Review Article CODEN: IJPRNK ISSN: 2277-8713
Bhumi Panchal, IJPRBS, 2014; Volume 3(1): 237-251 IJPRBS

INTERNATIONAL JOURNAL OF
PHARMACEUTICAL RESEARCH AND BIO-SCIENCE

IMERGING NATURAL POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEM

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Accepted Date: 13/01/2014; Published Date: 27/02/2014

Abstract: Poor Patient compliance , Increased chances of missing the dose of a Drug with short half–life for which Frequent administration is necessary. Floating system have bulk density lower than that of the gastric fluid and thus remain buoyant in stomach for a prolong period. Various approaches have been worked out to improve the retention of oral dosage form in the stomach as Floating systems, Swelling or Expanding systems, Bio adhesive systems and High density systems. Floating systems are low density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. Natural gums are among the most Popular hydrophilic Polymers because of their cost –effectiveness and regulatory acceptance. Polymer are generally employed in floating Drug Delivery system so as to target the Delivery of Drug to a Specific region in the gastrointestinal tract i.e. stomach .More ever, these polymers are safe, Non-toxic ,and capable of chemical modification and gel forming nature.

Keywords: Floating Drug Delivery System, Natural Polymer, Swelling or Expanding System.

PAPER-QR CODE

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Access Online On:

www.ijprbs.com

How to Cite This Article:

Bhumi Panchal, IJPRBS, 2014; Volume 3(1): 237-251

INTRODUCTION

Poor Patient compliance , Increased chances of missing the dose of a Drug with short half–life for which Frequent administration is necessary. The unavoidable fluctuation of Drug concentration may lead to under medication or over medication. A Typical peak –valley plasma Concentration–time profile is obtained which makes attainment of steady–state condition difficult. The fluctuations in drug levels may lead to Precipitation of adverse effect. Especially of a Drug with small therapeutics index whenever Over-medication occur.

There are two ways to overcome such a situation:

1) Development of new, better and safer drugs with long half-life and large

Therapeutic indices.

2) Effective and safer use of Existing drugs through concepts and Techniques of

controlled and targeted delivery system[1].

Floating drug delivery system:

Floating system have bulk density lower than that of the gastric fluid and thus remain buoyant in stomach for a prolong period[2]. Swelling delivery systems are capable of swelling to a size that prevents their passage through the pylorus. Upon coming in contact with gastric fluid, the polymer imbibes water and swells; as a result the dosage form is retained in the stomach for a longer period of time [3,4].

Various approaches have been worked out to improve the retention of oral dosage form in the stomach as Floating systems, Swelling or Expanding systems, Bio adhesive systems and High density systems. Floating systems are low density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. While the system floats over the gastric contents, the drug is released slowly at the desired rate, which results in increased gastro-retention time and reduces fluctuation in plasma drug concentration. After release of drug, the residual system is emptied from the stomach. This results in an increased Gastric retentions time and a better control of the fluctuations in plasma drug concentration .

Definition:

Floating Drug Delivery Systems are the drug delivery systems which prolong the retention of the dosage form in the GIT and aid in enhancing the absorption. Floating drug delivery system is also considered as “Hydrodynamically Balanced Systems (HBS).”These systems are best suited

for drugs with having a better solubility in acidic environment. Also for the drugs having specific site of absorption in the upper part of small intestine. To remain in the stomach for a prolonged period of time the dosage form have a bulk density<1. It should stay in the stomach, maintain its structural integrity, and release drug constantly from the dosage form.

Advantages of floating drug delivery systems:

- Enhanced bioavailability-The bioavailability of some drugs (e.g. riboflavin and levodopa) CR-GRDF is significantly enhanced in comparison to administration of non- GRDF CR polymeric formulations[5].
- Enhanced first-pass biotransformation-When the drug is presented to the metabolic Enzymes (cytochrome P-450, in particular CYP-3A4) in a sustained manner, the presystemic metabolism of the tested compound may be considerably increased rather than by a bolus input [6].
- Sustained drug delivery/reduced frequency of dosing-The drugs having short biological half-life, a sustained and slow input from FDDS may result in a flip-flop pharmacokinetics and it reduces the dose frequency. This feature is associated with improved patient compliance and thus improves the therapy[7].
- Targeted therapy for local ailments in the upper GIT-The prolonged and sustained administration of the drug from FDDS to the stomach may be useful for local therapy in the stomach.
- Reduced fluctuations of drug concentration- The fluctuations in plasma drug concentration are minimized, and concentration-dependent adverse effects that are associated with peak concentration can be prevented. This feature is of special importance for drugs with a narrow therapeutic index [8].
- Improved Receptor activation selectivity – FDDS reduces the drug concentration Fluctuation that makes it possible to obtain certain selectivity in the elicited Pharmacological effect of drugs that activate different types of receptors at different Concentration[9].

Application of floating drug delivery system

Floating drug delivery offers several applications for drugs having poor bioavailability because of the narrow absorption window in the upper part of the gastrointestinal tract. It retains the dosage form at the site of absorption and thus enhances the bioavailability.

These are summarized as follows.

- Sustained Release Drug Delivery:

HBS systems can remain in the stomach for long periods and hence can release the drug over a Prolonged period of time. The problem of short gastric residence time encountered with an oral CR formulation hence can be overcome with these systems. These systems have a bulk density <1 as a result of which they can float on the gastric contents. These systems are relatively large in size and passing from the pyloric opening is prohibited[10].

- Site-Specific Drug Delivery:

Floating drug delivery system is particularly advantageous for drugs that are specifically Absorbed from stomach or the proximal part of the small intestine, e.g., riboflavin and Furosemide[11].

- Absorption Enhancement:

Drugs that have poor bioavailability because of sites specific absorption from the upper part of The gastrointestinal tract are potential candidates to be formulated as floating drug delivery systems, there by maximizing their absorption. FDDS also serves as an excellent drug delivery system for the eradication of Helicobacter pylori, which causes chronic gastritis and peptic ulcers. The treatment requires high drug concentrations to be maintained at the site of infection that is within the gastric mucosa. By virtue of its floating ability these dosage forms can be retained in the gastric region for a prolonged period so that the drug can be targeted[12].

- Delivery of sparingly soluble and insoluble drugs:

Especially effective in delivery of sparingly soluble and insoluble drugs, as the solubility of a Drug decreases, the time available for drug dissolution becomes less adequate and thus the transit time becomes a significant factor affecting drug absorption. To address this, oral administration of sparingly soluble drugs is carried out frequently often several times per day.

- Pharmacotherapy of the stomach:

GRDF's greatly improve the pharmacotherapy of the stomach through local drug release leading to high drug concentrations at the gastric mucosa making it possible to treat stomach and duodenal ulcers, gastritis and esophagitis, reduce the risk of gastric carcinoma and administer non-systemic controlled release antacid formulations (calcium carbonate).

Polymer Used in Floating Drug Delivery System:

Classification of polymer[13]:

Role of Natural Polymer in floating

NATURAL	SYNTHETIC/SEMISYNTHETIC
Guar gum	HPMC K4M, K15M , K1OOM
Chitosan	CARBOPOL 934P
Xanthan gum	Ethyl cellulose
Pectin	Methyl cellulose
Psyllium husk	Sod. Carboxy methyl cellulose
Carrageenan	Hydroxy Ethyl cellulose
Tara gum	Polyamides
Karaya gum	Polycarbonate
Okra gum	Polyalkylene glycols
Gelatin	Polyvinyl ethers
Locast Gum	Polyvinylalcohol
Gellan gum	Polymethylacrylic acid

Drug delivery system:

The aim of this Work is to give a brief overview to the role of Natural Polymer in the development of floating drug delivery system. The use of natural polymer is valuable based on proven biocompatibility and safety . Natural gums are among the most Popular hydrophilic Polymers because of their cost –effectiveness and regulatory acceptance. Polymer are generally employed in floating Drug Delivery system so as to target the Delivery of Drug to a Specific region in the gastrointestinal tract i.e. stomach .More ever, these polymers are safe, Non-toxic ,and capable of chemical modification and gel forming nature[14].

Advantage of Natural Polymer:

- Biodegradable : Biodegradable is naturally available; They are produced by all living organisms.
- Biocompatible and Non -toxic : Basically , all of these plant materials are repeating sugar polysaccharide.
- Low cost: Cheaper to use as natural sources. the production cost is less compared with the synthetic material. In India and many other developing countries are dependent on agriculture and they are large amount of money investment on agricultures.
- Environmental-friendly Processing : There are many types of natural compounds obtained from different plant sources which are widely used in pharmaceutical industry and collected in Large quantities due to the simple production processes involved.
- Local availability : In India and similar developing countries ,there is promotion for the Production of plants as pharmaceutical excipients being done by government and it also Provide the facilities for bulk Production ,like gum and mucilage's because of their wide application in industries.
- They have better Patient tolerance as well as public acceptance: there is less chance of side and Adverse effect with natural materials compared with synthetic.

Commonly Used Natural Polymer in floating drug Delivery System:

- **Guar Gum:**

Guar also Known as cluster bean. Guar gum is a non-ionic natural polysaccharide Derived from seeds of cyamposis tetragonolus. guar gum is solid doasage form used in binder ,disintergrant and a polymer used in Floating Drug Delivery System. Chemically, guar gum is polysaccharide composed of the sugar galactose And mannose. The backbone is linear chain of 1,4-linked mannose residues to which galactose residues are 1,6 -linked a every second mannose, forming short side branches . Guar gum is more soluble than locust bean gum and is a better emulsifier as it has more galactose branch points. It has excellent thickening, emulsion, Film forming properties [15].

- **Chitosan:**

Chitosan is Natural and Versatile polymer obtained by acetylation of chitin. The Deacetylation chitin derivative chitosan is more useful and bioactive Polymer.Play Important role in stomach Specific Drug Delivery System, Cloln specific drug Delivery System, intestinal Delivery. Biological Properties of Chitosan like Biocompatible, safe , Non-Toxic . Chitosan granules

and Chitosan – laminated Preparation Could be Helpful in Developing drug delivery system and reduce effect Of gastrointestinal Transit time[16].

- **Xanthan gum:**

Xanthan is an extracellular heteropolysaccharide produced by fermentation of the bacterium Xanthomonas campestris. The primary structure (fig.1) of this naturally produced cellulose derivative contains a cellulose backbone (-D-glucose residues) and a trisaccharide side chain of -Dmannose-Dgluronic acid – D-mannose attached with alternate glucose residues of the main chain. It is a hydrophilic polymer, which until recently had been limited for use in thickening, suspending, and emulsifying water-based systems It appears to be gaining appreciation for the fabrication of matrices with uniform drug release characteristics [17].

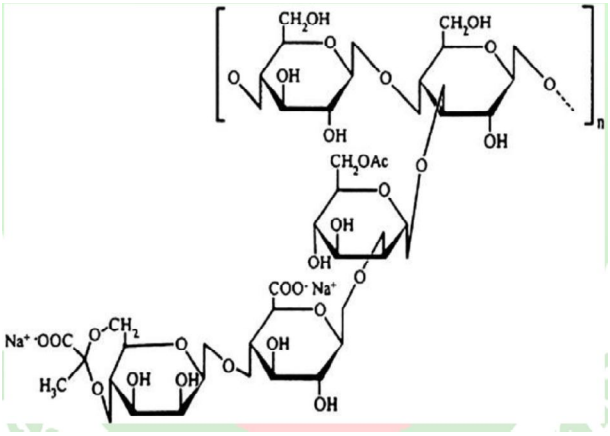

fig.- Structure of xanthan**.**

- **Pectin:**

Pectin are Non starch ,linear polysacharied present in the walls that surround Growing and divding cells. They are linear polymer of primarily a-(-1,4), Linked D-galactoglucornic acid residues having an molecular weight about 50,000 to 1,80,000.Pectin contain Few hundred to about 1000 polysacharide Units in Chain like Confugration. pectin are Gelling agent, Thickener, stabilizer And emulsifying agent[18] .

- **Psyllium Husk:**

Psyllium husk obtained from dried seed coats of Plantago ovata.Husk and seed of plantago ovata is commonly referred to as psyllium. Psyllium is widely used as fiber supplement for the treatment of constipation. Psyllium Husk Contain a High Proportion of hemicellulose, composed of Xylan backbone Linked with arabinose, rhamnose, galacturonic acid units.The seed contain 35% soluble and 65%insoluble Polysacharide.The seed contain 5-10% lipid with

Unsaturated fatty acid ,sterol,protein. Psyllium husk May be used in several Disease like constipation ,diabetes mellitus ,Appetie, Hyperlipidemia ,Ulcerative Colitis. Advantage of psyllium husk in floating Drug Delivery is that It has also release Retardant Properties [19].

- **Carregeenam:**

Carrageenam are family of linear sulfated polysaccharides that are extracted from red edible seaweeds. They are widely used in the food industry, for their gelling, thickening, and stabilizing properties. Their main application is in dairy and meat products, due to their strong binding to food proteins. There are three main varieties of carrageenan, which differ in their degree of sulfation. Kappa-carrageenan has one sulfate per disaccharide. Iota-carrageenan has two sulfates per disaccharide. Lambda carrageenan has three sulfates per disaccharide.

All carrageenans are high-molecular-weight polysaccharides made up of repeating galactose units and 3,6 anhydrogalactose (3,6-AG), both sulfated and nonsulfated. The units are joined by alternating alpha 1–3 and beta 1–4 glycosidic linkages[20]. Clinical studies have shown carrageenans are the first substances found to be active against common cold viruses[21].

- **Tara Gum:**

Tara gum is obtained from the endosperm of seed of Caesalpinia spinosa, commonly known as tara. It is small tree of the family Leguminosae or Fabaceae. Tara gum is a white, nearly odorless powder. It is produced by separating and 56 grinding the endosperm of the mature black color seeds. The major component of the gum is a galactomannan polymer similar to the main components of guar and locust bean gums, consist of a linear main chain of (1-4)-Dmannopyranose units with D-galactopyranose units attached by (1 -6) linkages. The ratio of mannose to galactos e in tara gum is 3:1. Produce highly viscous solutions, even at 1% concentration. Tara gum requires heating to disrupt aggregation and full dissolution, whereas guar gum is soluble in cold water. Tara gum is used as a thickening agent and stabilizer in a wide range of food application around the world. The use of tara gum as a controlled release carrier in the formulation of gastro retentive controlled release tablets and emulsion[22].

- **Karaya gum:**

It is a hydrophilic naturally occurring gum obtained from Sterculia urens and composed of galactose, rhamnose and glucuronic acid. It swells in water and thus used as release rate controlling polymers in different formulations. It possessed very low hydration capacity and higher erosion. When release studies were investigated, karaya gum was found to produce zero order drug release along with erosion of matrices[23].

- **Okra gum:**

Okra gum, obtained from the fruits of Hibiscus esculentus, is a polysaccharide consisting of D-galactose, L-rhamnose and L-galacturonic acid . Okra gum is used as a binder[24,25].

- **Gelatin:**

Gelatin is a translucent, colorless, brittle , flavorless solid substance, derived from the collagen inside animal s skin and bones. It is commonly used as a gelling agent in food and pharmaceuticals. Gelatin is produced by partial hydrolysis of collagen extracted from the boiled bones, connective tissues organs and some intestines of animals such as domesticated cattale, and pigs.

The approximate amino acid composition of gelatin is glycine 21%, proline 12%, hydroxyproline 12%, glutamic acid 10% alanine 9%, arginine 8%, aspartic acid 6%, lysine 4%, serine 4%, leucine 3%, valine 2%, phenylalanine 2%, threonine 2%, is oleucine 1%, hydroxylysine 1%, methionine and histidine<1% and tyrosine<0.5%[17].

- **Locust Bean Gum:**

Locust Bean Gum (LBG) (also known as Carob Gum) is obtained from the refined endosperm of seeds from the carob tree Ceretonia Siliqua L. It is an evergreen tree of the legume family. Carob bean gum is obtained by removing and processing the endosperm from seeds of the carob tree. Processing of the ground endosperm is accomplished by dispersing the fine powder in boiling water and filtering to remove impurities. The gum is recovered by evaporating the solution and tray or roll drying[26] . Locust bean gum (LBG) is a plant seed galactomannan, composed of a 1-4 linked -D-mannan backbone with 1- 6 linked "-D-galactose side groups[27] . This neutral polymer Is only slightly soluble in cold water; it requires heat to achieve full hydration, solubilization and maximum viscosity[28] . The physico-chemical properties of galactomannan are strongly influenced by the galactose content[29] .

- **Gellan gum:**

Gellan gum consist of polysaccharide , obtained from cultured solution of pseudomonas species . gellan gum Produced as a Fermemtation product by Pure culture of the microbe spingomonas elodea.the production Oranigsm is an Aerobic , well Characterised ,Non – pathogenic , gram Negative Bacterium. Gellan gum is a food additive that acts as a thickening or gelling agent. Gellan gum also Comercially known as Phytgel or gelrite. It is capable of gelation In Presence of Mono and Divalent Ions.This gum has an outstanding high gel strength, an excellent stability,high Flexibility,high clarity,good film former[30].

- **Synthetic/Semisynthetic polymer :**

Synthetic Polymer Can Be Wide Range Of Properties Such as Necessary Mechanical Properties (strength and Flexibility) and required degree Of Degradation. In addition Synthetic Polymer are Cheaper and More reliable Source of raw material (new material for Intended for Futher Processing).

Commonly used Synthetic/Semisynthetic Polymer in floating drug Delivery System:

- **Hydroxy Propyl Methyl cellulose:**

Based on Source and Nature of Polymer water interaction is used classified as Semi synthetic and Hydrophilic Polymer.Hydro propyl Methyl Cellulose used as basis for Sustained release hydrophilic matrix tablet. Hydroxy Propyl Methyl cellulose is an enteric coating material or matrix binder in Solid dosage form. 10-80% w/w hydro propyl methyl cellulose is used to Retard release of drugs From oral delivery system because of its non-toxic Nature, Easy compression and swelling Properties and accommodation for high Level of drug. addition of soluble filler(Lactose) to Hydro Propyl Methyl cellulose matrix System increase porosity Which Lead to rapid diffusion of drug and also lead to increase rate of erosion which result in acceleration of Drug Release, addition of insoluble filler inversely effect release of drug from these system dependant on its level. The Performance of Matrix tablet is strongly dependant on matrix material used , which are Normally used synthetic and semi synthetic Polymer [31].

- **CARBOPOL 940**:

It also Known as Sodium Acrylate. It is High Molecular Weight , Non Polyacrylic acid cross-linked Polyalkenyl polyether. It has High viscosity, High suspending ability, High clarity[32].

- **Ethyl cellulose:**

Ethyl cellulose also Known as Cellulose ethyl ether. Ethyl Cellulose is used as Coating agent ,flavouring agent ,tablet Binder ,tablet filler ,Viscosity Enhancing Agent. ethyl cellulose can be used in sustained product Including Film Coated tablet, Microsphere ,Microcapsule and matrix tablet for soluble drug and Poorly Soluble drug. It is non –toxic ,stable ,compressible ,inert , Hydrophobic polymer[33].

- **Methyl Cellulose:**

Based on Source and nature of Polymer water interaction Methyl Cellulose is Classified as Semisynthetic and hydrophilic Polymer.It also Known as benecel. Methyl Cellulose is used to produce sustained Release Preparation[34].

- **Sodium Carboxy Methyl cellulose:**

Based on nature and source of polymer water interaction Sodium carboxy Methyl Cellulose is semisynthetic and hydrophilic polymer.It is also Known as Sodium Cellulose Glycolate.It is chemically Known as sodium salt of carboxy Methyl Ether of cellulose.it is anionic water soluble polymer.It is used as thickening agent ,Stabilizer ,Suspending Agent[31].

- **Hydroxy ethyl Cellulose:**

It is also Known as Cellulose Hydroxy Ethylate.It is also used as thickening agent in Ophthalmic and topical formulation and also used as Binder and Film Coating agent in Tablet.It is Present in Lubricant preparation For Dry Eye, Contact Eye Lens , Dry Mouth[35].

- **Poly amides:**

A polyamide is a macromolecule with repeating units linked by amide bonds. Polyamides (PA) are semi-crystalline polymers. A distinction is made between two types. Polyamides made of one basic material (e.g. PA 6) and polyamides, which are made of 2 basic materials (e.g. PA 66). Polyamides have very good mechanical properties[36].

- **Poly Carbonate:**

Polycarbonates are a particular group of thermoplastic polymers. polymers containing carbonate groups (–O–(C=O)–O–). Most polycarbonates of commercial interest are derived from rigid monomers[37].

- **Polyalkylene Glycol:**

Polyethylene glycol (PEG**)** is a polyether compound with many applications From industrial manufacturing to medicine. Polyethylene glycol is synthesized by the interaction of ethylene oxide with water, ethylene glycol, or ethylene glycol oligomers. n general, a low polydispersity index (PDI) is a prerequisite for the polymer to have pharmaceutical applications. A PDI value below 1.1 makes the polymer more homogenous so that it provides reliable residence time in the body [38].

- **Poly Vinyl Ether:**

Poly vinyl ether, also known as divinyl ether, divinyloxide, Vinethene . A synthetic lubricant prepared from vinyl ether monomers. The main chain of the molecule consists of carbon-to-carbon bonds, with ether-based side chains. Advantage of Poly Vinyl Ether Has Flexible Polymer Properties[39].

- **Poly Vinyl Alcohol:**

Poly Vinyl Alcohol is soluble in highly polar and hydrophilic solvents, such as water, Dimethyl Sulfoxide (DMSO), Ethylene Glycol (EG), and N-Methyl Pyrrolidone (NMP) .Water is the most important solvent for PolyVinyl Alcohol. The solubility of PVA in water depends on the degree of polymerization (DP), hydrolysis, and solution temperature. Any change in these three factors affects the degree and character of hydrogen bonding in the aqueous solutions, and hence the solubility of Poly Vinyl Alcohol [40]. PVA is mainly used in topical pharmaceutical and ophthalmic formulations [41,42]. It is used as a stabilizer in emulsions. PVA is used as a viscosity increasing agent for viscous formulations such as ophthalmic products. It is used as a lubricant for contact lens solutions, in sustained release oral formulations and transdermal patches[43].

- **Poly Methyl acrylic Acid:**

Poly(methacrylic acid) (PMAA) is a polymer made from methacrylic acid. It is often available as its sodium salt, poly(methacrylic acid) sodium salt[44].

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