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NATURAL POLYMER-BASED MICROBEADS FOR CONTROLLED DRUG DELIVERY: A COMPREHENSIVE REVIEW

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ABSTRACT

In recent times, there has been an increased search for new, safe, and sustainable alternatives to existing pharmaceutical excipients.This is because traditional pharmaceutical excipients synthesized in laboratories are considered toxic and pose adverse environmental concerns. Natural polymers have been considered promising materials for the preparation of pharmaceutical excipients in the form of microbeads for drug delivery. Microbeads are very fine, spherical, and multiparticulate formulations that can encapsulate drugs to release them in a controlled manner. This paper presents a comprehensive review of the recent developments in the production of microbeads based on natural polymers for medicinal application. It not only includes the information about other naturally produced copolymers such as tamarind seed polysaccharide, khaya gum, gum arabic, fenugreek seed mucilage, sweet potato starch, and kokilaksha seed mucilage, but it also encompasses the detail about other widely used natural polymers such as alginate, chitosan, gelatin, cellulose, chitin, and starch. Details about the physicochemical properties, methods of extraction, gelation properties, and applications of microbeads based on natural polymers are included. The method of microbead formulation, cross-linking processes, efficiency of encapsulation, and factors related to stability for pharmaceutical applications are also described. The applications and potential of microbeads made from natural polymers for their effectiveness in modern medicinal dosage systems are given emphasis.

KEYWORDS: Microbeads, Polymer, Extraction, Natural, Control, Crosslink.

INTRODUCTION

Excipients are defined as chemicals or compounds that affect the quality of the final product and are different from the active pharmaceutical ingredient and packaging materials. Due to the safety, nontoxicity, biocompatibility, lower cost, and greater accessibility of natural resources, industries are turning away from currently used synthetic excipients in pharmaceutics, which have a range of negative impacts. Excipients partially determine the status of medicines.[1] Some plant-derived pharmaceutical excipients are starch, agar, alginates, carrageen, guar gum, xanthan gum, gelatin, pectin, acacia, tragacanth, and cellulose. The pharmaceutical industry uses these as bases in suppositories, stabilizers, thickening agents, gelling agents, binding agents, disintegrates, sustaining agents, and coating materials.[2]

Recently, production of natural polymer-based multiparticulates has gained interest among researchers, including microspheres, microcapsules, and microbeads. These multiparticulates can evenly disperse on a larger area of the gastrointestinal tract, release drugs in a sustained/controlled manner, decrease exposure to higher drug concentrations, and they can pass easily throughout the digestive tract.[3] Natural polymers are nevertheless attractive due to several reasons such as cost-effectiveness, accessibility, capable of modification, and potentially biodegradable compatibility because of their natural origin.[4] Natural polymers are biodegradable in nature; hence, they can be safely used without causing any toxic effects for oral administration. Despite extensive use of synthetic polymers during the formulation of microbeads, preparation of natural biodegradable polymer-based systems for controlled drug delivery is still of interest.[6] Recently, some strong microbead systems using sodium alginate, LM pectin, tamarind gum, karaya gum, and other naturally occurring polymers have been developed as drug-delivery carriers.[7] Three-dimensional inter-related molecules have formed "gels" by most of these naturally occurring gums.[8] To address the unique requirements of drug formulators and broaden the scope of innovative drug delivery systems, it is crucial to find and design novel polymers.[9]

Microbeads have a diameter of 1000µm and are close to being spherical in shape. What renders a sustained release or multiple release of treatment with different active substances possible without any serious side reactions is a solid and freely flowing-carrier substance containing dispersed drug particles either in solution or in crystalline form. Various polymers, such as cationic polymers, are employed for making microbeads.[10] In order to guarantee restored amounts to be attained at a designated site with a reduced effect on systemic attention to avoid bad goods, they can also be altered to incorporate details and deliver them at a higher attention.[11]

This article will discuss the ongoing developments in the formulation of microbeads employing natural polymers based upon the latest developments within the physicochemical characteristics and manufacturing techniques of microbeads used in drug delivery systems. In an effort to encourage more research towards the development of better drug delivery systems, it shall touch upon the latest developments in overcoming the challenges pertaining to encapsulation efficiency and microbeads stability.[12]

Natural polymer used in microbeads

Alginate

Alginates are bio-tides, which come from brown seaweeds. It is a method for delivering drugs under a highly regulated condition. The large quantity of carotenoid pigments, fucoxanthin, present in chloroplasts gives brown algae, a multicellular organism, its green-brown hue.Brown algae belong to multicellular organisms and attain a length of 60 meters. They are mostly found in the sea.Specific bacteria, such as Azotobacter vinelandii, Pseudomonas aeruginosa,

and Pseudomonas fluorescens, have been known to synthesize alginates extracellularly.[13] Block polymers, alginates, made of mannuronic acid, glucuronic acid, and mannuronic-glucuronic blocks, can be defined this way. Both homopolymeric and heteropolymeric blocks carry these units. Adding polyvalent and divalent ions, Ca2+, to alginate solutions leads to cross-linkages, ultimately forming alginate gel. In alginate, a matrix for a controlled release, there are a variety of specific properties. These properties are dissolution and BROZE breakdown in normal physiology, a relatively inactive aqueous environment, and a highly porous matrix, allowing easy diffusion.[14]

Chitosan

A widely used polysaccharide biomaterial, chitosan is prepared by deacetylating chitin, and it consists of β-(1–4)-2-acetamido-2-deoxy-β-d-glucopyranose and 2-amino-2-deoxy-β-d-glucopyranose. Its pKa value lies in the range from 6.3 to 6.5. Due to its non-mammalian origin, biocompatibility, degradability, and antibacterial properties, much attention has been given to chitosan. The antibacterial activity of chitosan was attributed to its positive surface charge given by the amino groups of the glucosamine monomer at pH < 6.3, which allows interaction with negatively charged microbial cell membranes to take place and consequently causes internal components to flow out. Due to the low mechanical strength and limited chain flexibility of chitosan, many techniques have been developed for its modification, such as crosslinking, grafting, and mixing, in order to extend its applications. Recently, food science has made intensive use of chitosan and its derivatives. One of the interesting applications of using chitosan as a food-grade excipient covers the area of encapsulation technique. The encapsulated elements, such as bioactive compounds, additives, or flavors, are protected by chitosan matrices, which also control their external release, reduce their toxicity,and provide targeted distribution following absorption from the gastrointestinal (GI) tract.These properties of chitosan, including its mucoadhesive properties, penetration properties, propensity for easy modification, and biocompatibility, contribute greatly to its benefits. Also, since electrostatic interactions between chitosan and anionic compounds are the major driving forces in the case of chitosan-based encapsulation systems, the basic nature of chitosan in an acidic environment could possibly ensure easier preparation of capsules for nutritional purposes. However, in recent times, there has been an increasing trend of applications of chitosan-based hydrogel beads in agriculture owing to their abundance, economy, and abundance of amino and hydroxyl functional groups. Adsorbent-capable uses in the treatment of effluents and fertilizer, herbicide, and micronutrient delivery have already proved fruitful.[15]

However, the versatility of the raw chitosan is limited due to its ability to dissolve in a dilute acid solution. Also, the application of the chitosan is made more difficult by some limitations, including its lack of strength, thermal Sta Resistor, and selectivity of adsorption. Based on the optimised form for a given purpose, the raw chitosan could have been altered physically in different ways, including powder, flake, and finally, the hydrogel form, in the likes of beads, membrane, and film, respectively. However, some shortcomings exist in the application of chitosan as an adsorbent in its bead, flake, and powder forms, in terms of its low ability for adsorption owing to its crystal form. Ad erosion can however occur on the amorphous part of its crystals, hence limiting their ability for adsorption. Prepared chitosan could act as an alternative in the form of hydrogel beads, improving on porosity, size of the polymer, surface area, degree of crystallinity, and accessibility of the sorption sites, among other factors, in addition to having an advantage of easy preparation and high capacity.[16]

Gelatin

One of the most popular and widely researched natural polymers is gelatin. A denatured version of collagen, a protein/polypeptide, has been prepared in a number of fashions for a variety of applications. Gelatin-cross-linked hydrogel beads have been successfully designed and fabricated for matrices with controlled or sustained release, particularly for molecules sensitive to the environment, such as a number of growth factors utilized in various medical applications. The application of gelatin matrices in these types of biomedical applications has a number of advantages. Gelatin represents a hydrolyzed form of endogenous collagen that is readily absorbed in the body, highly biocompatible, and moderately inexpensive. Matrices of gelatin can be easily cast and then cross-linked at different levels (means) with different cross-linking densities to produce hydrogels. These hydrogels swell in water fairly rapidly and absorb the aqueous surrounding phase with its contents, thereby easily enabling their loading with very high loading efficiencies (close to 100%) of water-soluble materials under very mild conditions without inactivating biological molecules such as growth factors.[17]

Cellulose

Cellulose demonstrates the richest amount and naturalness of all polymers, making up 1.5 × 10^12 tons of cellulose annually for total biomass for green and biologically compatible materials. Cellulose has a number of sources, including various species such as plants, algae, and bacteria that make up the most widely available biopolymer in nature. Cellulose is an important part of plant cell walls and has been broadly used in making pulp, paper, and textiles. In addition to that, other marine life such as tunicates that produce “tunicin,” a cellulose variation, also take part in cellulose production.In vitro enzymatic processing and biological processing of algae, fungus, and various non-pathogenic bacteria such as Agrobacterium, Sarcina, Rhizobium, and Acetobacter are some of the ways that cellulose is produced in industry. Cotton fiber, coniferous wood fiber, date palm fiber, straw fiber, sugarcane bagasse fiber, hemp fiber, jute fiber, banana fiber, kenaf fiber, ramie fiber, and sisal fiber are to name a few of the cellulose sources that are harvestable from various plant materials for cellulose production that are further used to produce fibers, beads, membranes, films, sponges, aerogels, hydrogels, and other cellulose derivatives in different cellulose form variations.Moreover, cellulose possesses outstanding properties such as availability, biodegradability, nontoxicity, renewability, durability, and biocompatibility. From a structural perspective, cellulose is one of the linear homopolymers with the chemical formula $(C_6H_{10}O_5)_n$, comprising β-(1 → 4) glycosidic units linking d-glucopyranose moieties (Fig. 1). Every unit of cellulose typically consists of three different hydroxyl groups on carbons 2, 3, and 6. The presence of hydroxyl groups in cellulose imparts hydrophilic characteristics to it, and its primary hydroxyl group on carbon 6 is said to be more reactive than the hydroxyl groups on carbons 2 and 3.Because of these reactive hydroxyl groups, cellulose can be easily modified by grafting different types of functions onto its surface or by incorporating it with both organic and inorganic materials. Depending on the intended application, the modification of cellulose improves either the properties of the final product or imparts new properties in it. Functional materials based on cellulose are thus a perfect candidate for applications in various fields, including but not limited to air filtration, food packaging, medical, desalination, wastewater, and agriculture.[18]

Chitin

Chitin is an important class of naturally occurring hydrophilic polymers that have already found uses in the preparation of microspheres, mainly due to its beneficent properties in biological systems. Moreover, chitin, a naturally occurring polysaccharide with a repeating unit constituted by 1, 4-N-acetylglucosamine, can be converted into a suitable

derivative with superior properties, which might help to sustain the usage of CMs in a specified domain such as tissue engineering and wound repair. The limited solubility properties of chitin, especially due to its complex hydrogen bond networks and crystalline regions, limit the preparation of CMs. Some established solvents presently being utilized for microsphere synthesis are ionic liquids, alkali/urea aqueous solutions, and lithium chloride/polar solvent solutions. Several microspheres have already been synthesized from these systems by researchers, thereby largely widening their applications within diverse industries.[19]

Natural copolymer extracted from natural ingredient

Tamarind seed polysaccharide

Tamarind seed polysaccharide or TSP is the seed kernel of the native South East Asian and Indian plant Tamarindus indica. It is a polysaccharide comprising a substituent (1→4)-b-d-glucan backbone with side chains of a-d-xylopyranose and b-dgalactopyranosyl (1→2)-a-d-xylopyranose linked (1→6) to glucose residues. The ratio of glucose, xylose and galactose units is 2.8: 2.25: 1.0. The TSP is biocompatible, mucoadhesive, and noncarcinogenic. It has a wide pH tolerance and a high viscosity. In food and pharmaceutical industries, it works as a stabilizer, thickener, gelling agent, and binder. A tamarind seed mainly comprises the seed coat and kernel. Crude fiber and tannins are the major composition of seed coat that constitute about 28.6% of the total mass of the seed. On the contrary, the major constituent of seed kernel is 15–20% protein, 6–8% fat, and 65–73% non-starch polysaccharide.[20]

Isolation of Tamarind seed polysaccharide

To remove the sticky materials, Tamarindus indica seeds were washed with water. Then, to remove the testa, which is the reddish part, the Tamarindus indica seeds were boiled in an equal ratio of 1:4 (Seed to Sand). The testa came out. Then, they crushed the Tamarindus indica seeds. To release the mucilage in the water, they steeped the crushed Tamarindus indica seeds in separate containers filled with water for 24 hours, heated it for an hour, and left it to stand for two hours. Marc was extracted from the filtrate by squeezing it inside a cotton bag soaked with Marc. Then, they added an equal amount of acetone to make the mucilage precipitate. They isolated the mucilage. Then, after being isolated, they dried it in a temperature of 50°C, powdered it, and screened it using sieve number 80. Dried powdered mucilage was stored in an airtight container in room temperature.[21]

Khaya gum

The notched trunk of Khaya grandifolia (Meliaceae), a common west African mahogany, native to Western Nigeria, is a source of khaya gum. This has been shown to have adhesive properties, and studies have been undertaken to determine whether it can be employed as an adhesive and a copolymer in the production of microbeads.[22]

Extraction and purification of Khaya senegalensis gum

The khaya gum extraction was carried out using the procedure proposed by Ofori-Kwakye et al. To put this briefly, a kilogram of dried crude Khaya senegalensis exudate was reduced, macerated with double strength chloroform and water, and allowed to stand with intermittent stirring for a total of 120 hours. To remove any suspended impurities, the khaya gum mucilage was pressed using a muslin cloth. The khaya mucilage was then precipitated using absolute ethanol. Subsequent to that, the khaya mucilage was collected, washed with diethyl ether twice, and drying took place for 24 hours at 40°C in a hot air oven (Uniscope SM9053, England). The obtained khaya gum was also dried for 24 hours at 40°C. After grinding using a pestle and a mortar for the drying khaya gum, the khaya gum powder was passed through a 210 µm sieve. Finally, the khaya powder was stored in a tightly sealed container for use when needed.[23]

Gum arabic

Gum Arabic is a natural gum obtained from the Acacia Senegal tree, which is biodegradable and biocompatible. In the food sector, it has been widely used for its role in acting as an emulsifier, thickening agent, and stabilizer. Owing to its properties like high solubility, non-toxicity, pH stability, and ability to form a gel, gum Arabic is increasingly finding applications in the pharmaceutical sector. Gum Arabic is an intricate, highly branched polymer formed by a combination of calcium, magnesium, and potassium salts of the polysaccharidic acid. The primary chain is based on units of 1,3-linked β-d-galactopyranoses, and its side chain is established by 1,6-linkages between the units comprising two to five 1,3-linked β-d-galactopyranoses. α-arabinofuranosyl, α-rhamnopyronosyl, β-glucuronopyranosyl, and 4-O-methyl-β-glucuronopyranosyl units form the primary and side chains.[24]

Extraction Process

By using sieving, vibration, and air flow machines, the crude gum nodules are purified in order to eliminate any adulterating materials present in them, such as sand, bark, and/or soil. To increase its surface area for easier solubility, the purified nodules are broken down further into pieces/larger particles/powder form using jaw-crushers, hammer mill machines, and/or pulverizers. Heating the solution obtained after dissolving in water (1:7-9) at 45-55°C and using protective agents, it is further heated at 70-80°C for 6-10 hours.[25]

Sweet potato starch

In many underdeveloped countries, sweet potato (Ipomea batatas) is an important crop. Although it is native to Central America, the sweet potato can also grow in Africa, Asia, and America because it can withstand various climatic conditions. The amount of starch in sweet potato is high (6.9-30.7% on wet basis), and its chief industrial application is in starchy production. It is also mentioned that sweet potato starch granules are between 2 to 42 cm in size and are circular, oval, and polygonal in shape. Amylose content in sweet potato starch varies between 8.5 to 38%. Sweet potato starches are less soluble and less swollen when compared to potato and cassava starch. Various sweet potato starches show single-stage and two-stage swelling. Sweet potato starchy gels are said to have an enthalpy value between 58-84°C, whereas its value is 10.0 to 16.3 J/g.On pasting, sweet potato starch has high peak viscosity, which quickly decreases in consistency when boiled for prolonged periods to form a thick mass when cooled. Although sweet potato starch takes longer to retrograde than wheat and corn starches, its retrogradation is almost similar to that of potato starch. Though sweet potato amylose takes longer to retrograde than potato amylase, it appears to retrograde similarly to tapioca amylose. On the other hand, it takes longer for sweet potato amylopectin to retrograde than tapioca amylopectin, and it takes longer for sweet potato amylose to retrograde than tapioca amylose.[26]

Extraction

A kilogram of potatoes was thoroughly cleaned using water from the tap, dried, and then pressed using a juice presser (Moulinex). The cell wall material is separated by filtering the remainder through a sieve with a mesh size of 125lm, and 1 L of water from the tap is added. A total of two liters is added to the residue paste of starch. The mixture is allowed to settle for thirty minutes after adding a further 2mL of a solution of sodium bisulphate, which is 38-40%. The starch pellet is then allowed to settle for thirty minutes after washing it twice using one liter of water from the tap. Finally, the starch is allowed to dry overnight on a piece of filter paper at room temperature.[27]

Kokilaksha seed mucilage

Asteracantha longifolia (also known as Hygrophila auriculata) giveskokilaksha seed mucilage used as a bio-polymer to make sustained release microbeads. Kokilaksha in Unani medicine, also called Talimakhana, gives seeds that have mucilage. It also has binding properties. Its mucilage is used as a pharmaceutical. Like other seed mucilages, it is used in drug swelling and controlled release.

Extraction of mucilage Kokilaksha seed

Hygrophila auriculata seeds, weighing about 100 grams, were soaked in distilled water, heated at 60 degrees Celsius for one hour, and then left at room temperature for one entire day. The muslin fabric acted as a filter for the extracted mucilage. This mucilage was then cooled until needed. Subsequently, equal amounts of ethanol were added, and the contents were stirred well at room temperature to enable the formation of mucilage. After straining out the mucilage, it was dried in the oven at 50°C. Thereafter, the mucilage was crushed, sieved (#60), and freed-flowing powder 23-24 was obtained. This powder was used as the final product to make microbeads.[28]

Fenugreek seed mucilage

A (1→ 4) β-D-mannan backbone comprises the seed mucilage, which falls under the category of galactomannans. The ratio of D-galactose to D-mannose is either 1:1 or 1:1.2, as it contains α-D-galactopyranosyl groups that are linked to the O-6 position of the D-mannopyranosyl residues. Except for mannose and galactose, trace quantities of other sugars are also present in the mucilage.[29] The plant named Fenugreek, Trigonella Foenum-Graecum L., occurs universally, and it belongs to the family Leguminosae.The Trigonella Foenum-Graecum plant has leaves with long stalks, and they are about 5 cm long. The lanceolate, triangular stipues and leaflets are obovate to obanceolate, measuring about 2.5 cm. Steroidal sapogenins are one among several chemical constituents of Fenugreek.The oily embryo in Fenugreek contains a diosgenin constituent. Fenugreek contains two furastanol glycosides and hederagin glycosides, F-ring opening diosgenin precursors, one of which has been proved cultivar-specific.Fenugreek seed contains one special constituent, that being the mucilage component. The stem holds about 28% mucilage, volatile oil, two alkaloids, trigonelline, and choline, 5% fixed oil with a stronger aroma and bitter taste, 22% protein, and a yellow-dye material, a coloring substance named Grieve, in 1984.23–26% protein, 6–7% fat, and 58% carbohydrates—of which roughly 25% are dietary fiber—are found in fenugreek.[30]

Extraction Method of Fenugreek

The powder of fenugreek seeds crushed to 100 mg was added to 500 ml of double-distilled water and cooked in a water bath at 800 degrees Celsius for four hours in a stirred condition. After getting the thick mass, it was kept at room temperature in a stirred condition for four hours, and was then allowed below 200 degrees for the whole night.(c). Muslin cloth was used for separating the aqueous mucilage. Then, with the help of 300 milliliters of alcohol, mucilage precipitate was formed. Again, this precipitated mucilage was filtered using muslin cloth. To dehydrate the isolated mucilage, 200 milliliters of acetone were utilized. In addition to this, it also helps in removing oil extract that may be present in aqueous mucilage. The filtrate precipitated substance was dried for 12 hours in a hot air oven at 500 degrees Celsius. After drying, it was crushed in a consistent powder by a mortar and pestle and was passed through a sieve of mesh #60. Dried mucilage obtained was subjected to a pharmacotechnical analysis in order to compare and assess its potentiality as a controlled release polymer.[31]

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