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Natural Polymers In The Development Of Gastroretentive Systems: A Review

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Abstract

The current review is prepared with the prime intention of presenting potential natural polymers used in gastroretentive drug delivery systems (GRDDS), as well as their features, current research, future development trends, and applications in gastroretentive systems. Natural polymers currently are used in numerous industrial applications such as medicine, agriculture, and other disciplines are rising rapidly. The use of natural excipients in the pharmaceutical field has been seen to increase as they are safe, nontoxic, biodegradable, biocompatible, ecofriendly etc. Again these polymers tend to excrete very easily from the body without altering the normal physiological mechanisms. Various natural polymers are used to enable drug delivery systems remain further as drug carriers, to attain the objective of boosting therapeutic efficacy and bioavailability. Natural gastroretentive excipients are very useful for drugs having narrow therapeutic index like itopride, carvedilol and glipizide to ameliorate their residence in stomach for maximum duration of time. Long time residence of drug in stomach enhances its dissolution, absorption and ultimately the bioavailability. Natural polymers are provides gastric retention through various mechanisms like low density approach, high density approach, mucoadhesive system, swellable system etc. Natural polymers' physical properties aid in their long-term swelling and mucoadhesive properties. As a result, natural polymers, like synthetic or semi-synthetic polymers, are potential sources of GRDDS.

Key words: Gastroretentive System, Gastric fluid, Mucoadhesive, Natural Polymers, Residence time

1. Introduction

Natural polymers and their derivatives are routinely used for the production of newer dosage forms due to their compatibility with other materials, biodegradability, and chemical modification ability. Synthetic excipients induce undesired side effects in humans, hence natural polymers are favored. Herbal remedies are becoming increasingly safer to use, thus patients and researchers are looking for natural ingredients rather than synthetic or semi-synthetic polymers. [1]

According to several studies it is observed that the physiochemical characteristics of natural polymers, their morphology, release behavior, dosage form shape and particle size influence drug release pattern in many cases. [1] Natural polymers are advantageous because of their demonstrated biocompatibility and safety. The polysaccharides chitosan, xanthan gum, and guar gum, which seem to be cationic, anionic, and nonionic agents respectively, have garnered special attention in this regard.[2] Natural gums are one of the most widely used hydrophilic polymers due to their low cost and regulatory acceptability. Natural polymers have advantageous features and are thus used in the pharmaceutical and biomedical industries. [3] Xanthan Gum, Guar Gum, and Chitosan are common natural polymers utilized in floating drug delivery systems. The floating tablets made from synthetic polymers have floating qualities, but they don't support cell adhesion or tissue formation in the majority of cases. Natural polymer-based floating systems, on the other hand, are biologically friendly, biodegradable, and support a variety of cellular activities. Swellability, non-toxicity, and modifiability

are all advantages of natural excipients. Derivatization of natural polymers through grafting, complexation, and crosslinking has a lot of potential for achieving the research goal. [4]

Table 1: Natural polymers vs synthetic polymers

Sr. No.	Natural polymers	Synthetic polymers
1	Found naturally in the environment.	Produced artificially by human.
2	Produced from biological processes.	Produced by various chemical processes.
3	Very easy to degradation in-vivo.	Very difficult to degradation in-vivo.
4	Generally they are less toxic and safe.	They may cause toxic effect in body.
5	Free from chemical processes; thus non-carcinogenic.	Involve chemical processes; thus may be carcinogenic.
6	Most of the natural polymers are compatible to gastric fluid (0.1N HCl).	Some of the synthetic polymers cause chemical interaction with gastric fluid (0.1N HCl).
7	Processing is ecofriendly.	Processing is non-ecofriendly.
8	Easily available.	Not easily available.
9	Economically cheaper.	Economically costly.

Natural gums are used as suspending agents, binders, disintegrants, swelling agents, emulsifiers and mucoadhesives, among other things. They can also be used to make formulations for both prolonged and quick release. [5] Gastroretentive drug delivery systems (GRDDS) come in a variety of forms, including effervescent, non-effervescent, mucoadhesive, raft forming, low-density, and high-density systems. These systems float or adhere to the stomach mucous membrane for longer periods of time without altering gastric emptying rates because their density is lower than gastric fluid (1.004 g/cm^3). When the system floats or adheres the mucosa of stomach region, the drug dissolves and enters solely in solution form into the duodenum, which has a bigger surface area and thus allows for more drug absorption.These system's main events are well-controlled changes in plasma drug concentration, especially for medicines with a narrow therapeutic index and a longer gastric residence time. [6]

1.1 Criteria for GRDDS

1. **Local effect**

   Drugs that have local effect in the stomach could be selected as ideal candidates for gastroretentive drug delivery systems.

   e.g. Antacids, Misoprostol etc.

2. **Narrow absorption window**

   Drugs that shows very slow or no absorption from small or large intestine but better absorption specifically from stomach are selected.

   e.g. Riboflavin, Furosemide etc.

3. **pH sensitive drugs**

Some drugs are unstable in small / large intestine or colon. Such drugs at higher pH conditions undergo ionisation or get degraded and ultimately their absorption and bioavailability decreases. e.g. Metronidazole, Captopril.

4. **Colonic microflora destructing drugs**

Some drugs may disrupt the usual microflora of the colon which may affect the normal physiology of the digestive system which furthermore alters the absorption of many drugs as well as various nutrients from the meal.

e.g. several antibiotics.

5. **Low-solubility at higher pH**

Some drugs shows very low solubility in alkaline pH environment and hence insoluble drug is very difficult to absorb in to systemic circulation.

e.g. Chlordiazepoxide, Verapamil HCl.[7, 8]

1.2 Merits of GRDDS

a. Enhanced bioavailability

Due to longer retention of medicine in stomach, drugs with low lipophilicity are absorbed more thoroughly, increases the bioavailability.

b. Reduced dosing frequency

Drugs having short elimination half-life are generally designed as sustained or controlled types of dosage forms. Such formulations alter the dosage regimen in such a way that the dosing frequency can be reduced.

c. Less fluctuations of drug level

In stomach uniform pH is maintained; thus drug release takes place uniformly which ultimately maintains the plasma concentration of drug in therapeutic range for longer duration. Such behaviour of drug in stomach achieves very less fluctuation of drug concentration in blood.

d. Reduced counter-activity of the body

When a treatment response interferes with normal physiological processes, the body often responds by reducing medication activity through rebound activity. It has been established that slowing the drug's entry into the body reduces counter-activity, resulting in increased pharmacological efficacy.

e. Reduced undesirable activity at colon

The amount of medicine reaching the colon is reduced when the drug is retained in the GRDDS at the stomach. As a result, the drug's unwanted effects in the colon may be avoided. This pharmacodynamics feature explains why GRDDS was developed for beta-lactam antibiotics. Such antibiotics should only be absorbed from small intestine. Their retention in colonic region may cause resistance due to microorganisms.

f. Site specific drug delivery

Certain drugs are better absorbed from upper gastrointestinal tract. GRDDS offers a very popular system for such types of drugs. The controlled, gradual distribution of the medicine in stomach ensures enough local therapeutic levels while limiting the drug's systemic exposure.The

drug's adverse effects in the blood circulation are reduced as a result. Furthermore, a site guided delivery system's longer stomach availability may lower dose frequency.[9]

1.3 Demerits of GRDDS

a. Contradictory with medications that have a low acid solubility. E.g. Phenytoin.
b. It is unsuitable to acid labile drug molecules. E.g. Erythromycin.
c. Slow-release drugs that irritate or induce stomach lesions. E.g. Aspirin & nonsteroidal anti-inflammatory drugs (NSAID's).
d. It is unsuitable to drugs having absorption window primarily from the colon. E.g. Corticosteroid.
e. It is unsuitable to drugs which are as well absorbed by the entire GI tract. E.g. Isosorbide dinitrate, Nifidipine.
f. Enough gastric fluid is required to float the dosage form.[9]

2. Approaches to GRDDS

Most commonly used approaches to GRDDS are mentioned in fig. 1.

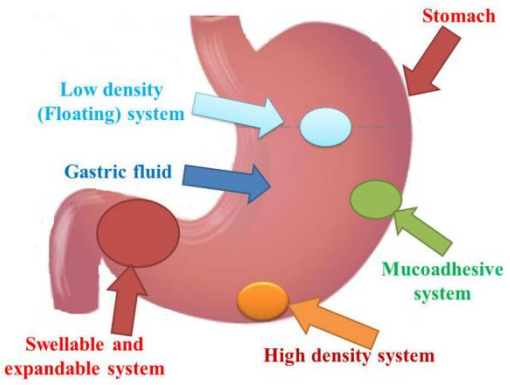

Fig. 1: Approaches to enhance GI transit

2.1 Low density (Floating) system

One of the most essential techniques to achieving stomach retention and appropriate drug bioavailability is to use floating device. Dosage form should have less bulk density than that of the gastric fluids (1.004–1.001 gm/cm^3), so that it can float on gastric fluid for entire duration of therapy, and the medicine is released slowly with a controlled rate. [10]

2.2 High density (Non-floating) system

This method entails creating dose forms with a density greater than that of gastric fluid (1.004 gm/cm^3). In this system heavy core of the inert ingredients like barium sulphate, iron powder, zinc oxide, and titanium oxide is coated with or well mixed as matrix with the drug powder. This attains the density of the dosage form up to 1.5-2.4 gm/cm^3. To achieve longer retention of formulation in the stomach, it should have the density at least 2.5 gm/cm^3. However, the efficiency of this system in humans has yet to be determined, and so no system has been commercialised. [11]

2.3 Mucoadhesive system

Bioadhesive drug delivery systems are utilised to ameliorate the absorption of drug from particular site in the human body. Bioadhesive polymers stick to the mucosal surface lining of stomach

which result in increase in contact time of dosage form to the stomach. Various mechanisms of mucoadhesion are based on diffusion theory, wetting theory, electron theory and absorption theory. [12]

The examples of mucoadhesive polymers used are chitosan, polyacrylic acid cholestyramine etc. [13, 14]

2.4 Swellable and expandable system

In swellable and expandable type of system, the dosage form is designed in such a way that its size is small enough to administer through oral route but once it reaches the stomach, it imbibe surround gastric fluid and swells; thus its size is expanded and will be difficult to move on through the pyloric sphincter. This improves the residence time of formulation in stomach. [15, 16] Fig. 2 depicts a typical swellable and expandable system mechanism.

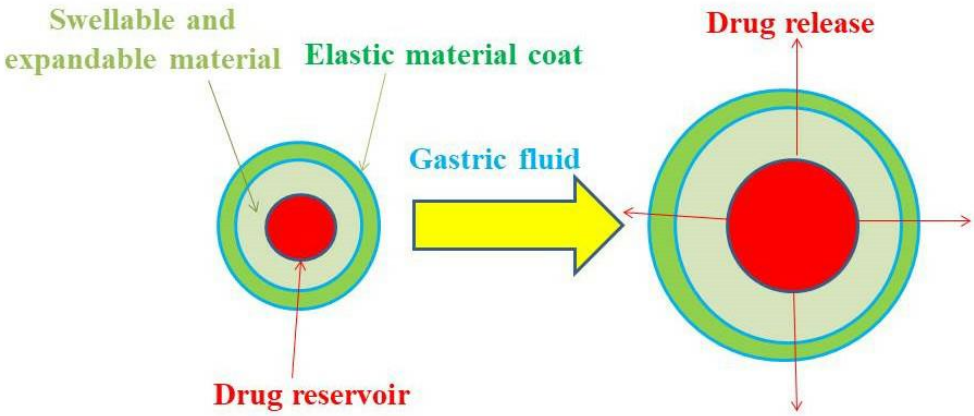

Fig. 2: Drug release from swellable system

2.5 Effervescent (gas generating) systems

These methods fall into the low density category because they allow the dosage form to float on gastric fluid due to CO_2 effervescence. The effervescent agents used in this system are citric acid, tartaric acid, sodium bicarbonate etc. CO_2 is released by the reaction of these effervescent agents with water molecule in gastric fluid, which results in to floating of formulation on gastric fluid. [17] The common mechanism of effervescent system is well explained in fig. 3.

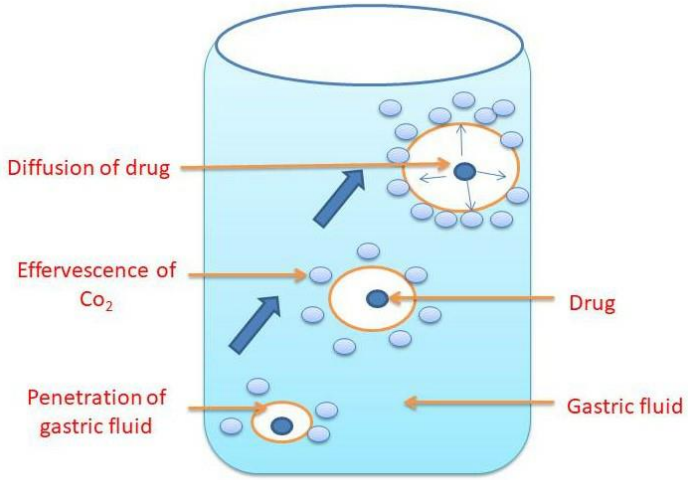

Fig. 3: Effervescent (gas generating) systems

3. Potential natural polymers for GRDDS

Plant-based polymers are naturally available and can be made into natural polymers. They have no negative effects on humans. Because these plant components are high in carbohydrates, most natural polymers are non-toxic, non-irritant, and biocompatible.Natural polymers are extracted from natural sources using organic solvents and can be gathered in big numbers at minimal cost over different seasons. Because of its widespread use in industries, developing countries' productions are now being encouraged.Variable species have different percentage yields and contents in natural materials, as well as variances in seasonal collection from various regions and at various seasons. They have very low manufacturing rate. [18] Table 1 shows various commonly used natural polymers in GRDDS.

Table 2: Natural polymers in GRDDS

Sr. No.	Natural polymers	Applications in GRDDS
1.	*Locust Bean Gum* (LBG)	Swelling agent, Mucoadhesive, Sustained effect
2.	*Colocasia esculenta gum*	Swelling agent, Mucoadhesive, Sustained effect
3.	Psyllium husk	Swelling agent, Sustained effect
4.	Gum karaya	Swelling agent, Mucoadhesive, Sustained effect
5.	Guar gum	Swelling agent, Mucoadhesive, Sustained effect
6.	*Limonia acidissima* gum	Swelling agent, Mucoadhesive, Sustained effect
7.	*Mimosa pudica gum*	Swelling agent, Mucoadhesive, Sustained effect
8.	Okra gum	Swelling agent, Mucoadhesive, Sustained effect
9.	Tamarind gum	Swelling agent, Mucoadhesive, Sustained effect
10.	Tara gum	Swelling agent, Mucoadhesive, Sustained effect
11.	Xanthan gum	Swelling agent, Mucoadhesive, Sustained effect
12.	Carrageenan	Swelling agent, Sustained effect
13.	Chitosan	Swelling agent, Sustained effect
14.	Pectin	Swelling agent, Sustained effect
15.	Peanut husk powder	Low density excipient

3.1 *Locust Bean Gum* (LBG)

It is commonly known as Carob bean gum which is obtained from the seeds of the *Ceratonia silique* Linn a leguminous plant. LBG is composed of a neutral galactomannan polymer. It contains D-galactose and D-mannose and their proportions vary based on the sources of raw gum materials and the plant's development conditions throughout manufacture. LBG is a more effective gelling, stabilising, and thickening agent, with numerous pharmaceutical applications in the formulation and development of newer drug delivery systems. [19, 20]

3.2 *Colocasia esculenta gum*

Colocasia esculenta is a plant in the Araceae family that is frequently cultivated in Southeast Asia's tropical climates. Underground tubers (corns and cormels) have high glucose content. When water comes into touch with the mucilage of Colocasia tubers, it quickly hydrates and expands.Mucilage from isolated tubers has long-term releasing characteristics and is ideal for use as a swelling polymer in various GRDDS. [21]

3.3 Psyllium husk

Psyllium is made from the plant *Plantago psyllium*, as well as the husk and seed of *Plantago ovata*. Because of its propensity to create a strong gel in water, psyllium is categorised as a mucilaginous fibre. Biocompatible, inert, swellable, biodegradable, affordable, and widely available, psyllium husk is a good choice. Sterols; unsaturated fatty acids ranging from 5 to 10 % lipids, minute quantity alkaloids, 15 to 18 % proteins, trisaccharide, carbohydrate- splanteose, and 10 to 12 % heteroxylan mucilage are all found in the seed. Because of its release retardant qualities, psyllium husk is a reliable source of GRDDS.Long-term retention of dose forms in the stomach has also been studied. [22]

3.4 Gum karaya

Gum Karaya is obtained from *Sterculia urens* belonging to family Sterculiaceae. Gum Karaya upon acid hydrolysis usually yields D-galacturonic acid, D-galactose and L-rhamnose as principle constituents. It is only marginally soluble in water, 0.1 N HCl, and gastric fluid and slightly insoluble in 95 % ethanol. As gum Karaya has ability to swells in presence of water, it is employed as drug release modifier in many formulations. It has a high rate of erosion and a low hydration capacity. Zero-order drug release is being investigated, as well as matrices erosion. [23]

3.5 Guar gum

It is collected from the dried kernels of *Cyamopsis tetragonolobus* and belongs to the Leguminosae family. Guar gum is recognised by various synonyms such as Cluster bean, Guaran, Calcutta lucerne, Cyamopsis and Guarina. [24] Its a whitish-yellow powder with no odour or taste. Guar gum is water soluble but insoluble in organic solvents. It has the capacity to improve viscosity and is utilised in pharmaceutical industries as a disintegrating agent and binder in tablets. [25]

3.6 *Limonia acidissima gum*

Gum of *Limonia acidissima* (Rutaceae), often known as wood apple or elephant apple, is a tropical and subtropical tree widespread throughout India. Mucilage is a carbohydrate-rich mucilage derived from tree trunks. When mucilage comes into contact with water, it quickly hydrates and expands.Isolated stem mucilage with long-term releasing characteristics and mucilage suited for use as a swelling polymer in various GRDDS. [26]

3.7 *Mimosa pudica gum*

Mimosa pudica (Mimosaceae), often known as sensitive plant, is a tropical and subtropical undershrub that can be found throughout India. When water comes into touch with mimosa seed mucilage, it hydrates and expands quickly.Using diclofenac sodium as a model medication and mucilage suited for various GRDDS as a swelling and mucoadhesive polymer, the isolated seed mucilage with sustained release capabilities was developed.[27]

3.8 Okra gum

Okra gum is obtained from the pods of *Hibiscus esculentus*. At low concentration, it produces highly viscous mucilage. It is a type of polysaccharide with a hydrophilic character that is now employed as a swellable polymer in various formulations. Okra gum is a tablet binding material that comprises several polysaccharides such as galactose, rhamnose and galacturonic acid. It is used to make tablets with superior friability, hardness, and drug release characteristics. It is more advantageous than various commercial synthetic polymers since it is safe, biodegradable, chemically inert, non-irritant, eco-friendly, and biocompatible. It is also commonly collected and no toxicological testing is required. Okra gum is used as a release rate modifier in several sustained and controlled release products. [23]

3.9 Tamarind gum

Tamarind is a kind of xyloglucan that comes from the tamarind tree seeds, which belongs to the *Tamarindus indica* family. It is a polysaccharide with a 1:2:3 ratios of galactosyl, xylosyl, and glucosyl. In the pharmaceutical and food sectors, xyloglucan, a key structural polysaccharide found in higher plant main cell walls, is employed as a binder, gel-forming agent, stabiliser, and thickening.Wet granulation technique is used to test the drug release characteristics of tamarind gums utilised in the formulation of matrix tablets. In the production of tablets, several polymer concentrations are used. Increased polymer content leads to a decrease in medication release.[20]

3.10 Tara gum

Tara gum is made from the *Caesalpinia spinosa* seeds endosperm and comes from the Leguminosae family. Tara gum is a white powder with no odour. At a concentration of 1 percent, galactose to mannose (1:3), it results in highly viscous solution. Tara gum is used in the pharmaceutical industry to make gastroretentive controlled release tablets and emulsions for medications such glipizide, carvedilol, metformin hydrochloride, clozapine, and ciprofloxacin hydrochloride, and itopride is a patent claim.Tara gum, when combined with other ingredients, has a good gastroretentive effect and enhances the floating time of the dosage form. It is also used to make an emulsion. [20]

3.11 Xanthan gum

Xanthan gum was spontaneously synthesised by the bacteria *Xanthomonas campestris*. This gum comes in the form of a fine powder or cream that is odourless and free-flowing. This gum contains a stable polysaccharide with a D-glucose backbone similar to that of cellulose. The aqueous solution is stable at wide range of pH (3–12) and temperatures of 10–60 °C in the presence of enzymes, bases, salts, and acids.It's utilised in cosmetics and food goods, as well as oral and topical preparations, because it's non-toxic and non-irritating. It's also employed as a thickening agent, stabilising agent, gelling agent, viscosity modifier, suspending agent, and emulsifier. [25]

3.12 Carrageenan

Carrageenan is an anionic gel-forming polysaccharide having high molecular weight. It is isolated from red seaweed species like *Euchema*, *Gigartina stellate* etc. Is a naturally occurring repeating unit of galactose and 3, 6-anhydrogalactose. Carrageenan is divided into 3 forms based on the degree of sulfation: carrageenan (three-sulfate), carrageenan (di-sulfate), and carrageenan (non-sulfate or monosulfate). They have thickening and release modifying properties. [11] The functional qualities of the carrageenan like bulking, thickening, stabilising and gelling are highly popular choice

in food industries. It showed to be beneficial as tablet excipient due to its well compatibility, high stability and persistent viscoelasticity during the process of compression and granulation. Carrageenans are thus appropriate excipients for prolonged release formulations. [23]

3.13 Chitosan

It is a cationic polysaccharide composed of glucosamine and N-acetylglucosamine. Deacetylation of chitin derived from crab shells is used to make chitosan. It's non-toxic, biodegradable, and biocompatible. It comes in the form of odourless white coloured powder that is partially soluble in 95 % ethanol and water. It's utilised as a viscosity improver, mucoadhesive, film former, binder in tablets, coating agent, and disintegrating agent, along with other excipients. [28]

3.14 Pectin

Pectin is a safe and cost-effective polysaccharide found in citrus peels and apple pomaces. A complex structure underpins both the extraction procedure and the source pectin. Pectin has a tendency to form gel upon esterification; thus serves as an important drug carrier in the design of gastroretentive control release formulations. [29]

3.15 Peanut husk powder

Peanuts, commonly known as groundnuts and classed as Arachishypogaea in taxonomy, are a legume crop produced primarily for their edible seeds. Peanut husk powder (cellulose 35.7 percent, hemicelluloses 18.7%, lignin 30.2%) is biodegradable, biocompatible, nontoxic, inexpensive, free of unpleasant and side effects, and widely available. C. Saravanan *et al*, 2016 used peanut husk powder as natural low density excipient for the development of gastroretentive tablet. [30]

Conclusion and future perspective

The prime goal of writing this review is to offer an overview of the functions and dynamic roles of natural polymers in GRDDS, their characteristics, current research perspectives, future development trends, and their pharmaceutical applications. Physical and some chemical properties of natural polymers make them an ideal candidate to use as drug carriers in GRDDS. On the other hand there is wide scope for the modification of natural polymers so as to obtain some derivatives with alteration in some physicochemical characteristics. After thorough literature study it was noticed that there are various polymers on which very less research has been carried out. So we can focus much to such polymers to develop gastroretentive dosage forms. Natural polymers in gastroretentive formulations could replace already existing synthetic polymers and may launch their gastroretentive products in to market with enhanced overall effectiveness. So this review would be helpful to the researchers in future for the development of gastroretentive systems by using various natural polymers.

Conflict of interest

Authors declared no conflict of interest.

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