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PROSPECTIVES OF NATURAL POLYMERS IN GASTRORETENTIVE FLOATING DRUG DELIVERY SYSTEM: A REVIEW

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ABSTRACT
The main objective of review is to collate the current literature on natural polymers being used for production of different floating systems which includes effervescent and non-effervescent systems. Natural polymers are versatile in characteristics, they are safe, non-toxic and inexpensive for use. All these characteristics of natural polymers make them suitable for Gastroretentive system. Natural polymers are widely investigated for their medicinal use and there more effectiveness than synthetic polymers. Thus, the present study focusses on the various polymers being utilized in floating drug delivery system. Use of polymers including guar gum, xanthan gum, tamarind gum, starch, pectin, okra has been reported by researchers to sustained the release of drug over prolonged period.

KEYWORDS; *FDDS, natural polymers, sustained release, GRDDS, effervescent, non-effervescent system*

INTRODUCTION

Oral administration of drug is the most promising route of administration due to its patient compliance and ease of manufacturing. However, this route has several limitations including variable gastrointestinal transit, incomplete release of drug and short residence time. This results in incomplete drug absorption. Gastroretentive drug delivery system has emerged as the ultimate approach to overcome these limitations. For local or systemic effects GRDDS is a technique used to lengthen gastric residence time of dosage form in upper GIT.[1] In the formulation of GRDDS variety of approaches have been attempted. These encompass floating, swellable and expandable, high-density, bio adhesive and gel-forming systems. The main goal of GRDDS is to increase GRT of dosage forms up to several hours which leads to enhancement of time between the dose administration and drug release occurs at desired rate. Out of the major types of GRDDS, the most favorable are the low-density systems.[2] FDDS have density lower than stomach fluid which permits them to remain buoyant for a prolonged time.[3] The polymers used for the preparation low density system are complex in their characteristics. numerous polymers are being used for the formulation of tablet, capsules and microspheres etc.in last 2 decades the used of natural polymers have gathered attention because of easily availability, low cost, non-toxic etc.

MAIN TYPES OF GRDDS [4]

1. Bio adhesive DDS
2. Expandable DDS
3. High density systems
4. Low density System (FDDS)

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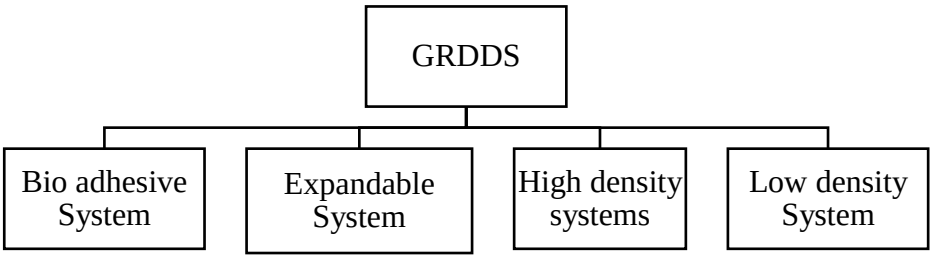
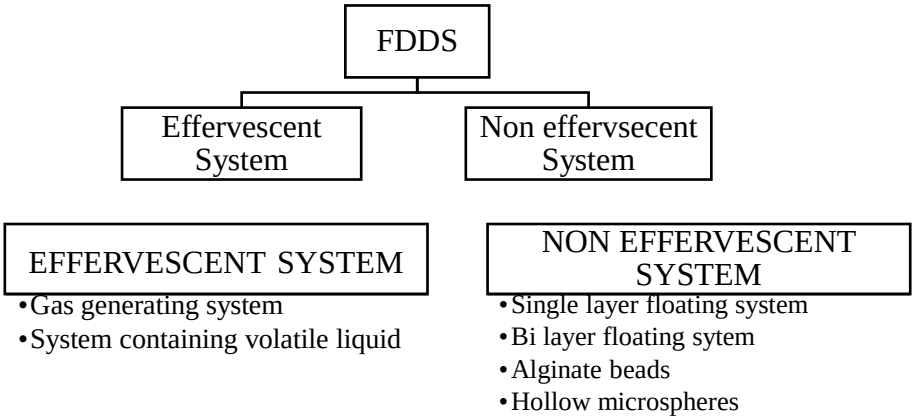
a) Non-effervescent system



b) Gas-generating system



FLOATING DRUG DELIVERY SYSTEM

It has lower density than gut fluid which makes them remain buoyant in gut without influencing gastric emptying rate. thus, the release of drug occurs at desired rate for prolonged time. From the stomach the residual system gets cleared when the drug is fully released. As an outcome plasma drug concentration fluctuations are controlled and GRT is increased.

Gas-generating (Effervescent) systems

These buoyant systems contains matrices developed with polymers which are swellable and contain effervescent components (e.g., sodium hydrogen carbonate, calcium carbonate). The drug when reaches gut, carbon dioxide is produced which causes it to float over the stomach fluid.

Non effervescent systems

These are referred to as plug type as they work by obstructing pyloric sphincter of the stomach by swelling in the gastric fluid. In these systems the drug and gel are mixed together and when the formulation comes in contact with the gastric fluid gel begins to swells and shut off the pyloric sphincter.

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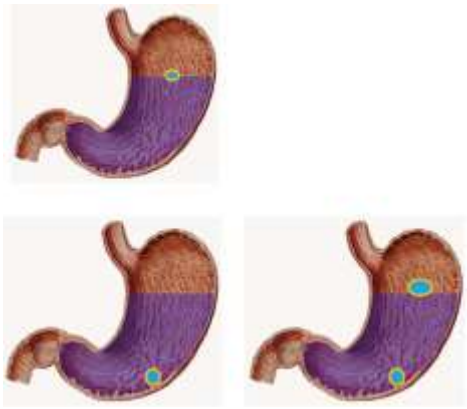

Figure 1 Floating systems. Low-density system. [5]

ADVANTAGES OF FDDS

1. It causes better patient compliance by declining frequency of dosing.
2. It shows better therapeutic effect for drugs which have short half-life.
3. Buoyancy leads to enhanced Gastric retention time of dosage form.[6]
4. Drug releases in controlled manner for longer time.
5. It directs site-specific delivery of drug in stomach.
6. Drugs which solubilizes in gut region only, it intensifies absorption of drugs.

LIMITATIONS OF FDDS

1. Higher amount of fluid in stomach is important for maintaining buoyancy.
2. It is not good fit for drugs having solubility or stability issues in gastric fluid.[6]
3. It is not suitable for drugs which irritate gastric mucosa.

POLYMERS IN FLOATING DRUG DELIVERY SYSTEM

From last 20 years polymers researchers have are widely reported the used for delivery of active drugs. Because of the advantages of nature polymers over synthetic one's natural polymers has a promising scope in Gastroretentive drug delivery including floating drug delivery approach. On the basis of origin, the polymers can be natural (chitosan, sodium alginate) semisynthetic (Ethyl cellulose, HPMC) and synthetic (acrylic acid derivatives, lactic acid derivatives).[7]

ADVANTAGES OF NATURAL POLYMERS

1. They are biodegradable
2. They are biocompatible and non-poisonous.
3. They are economical.
4. They are non-polluting
5. They are easily accessible.

DISADVANTAGES OF NATURAL POLYMERS

1. They can be microbially contaminated.
2. There may be batch to batch differences.
3. They can have rate of hydration unrestricted.
4. The consistency may get reduced on storage.

Table 1. Structural features and sources of natural polymer for FDDS [1,12,14,17]

Natural polymer	Basic chain	Source
Chitosan	Deacetylated P-1, 4-N-acetyl-1-D-glucosamine	Shell of marine invertebrates
Guar gum	β-D-mannopyranose	*Cyamopsis tetragonolobus*
Xanthum gum	β-(1,4)-linked D-glucose	Fermentation of glucose by *Xanthomonas campestris*
Pectin	α-(1,4)- linked D-galacturonic acid	Citrus peel, sugar beet pulp etc.
Starch	α-(1,4)-linked D-glucose and α-(1,6)-	Storage polysaccharide in plants

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	linked D-glucose	
Tamarind gum		*Tamarindus indica*
Gellan gum	D-glucose, D-glucuronic acid and rhamnose in ß-1, 4 linkage	*Pseudomonas elodea*
Okra gum		*Hibiscus esculentus*
Locust bean gum	1, 4-linked D-mannopyranosyl unit	*Ceratonia siliqua*
Mimosa gum		*Mimosa pudica*
Aloe mucilage		*Aloe barbadensis*
Salep	D-glycopyranosyl and D-mannopyranosyl	*Orchis mascula*
Psyllium husk	ß-(1-4)-linked D-xylopyranosyl	*Plantago ovata* seed coats
Karaya gum	D-galactose, L- rhamnose and D-galacturonic acid mixture	Plant (*Sterculia urens*)
Cashew gum	(1-3) -linked β–D-galactopyranosyl units with β- (1-6) linkages.	*Anacardium occidentale*
Alginates	1-4' linked-ß-D-mannuronic acid and α-L-glucuronic acid	*Laminaria hyperborea, Ascophyllum nodosum, Macrocystis pyrifera etc.*

Chitosan

It is composed of glucosamine and Nacetylglucosamine which is a linear cationic polysaccharide.[8] it is obtained from crustacean shells which is formed by deacetylation of chitin. It is biocompatible, biodegradable, nontoxic and odorless in character. It is having creamy, white flakes or powder which is soluble in water and partially insoluble in 95% ethanol. It is used as disintegrants, binder, viscosity enhancing, mucoadhesive, film forming and coating agent.

Chavda H et al developed a superporous hydrogel composed of chitosan as natural polymer for floating and sustained delivery of rantidine hydrochloride. It was reported that formed drug delivery system floated for 17 hours and thus is a promising approch for stomach-specific delivery of Ranitidine hydrochloride. [9]

Guar Gum

Guar gum is a plant polysaccharide obtained from seeds of *Cymopsis tetragonolobus* belonging to family Leguminosae.[10] In existence of water it swells instantly forming translucent suspension which is due to presence of guar gum binary content. Its water-soluble fraction is called Guaran. It is incompatible with acetone, ethanol, tannins, strong acids and alkalis and compatible with other plant hydrocolloids. Guaran has high molecular weight and is made up of 2 units of D-galactose per unit of D-mannose. Because of ability of Guar to enhance its viscosity it is used as a disintegrants and binder in formulation of solid dosage forms.
Hajare A et al formulated the metformin hydrochloride floating tablets using guar gum and k-Carrageen as natural polymer and synthetic polymer as HPMC. The tablets formulated by wet granulation technique with natural polymers which exhibited good results in terms of in vitro buoyancy study, better matrix integrity and drug released in sustained manner. The study concluded that natural polymers containing FDDS is a promising approach. [11]

Xanthan Gum

It is a long-chain polysaccharide having large number of trisaccharide in side chains. The chains are produced with the help of bacteria named Xanthomonas campestris by aerobic fermentation of carbohydrates. It is having high molecular weight. The major chain is composed of b-(1,4)-linked D-glucose units and the side chains composed of two mannose and one glucuronic acid unit.[12] In water gum forms delicate structure, which at low concentration creates high viscosity solutions.

Rashmitha, V et al investigated floating tablets of fenoverine by utilizing xanthan gum and sodium alginate as polymers. The formulation was prepared by direct compression method. The study reported that the fenoverine alone can not release the drug for 12 hours but the drug containing polymers shows release efficacy of 12 hours. [13]

Pectin

Pectin is a linear polysaccharide, non-starch which surrounds dividing plant cells. They have average molecular weight between 50,000 to 180,000. It is linear polymers of primarily α-(1,4)-linked D galacturonic acid residues interrupted by 1,2-linked L-rhamnose residues It is soluble in water and insoluble in ethanol and other organic solvents. For trade purposes pectin is obtained from lemon, lime and grapefruit, and apple etc. Pectin act as gelling agents, thickeners, stabilizing agent in food and pharmaceutical. Pectin is classified on the basis of its degree of esterification DE. 50% DE or greater is high-methoxypectin, and the one with DE below 50% is low-methoxypectin. These both types of pectin is having different properties.[14]

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Jyotirmoy G et al designed metformin hydrochloride floating tablets using pectin as natural polymer and HPMC as floating agent. The tablets were formulated by wet granulation method. The In vitro release studies indicate that pectin containing tablets shows sustained release action and increased bioavailability. [15]

Starch

It is a carbohydrate reserve in green plants and is found in seeds. It appears in the form of starch grains which is comprised of polymers, nameld amylose and amylopectin. Amylose is crystalline in nature having average molecular weights 5,00,000 which is soluble in boiling water but amylopectin do not soluble in boiling water. The enzymes at acetal linkage hydrolyze these 2 fractions. Various types of starch have been studied for various pharmaceutical applications including maize (Zea mays), rice (Oryza sativa), wheat (Triticum aestivum) and potato (Solanum tuberosum).

Sonar S et al designed bilayer floating bio adhesive tablets of rosiglitazone maleate by using HPMC and starch as polymer. The formed tablets were evaluated and reported to have buoyancy of upto 8 hours in stomach. [16]

Tamarind seed polysaccharide

It is a galactoxyloglucan seed polysaccharide obtained from *Tamarindus indica*. It exhibits sustained release behavior for both water-soluble and insoluble drugs. Caffeine, acetaminophen, theophylline behaves as water-soluble drug and salicylic acid, indomethacin as water-insoluble drug.[17]

Nayak K et al designed gelled microparticles of tamarind gum and sterculia gum for sustained release of drug. The microparticle were made by using different techniques including ionotropic gelation, ionotropic emulsion gelation, covalent cross-linking, combined ionotropic gelation or covalent cross-linking technique. The both gums based microparticles were found to have higher encapsulation capacity of drug in sustained and prolonged release of drug. [18]

Gellan Gum

It is a linear polysaccharide obtained from *Spingomonas elodea* as a fermented product having high molecular weight, and is deacetylated extracellularly. It is anionic and shows good release, increased gel strength, better stability, possess flexibility, increased clarity, film forming and thermally reversible gel characteristics.

Rajinikanth P et al designed floating in situ gel of amoxicillin for eradication of H. Pylori bacteria. The study reported that the formed gel has sustained release of drug from gel for over 8 hours. the formulated in situ gels shows effectiveness in clearing H. pylori bacteria to some extent. [19]

Okra Gum

The gum is collected from the pods of *Hibiscus esculentus*. At lower concentration it yields increased viscosity mucilage. Different coil polysaccharides are present which consists of rhamnose, galactose and galacturonic acid. The gum is used as binding agent, increase friability, hardness and drug release profiles. It has an advantage over other commercial synthetic polymers as it is chemically safe, inert, biodegradable, nonirritant, and biocompatible..

Alalor CA et al formulated ciprofloxacin floating-bio adhesive tablet using Okra Gum as polymer having multiple functions. The ciprofloxacin granules were formulated by using wet granulation technique. The study investigated that the okra gum alone or in combination with HPMC and sodium alginate shows good floating and bio adhesive property. Thus, this Gastroretentive formulation can be used for elimination of H. Pylori and in treatment of Salmonella typhi induced enteric fever. [20]

Locust Bean Gum

It is obtained from the seeds of *Ceratonia siliqua Linn*, consisting of neutral galactomannan polymer made up of 1, 4-linked D-mannopyranosyl units. The gum is used as gelling, stabilizer and thickening agent. In the preparation and development of various novel drug delivery systems the gum has wide applications.

Jagdale, S et al designed and developed floating system of tapentadol hydrochloride by using mixture of Xanthan and Locust bean gum. The study revealed that the sodium bicarbonate and citric acid provides floating property to drug and on the other side xanthoma and locust bean gum in balanced ratio shows sustained drug release the floating ability. [21]

Mimosa Gum

The gum is scientifically known as e *Mimosa pudica* (Mimosaceae). It is a shrubby plant having bipinnate leaves with glandular hairs, spinouts stipules, Companulate calyxes and lilac pinkish axilary flower heads.[22] The active constituents from plant boost

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health and reduce illness. The gum is having pharmacological activities including anti-inflammatory, anticonvulsant, anti-ulcer, antifungal and anti-malarial activity.

Samala M et al formulated Gastroretentive dosage form of Nizatidine by utilizing mimosa gum as rate retarding polymer. The tablets were formulated to study increase in the bioavailability of the drug by suing statistical approach. [23]

Aloe Mucilage

It is found from leaves of *Aloe barbadensis*. The pulp of aloe contains proteins, lipids, amino acids, vitamins, enzymes, inorganic, organic and various carbohydrates. Because of its therapeutic, healing properties it has been since several centuries. In is used in tablets, capsules, ointments and in gel preparations.

N Ranade et al formulated bilayer floating dosage form of amoxicillin and powder of alo vera gel by using direct compression technique. Aloe vera has mucoprotective effect and is reported to have anti-ulcer activity. [24]

Salep

It is obtained from dried palmates of tubers of *Orchis mascula* belonging to family Orchidaceae.[25] Glucomannan is the major polysaccharide present. It is forms a viscous solution and is highly soluble in hot and cold water. It contains D-glycopyranosyl and Dmannopyranosyl units in ratio of 1:3.3.

Razavi M et al designed Gastroretentive matrix dosage form of famotidine. Evaluation and characterization of formed tablets by in vitro release study shows that formulation shows complete drug release in 24 hours with better buoyancy profile. [26]

Psyllium Husk

It is a polymeric substance obtained from dried seed coats of *Plantago ovate*. It is swellable, biocompatible, inexpensive and biodegradable. The seed contains lipids with unsaturated fatty acids, sterols, proteins, traces of alkaloids and carbohydrates. Psyllium husk shows better release retardant properties.

Kharia A et al developed floating tablets of acyclovir by utilizing psyllium husk and HPMC K4M as polymer. the formulations were made by wet granulation method. The study investigated that both polymers do not interact with each other and thus, can be used in floating systems. [27]

Karaya Gum

It is a vegetable gum obtained from trees as an exudate of the genus *Sterculia.* Chemically, it is an acid polysaccharide consisting of sugar such as galactose, rhamnose, and galacturonic acid. It is inexpensive gum and used in products, including cosmetics, hair sprays, and lotions. Even at low concentration it rapidly takes water and enlarge to form viscous colloidal solution.

Gangadharappa H V et al designed floating formulation of verapamil hydrochloride utilizing mixture of karaya gum and HPMC. The floating tablets were made by direct compression technique and evaluated for floating lag time, weight variation test, hardness, thickness, swelling and dissolution studies. The study reported that the optimized formulation shows satisfied floating capacity, less floating lag time, and drug release for 8 hours. [28]

Singh B et al formulated beads of alginate and sterculia gum utilizing $BaCl_2$ as a crosslinker by using ionotropic gelation technique. the beads were loaded with pantoprazole as a drug. The study reported that from beads the diffusion rate of drug was slower and thus, it is suitable for retention of drug in stomach. The drug can be released for longer period. [29]

Cashew Gum

Cashew gum obtained from from the cashew tree *Anacardium occidentale* belonginf to family, Anarcardiaceae. The gum consists of galactose, arabinose, rhamnose, glucose, glucuronic acid and other residue of sugars. L- arabinose, L- rhamnose, D- galactose and glucuronic acid are produced by the hydrolysis of gum.[30] The gum has wide applications in pharmaceutical industries like colloidal stabilizer, thickening and gelling agent.

Paula H et al developed floating beads prepared from alginate and cashew gum with essential oil for larvicide release. the beads were designed by ionotropic gelation technique. The parameters such as buoyancy, swelling, and dissolution studies were performed. The study reflects the result that alginate and cashew gum floating beads loaded with larvicide has enhanced oil entrapment efficiency, better ability to float, and suitable larvicide release profile. [31]

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Alginates

These are polysaccharides which are unbranched consisting of 1/4 linked b-D-mannuronic acid (M) and C-5 epimer a-L-guluronic acid (G). It is biodegradable liner polymer occuring in brown seaweed and marine algae namely *Laminaria hyperborea, Ascophyllum nodosum and Macrocystis pyrifera*.[32] alginates are used in wound dressing and alginate gel is being used in cystic fibrosis and diabetes treatment. The alginates are further modified to have additional crosslinking strength, improved biodegradation and increase hydrophobicity of the backbone.

Raafat et al designed floating alginate beads loaded amoxicillin trihydrate for the treatment of H pylori treatment. Beads were made by transformation of alginate with N, N-dimethylamino ethyl methacrylate by using graft copolymerization method. The beads also contain calcium carbonate as gas producing agent and calcium chloride as crosslinker. The formed (Alg-g-DMAEMA) copolymers shows increased gastric residence time of upto 24 hours and improved bioavailability. The study reports that the formed alginate beads loaded can eradicate 95% of H pylori after 10 hours. [33]

CONCLUSION

Natural polymers have been widely used in the formulations for many reasons like binding, thickening, suspending and disintegrating agent etc. In the recent years there has been increased interest in natural polymers because some they are inexpensive, easily available, biodegradable and non-toxic in comparison with synthetic polymers. The researches on natural polymeric material and its modifications have gained attention. However, a lot of work still needs to be done in field of low-density system. Utilization of various natural polymers in low-density system to deliver the drug in sustained over prolonged period for treatment of various diseases.

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