasthmatic) and antikaphic drugs (Kaphaghna)[19] Ocimum Tenuiflorum Linn. used as Binders. Binders are agents used to impart cohesive qualities to the powdered material during the production of tablets .In recent years, plant derived polymers have evoked tremendous interest in pharmaceutical industries. Mucilages are pharmaceutically important polysaccharides with their diverse pharmaceutical applications such as thickener, binder, disintegrant, superdisintegrant, suspending agent, gelling agent, emulsifier, stabilizing agent, drug release retardant, suppository bases, paper-making, humidifying agent, and also as film formers. By the term “plant mucilage” is meant those substances which are soluble, or at least swell very perceptibly in water and which, upon the addition of alcohol, are precipitated in a more or less amorphous or granular mass. These polymers such as natural gums and mucilage are biocompatible, cheap and easily available and are preferred over semi synthetic and synthetic excipients because of their lack of toxicity, low cost, availability, soothing action, non irritant nature, edible properties also capable of multitude chemical modifications[20].

PSYLLIUM HUSK

Psyllium comes from the plant Plantagopsyllium, the husk and seed of Plantagoovata (Plantaginaceae) is commonly referred to as psyllium. Psyllium is widely used as a fiber supplement for the treatment of constipation. Psyllium husk is obtained by milling the seed of P. ovata to remove the hulls. In some studies the seed has been used instead of the husk, and is also commercially available. Psyllium husk contains a high proportion of hemicellulose,

composed of a xylan backbone linked with arabinose, rhamnose, and galacturonic acid units (arabinoxylans). The seed consists of 35-percent soluble and 65-percent insoluble polysaccharides (cellulose, hemicellulose, and lignin). Psyllium is classified as a mucilaginous fiber due to its powerful ability to form a gel in water. This ability comes from its role as the endosperm of the P. ovata seed, where it functions to retain water in order to prevent the seed from drying out[21].

Mechanisms of Action

Many studies have shown dietary fiber shortens gastrointestinal transit time and increases stool weight[22]. When given to healthy volunteers, 18 grams daily of psyllium husk increased fecal weight and the production of short chain fatty acids[23].Most of the psyllium was shown to reach the cecum four hours after ingestion in an intact and highly polymerized form. The husk appears to be relatively resistant to fermentation. Psyllium husks also significantly increase the level of stool moisture, as well as wet and dry stool weight[24]. Anaerobic fermentation of the soluble non-starch polysaccharides from psyllium seed results in the production of the short-chain fatty acids acetate, propionate, and butyrate in the intestines[25]. Psyllium husk contains only the epidermis of the seed, while the actual seed has a higher amount of fermentable fiber. Because of this fiber content, psyllium seed degrades more slowly than pectin and produces fairly large amounts of butyrate and acetate. Butyric acid exhibits antineoplastic activity against colorectal cancer, is the preferred oxidative substrate for colonocytes, and may be helpful in the treatment of ulcerative colitis. In a study of resected colorectal cancer patients, those given 20 grams of psyllium seed daily for three months exhibited an average increase of butyric acid production of 42 percent, which decreased to pretreatment levels within two months of cessation of supplementation[26]. Psyllium also has hypocholesterolemic effects, although the exact mechanism by which psyllium husk brings about a reduction of cholesterol is not totally clear. Animal studies have shown psyllium increases the activity of cholesterol 7 alpha-hydroxylase (the rate-limiting enzyme in bile acid synthesis also referred to as cytochrome 7A [CYP7A]) more than twice that of cellulose or oat bran, but less than cholestyramine[27].

Clinical Indications

Hemorrhoids

With the known benefit of psyllium for both constipation and loose stools, it is not surprising it would also be of benefit for hemorrhoids. Fifty persons with internal bleeding hemorrhoids were given either a placebo of B vitamins or 11.6 grams of Metamucil® daily for 40 days. Individuals in the psyllium group had significant improvementin reduction of bleeding and a dramatic reduction of congested hemorrhoidal cushions. Bleeding on contact stopped after treatment in the psyllium group, while those in the control group experienced no difference[28]. It also appears psyllium treatment for this problem must be done for a minimum of one month, as a study of 30-day fiber supplementation failed to show improvement; whereas, when taken for 40 days significantimprovement was noted[29].

LOCUST BEAN GUM

locust bean gum is also derived from the endosperm of the seeds of Ceretoniasiliqua Linn belonging to the family Fabaceae. The gum is finally achieved by milling the endosperms. Cerqueria et al. have also extracted the gum from seeds with the help of water followed by precipitation with ethanol.Locust Bean gum has a wide potential in drug formulation due to their extensive application as food additives and their recognized lack of toxicity. It can be tailored made to suit the demands of applicants in both the pharmaceutical and biomedical areas. This group of polymers possesses a number of characteristics that makes it useful as a formulation aid, both as a conventional excipient and more specifically as a tool in polymeric- controlled drug delivery. It consists mainly of a neutral galactomanan polymer made up of 1, 4-linked D-mannopyronosyl units and every fourth or fifth chain unit is substituted on C6 with a D-galactopyranosylunit.The ratio of D-galactose to D-mannose and this is believed to be due to the varying origins of the gum materials and growth conditions of the plant during production[30].

The physico chemical properties of galactomanan are strongly influenced by the galactose content 41 and the distribution of the galactose units along the main chain.Longergalactose side chains produce stronger synergistic interactions with other polymers and greater functionality.Since it is a neutral polymer and its viscosity and solubility are therefore little affected by pH changes within the range of 3-11.

Various properties are there which make locust bean gum a good choice in drug delivery.

They are biocompatible, biosorbable and biodegradable in nature.

a. It is non-teratogenic and non-mutagenic according to Joint FAO/WHO Expert Committee on Food Additives held in Geneva, April'75.

b. Acceptable shelf-life.

c. Degradation products are excreted readily.

Locust bean gum has find a wide place in the preparation of mocoadhesive buccal tablets in combination with Chitosan in different combinations where the locust bean gum to chitosan ratios are 2:3, 3:2, 4:1. Vijayraghavan et al. prepared mocoadhesive buccal tablets of Propranolol HCl containing various weight ratios of Locust bean gum and Chitosan and coated it with 5% w/v Ethyl Cellulose[31].The mucoadhesive property of the formulation containing 2:3 was highest compared with other ones. Even its drug release profile was 98% in 60mins.Further bioavailability study was carried out taking sixteen healthy human volunteers. The bioavailability was highest for the formulation containing 2:3 of Locust bean gum to Chitosan. Therefore the study indicated that the locust bean gum along with Chitosan show a mucoadhesive property for buccal tablets[32].

CASHEW GUM

Cashew gum is the exudate from the stem bark of Anacardiumoccidentale Linn (family, Anarcardiaceae).The plant is native to Brazil and grows in many tropical and subtropical countries. In Ghana, the plant is found mostly in cashew growing areas such as Sampa, Wenchi, Bole, Jirapa and Ejura where they are commercially cultivated for the utilization of the nuts. Gums from cashew plants from various parts of Ghana are reported to possess the following physicochemical characteristics: moisture content (9.8 – 13.2 %), insoluble matter (1.9 – 4.8 %), total ash (0.5 – 1.2 %), protein content (1.27 – 1.80 %), total sugars (0.96 – 2.10 mg/g), and total phenols (0.21 – 2.26 %). Cashew gum is chemically composed of 61 % galactose, 14 % arabinose, 7 % rhamnose, 8 % glucose, 5 % glucuronic acid and < 2% other sugar residues 3,4 while hydrolysis of the gum yields L-arabinose,L-rhamnose,D-galactose and glucuronic acid. The gum has a highly branched galactan framework comprising of chanins of (1→3) linked β –D galactopyranosyl units interspersed with β-(1→6) linkages.[33] Cashew gum has been studied widely for various pharmaceutical applications as it is inexpensive, non toxic 5, 6 biodegradable, and possesses appropriate physicochemical characteristics. As cashew gum shares similar characteristics as gum Arabic, it has been suggested for use as an agglutinant for capsule and pills in place of gum Arabic in the pharmaceutical and cosmetic industries[34]. Cashew gum modified by carboxymethylation with monochloroacetic acid as etherifying agent was used to form polyelectrolyte complexes with chitosan for possible use in controlled drug delivery[35]. The gum was employed as a binder in lactose-based tablet of formulations containing tartrazine dye where the tablets produced were shown to exhibit good hardness and friability properties Cashew gum has also recently been utilized as a binder in paracetamol tablet formulations where the gum imparted better mechanical properties to the tablets than povidone or gelatin. The gum has been evaluated as a gelling agent in an aceclofenac topical gel formulation where the gel containing 5 % w/w cashew tree gum was found to be suitable for topical application based on its physicochemical properties[36]. Cashew nut tree gum is a polysaccharide comprising galactose, arabinose, rhamnose, glucose, glucurine acid and other sugar residues. It has been used as matrix former for controlled release tablet. Primarily cashew gum is used in industrial application for binding books, as adhesives for envelopes, label, stamps and posters[37].

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.Natural gums are promising biodegradable polymeric materials. Many studies has been carried out in fields including food technology and pharmaceuticals using gums and mucilages. Several

polymers from plant origin have been successfully used as excipient sustained release drug delivery. These semisynthetic polymers are extensively used in the formulation of conventional dosage forms.

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