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RAFT FORMULATION IN GASTRORETENTIVE SYSTEM: AN OVERVIEW

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ABSTRACT

Drug delivery is the most preferred route due to its convenience, patient compliance, and formulation flexibility. However, conventional oral dosage forms face challenges like low bioavailability and rapid gastric emptying, leading to frequent dosing.

Modern technology has advanced the study and creation of controlled release oral medication delivery systems to address a number of physiological challenges, including variations in stomach retention and emptying time. Because conventional oral dosage forms exit the stomach quickly and locally acting medications quickly empty the stomach, they have low bioavailability, particularly for pharmaceuticals that are less soluble at alkaline pH of the intestine. Therefore, in these situations, the frequency of dose administration is raised.

Numerous obstacles face the gastro-retentive drug delivery system, however they can be solved by the recently developed raft-forming technology. The current study demonstrates advancements in this raft forming technique and offers useful information. A summary of the various smart polymer types utilized in their formulation has also been provided. The review focuses on the raft forming system's mechanism, formulation, development, and system optimization elements. It also highlights and discusses parameters that could cause response differences under different physiological settings.

Keywords: GRDDS, Raft Forming System, Raft Formulation, Anatomy Of Stomach & Physiology Of Stomach.

I. INTRODUCTION

Oral controlled release dosage forms can sustain an effective drug concentration in the systemic circulation for an extended period of time and provide enhanced therapeutic advantages like patient compliance, ease of dosing administration, and formulation flexibility, there has been an increased interest in developing these forms.[1] Drugs that are easily absorbed from the gastrointestinal tract (GIT) and have a short half-life are quickly eliminated from the bloodstream. These drugs must be taken often in order to have a therapeutic effect. In an attempt to get around these limitations, oral sustained controlled release formulations were developed, which release the drug gradually into the gastrointestinal tract and maintain an effective drug concentration in the systemic circulation for a considerable amount of time. After oral administration, this kind of drug delivery would stay in the stomach and release the drug in a controlled manner, enabling continuous transport of the treatment to the site of absorption in the gastrointestinal tract.[2]

Certain medications can only be absorbed at one location. They need to be released at a certain location or in a way that ensures the maximum quantity of medicine reaches the designated location. The pharmaceutical industry is currently concentrating on these medications that need to be site-specific. One site-specific method for delivering medications to the stomach or intestines is gastro-retentive delivery. It is achieved by keeping the dose form in the stomach, from which the medication is gradually released to a designated location in the stomach, duodenum, or intestine.[3] GRDDS, or gastroretentive drug delivery systems, was one of these methods. The medications' stomach retention period is optimally extended by GRDDS, increasing their bioavailability.[4]

Due to their ability to stay in the stomach area for extended periods of time, gastroretentive dosage forms considerably extend the gastric retention time (GRT) of medications. [5] Prolonged stomach retention increases the solubility of medications that are less soluble under high pH conditions. Additionally, it improves absorption and reduces pharmaceutical waste. Gastro retention makes new medications more readily available and has the potential to significantly improve patient outcomes and therapeutic options.[6]

Numerous technological attempts have been made to develop different controlled release gastroretentive drug delivery systems, such as high density (sinking) systems that are retained in the stomach's bottom, low density

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(floating) systems that cause buoyancy in gastric fluid, mucoadhesive systems that cause bioadhesion to the stomach mucosa, unfoldable, extendible, or swellable systems that limit the amount of dosage forms that can be emptied past the stomach's pyloric sphincter, superporous hydrogel systems, and magnetic systems.[7]

The raft forming system is the most widely utilized of these systems since it is one of the most practical and favored methods for obtaining a consistent and extended drug delivery profile in the GI tract.[8]

Sometimes the medications we take cause the fluids in our stomach to become unstable or poorly soluble. A kind of floating drug delivery system called a raft forming system allows medications that are poorly soluble in the stomach stay in the stomach. [9]

One type of floating medication delivery device is the raft-forming system. Drugs that are insoluble or unstable in intestinal fluids can benefit from the floating drug delivery system, which is kept in the stomach. Because floating drug delivery systems (FDDS) are less dense than gastric fluids, they float in the stomach for an extended amount of time without slowing down the rate at which the stomach empties. The medicine is gradually removed from the system at the desired rate while it is floating on the contents of the stomach. The stomach's residual system is evacuated following the drug's release. This leads to a longer stomach residence duration and more effective management of variations in plasma drug concentration.[10]

ANATOMY AND PHYSIOLOGY OF STOMACH

ANATOMY : The human stomach may hold up to 1500 ml after a meal, with a resting volume of 25–50 ml. The stomach is an organ with a J shape. It is situated immediately below the diaphragm in the upper left section of the abdomen. It exited the hypochondriac region and took up some space in the epigastric area. The stomach's primary job is to process food, store it for a while, and then release it gradually into the duodenum. The development of dosage forms that are local to the upper small intestine will be advantageous because there is where the medications are absorbed. [11]

There are mainly three parts of the gastrointestinal tract:

1. The stomach
2. The duodenum, jejunum, and ileum in the small intestine
3. The colon[12]

Anatomically stomach is divided into 3 parts:

Fundic region: Balloons over the cardiac region that serve as a makeshift storage area. It is also known as the fundus and has a dome shape. The fundus is positioned above the diaphragm. It extends superolaterally to the cardia.[13]

Body region: The stomach's larger, dilated section. It is the big center section, sometimes referred to as the body, that connects inferiorly to the pyloric area.Here, food is mixed because the stomach contracts.[13,14]

Pyloric region: This funnel-shaped area of the stomach is narrower than the rest of it. It starts with a larger and superior pyloric antrum and develops into the pyloric canal as it approaches the small intestine. This comes to an end at the pylorus. The muscular wall thickens at its terminus to create the strong, circular pyloric sphincter, which functions as a valve to control the emptying of the stomach. In actuality, the duodenum and pylorus are one continuous organ.[13]

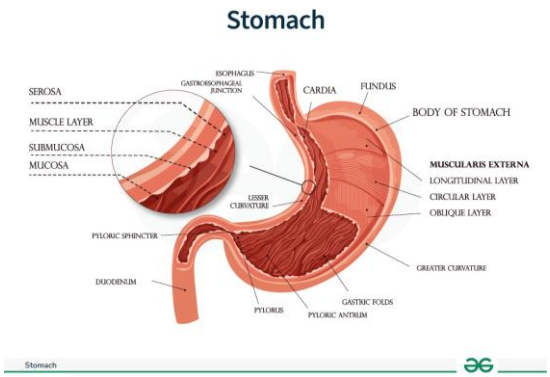

Fig:1 Anatomy of human stomach

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PHYSIOLOGY :

The fundus and body of the proximal portion serve as a repository for undigested material, while the antrum is the primary location for mixing motions and propels operations to act as a pump for stomach emptying (Fig. 1).[15]

Both when eating and when fasting, the stomach empties. An interdigestive sequence of electrical events cycles through the small intestine and stomach every two to three hours when a person is fasting (Fig. 2). The activity and transit of dosage forms are regulated by the migrating myoelectric complex (MMC), also known as the interdigestive myoelectric cycle.[16]

It is divided into four phases

1. Phase I (basal phase)
2. Phase II (preburst phase)
3. Phase III (burst phase)
4. Phase IV

1. **Phase l (basal phase):**There are no contractions during this quiescent phase, which lasts for 30 to 60 minutes.[17]
2. **Phase ll (preburst phase):**It lasts for roughly 20 to 40 minutes and is characterized by sporadic contractions that gradually get stronger as the phase goes on. Later in this phase, the stomach starts to release liquids and tiny particles.[18]
3. **Phase lll (burst phase):**This is a brief period of time that lasts between 10 and 20 minutes and is characterized by strong proximal and distal stomach contractions (4-5 per minute); these contractions, also referred to as the "house-keeper wave," sweep stomach contents down the small intestine.[19]
4. **Phase lV:** During this brief, transitional interval of 0 to 5 minutes, the contractions stop between the last stages of phase III and phase I quiescence.[17]

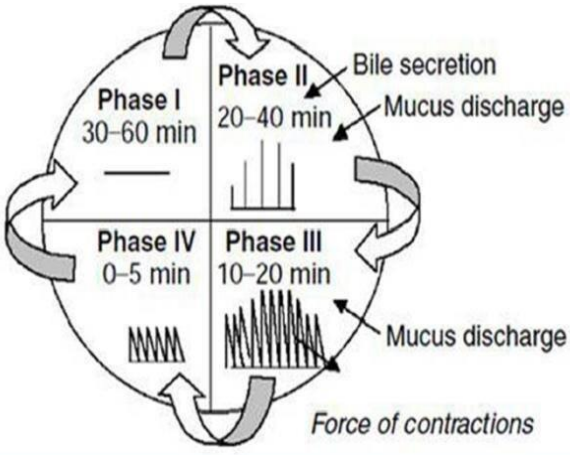

Fig 2: Gastric motility pattern.[20]

The contraction pattern shifts from the fasted to the fed condition once food is consumed. This is referred to as the "digestion motility pattern" and consists of constant concentrations similar to those in phase II of a fast. Food particles larger than 1 mm are reduced in size as a result of these contractions and are then transported in suspension form in the direction of the pylorus. The delayed start of MMC during the fed state causes the pace of stomach emptying to slow.

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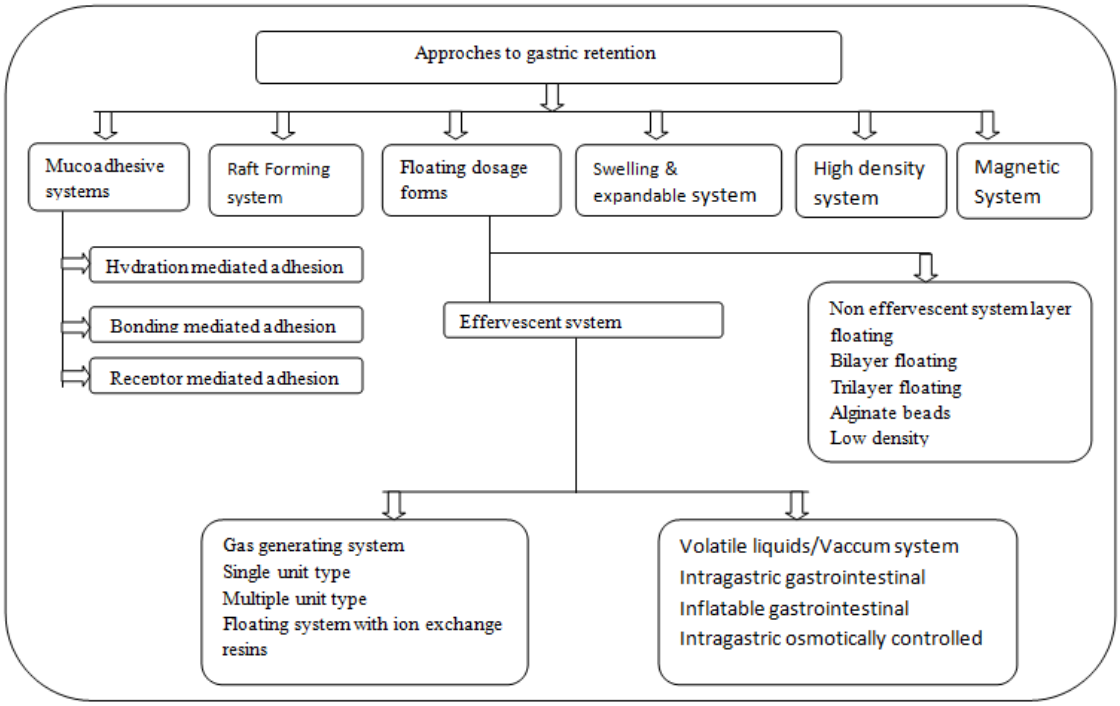
GENERAL APPROACHES TO GASTRIC RETENTION

TABLE 1: Approach for Gastric retention.[21]



Different methods for creating drug delivery systems that are retentive to stomach acid include

1. Floating drug delivery systems (low density)

These systems are distinguished by their density, which is less than that of gastric fluids (≈ 1.004 g/cm3). Because of their lower density, they were able to remain buoyant in the stomach for an extended amount of time while the drug was released gradually and increased GRT.[22]

Floating drug delivery systems is classified by:

1.1 Effervescent system

1.2 Non effervescent system

1.1 Effervescent system

These systems are matrix-type and are put together using a variety of effervescent substances, such as sodium bicarbonate, tartaric acid, and citric acid, as well as swellable polymers like methylcellulose and chitosan. They are designed so that CO2 is released and entangled in swollen hydrocolloids upon contact with the acidic stomach contents, imparting lightness to the measurement dose forms.[23]

1.2 Non effervescent system

Drugs are combined with highly swellable cellulose derivatives or gel-forming polymers to create non-effervescent systems.[33,34]

These gel hydrate formers, polysaccharides, and polymers combine with gastric fluid to produce a colloidal gel barrier that limits the amount of fluid that enters the device and releases the medication.[22]

2. Non-floating systems (high density)

In order to be retained in the stomach's rugae and impede its peristaltic movements, high-density systems have a density higher than that of gastric fluids [24].

These systems, with a density of around 3 g/cm3, can withstand the peristaltic movements of the stomach and are secured in place by its rugae. Such systems can be held in the lower stomach section until their density reaches a threshold of 2.6–2.8 g/cm3. In high density formulations, coated pellets are frequently utilised. Coatings are made of heavy inert materials such as iron powder, zinc oxide, titanium dioxide, barium sulphate, etc.[3]

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3. Mucoadhesive/Bio-adhesive systems

Drug delivery systems in the stomach can have their GRT extended by bio/muco-adhesive systems that attach to the mucin or gastric epithelial cell surface. The development of GRDDS based on bio/muco-adhesive polymers has made use of mucin's surface epithelial adhesive capabilities, which are widely known. Longer residency times in a specific organ site are made possible by a drug delivery system's capacity to adhere to the gut wall, which improves the systemic or local activity.[3]

The formula can adhere to the intestinal mucosa with the use of synthetic or natural bioadhesive agents, which causes a contact between the two.[25] These systems often include bioadhesive compounds such as lectins, chitosan, carbopol, and others.[26].

There are various types of mucoadhesion are:

3.1 Hydration-mediated adhesion:

Some hydrophilic polymers have the tendency to absorb a lot of water and becoming sticky, which gives them bioadhesive qualities.The rate at which the polymer dissolves also affects the bio/mucoadhesive drug delivery system's extended gastro retention.[27]

3.2 Bonding-mediated adhesion:

Polymers adhere to mucous or epithelial cell surfaces by a variety of bonding methods, including as chemical and physical-mechanical bonding. The adhesive material can form physical-mechanical linkages if it is inserted into the mucosa's folds and fissures. Chemical bonds can have two different types: main covalent bonds and secondary ionic links.Stronger specific interactions like hydrogen bonds and dispersive interactions like Vander Waals interactions make up secondary chemical bonds.[27]

3.3 Receptor-mediated adhesion:

The stomach retention of dose forms can be improved by polymers by binding to particular receptor sites on the surface of cells. Some plant lectins, like those of tomatoes, have a particular interaction with the sugar groups on the glycocalyx or in mucus.[3]

4. Superporous Hydrogels:

Conventional hydrogels, whose pores range in size from 10 nm to 10 μm, absorb water very slowly and take several hours to reach an equilibrium state. This can lead to an early evacuation of the dosage form. In contrast, superporous hydrogels (Fig. 3), whose average pore size is greater than 100 μm, swell to equilibrium size in just a minute because they absorb water quickly through capillary wetting through numerous interconnected open pores. Additionally, they have a significant swelling ratio (100 or greater) and are designed to be strong enough to endure the pressure caused by stomach contractions. Ac-Di-Sol (crosscarmellose sodium), a hydrophilic particle substance, is co-formulated to achieve this.[3,28]

5. Swelling/Expandable systems:

As can be seen, these systems grow after intake by absorbing gastric fluid, which blocks the pyloric sphincter and allows the medicine to be released gradually and remain in the stomach for a longer period of time.[29] Certain hydrophilic polymers such as carbopol, polyethylene oxide, and hydroxypropyl methylcellulose (HPMC) can be employed; these polymers create a network of physicochemical crosslinks that allows the polymer to swell extensively.[30]

6. Magnetic systems :

The medication, excipients, and a little amount of an intramural magnet are present in these systems, along with the option of an extramural magnet applied to the stomach. The location of the formula holding the internal magnet can be determined by this extramural magnet.[31] These systems are housed in the stomach's rugae and can endure the peristaltic movements of the stomach. They have a density of 3 g/cm3. Such systems may be retained in the lower stomach region over a threshold density of 2.4–2.8 g/cm3.[22]

7. Ion exchange resin system:

These systems are made up of a cationic or anionic lipid-soluble cross-linked polymer. Their purpose is to boost GRT, particularly for medications with low bioavailability. They are created by combining additional suitable excipients with the medication and ion exchange resin in a polymeric matrix.[32]

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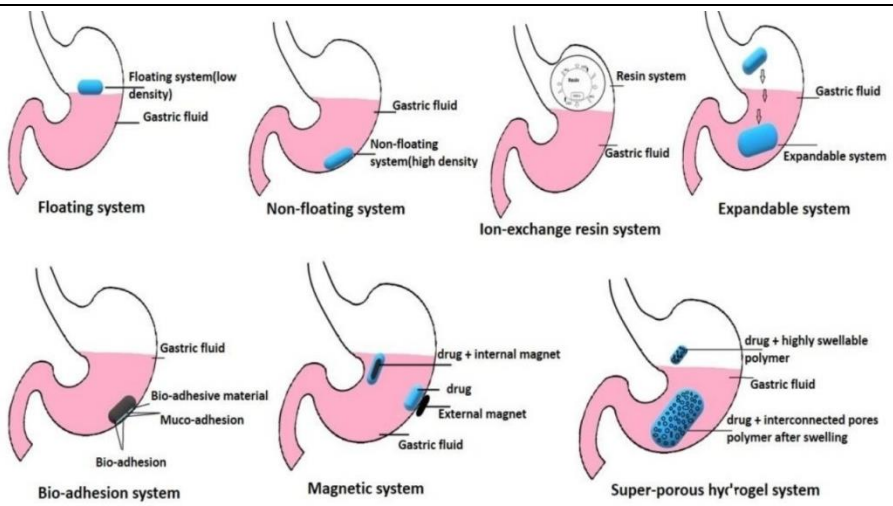

Fig 3: Illustrate the concept of different GRDDS application.[35]

RAFT FORMING SYSTEM:

By retaining the dosage form in the stomach, these systems aim to extend the retention duration. Among the many attempts, the raft forming mechanism marks a sophisticated breakthrough in the delivery of oral controlled medications. Raft-forming technologies have attracted a lot of interest for the delivery of medication for gastrointestinal diseases and disorders.[36]The administration of antacids and medications for gastrointestinal infections and illnesses has drawn a lot of attention to raft-forming mechanisms. A raft is a flat structure that floats on water and is usually composed of planks, logs, or barrels. It can be used for transportation or as a platform for swimmers.[3]

When stomach contents come into touch with the cohesive gel, it forms a viscous layer, which is the mechanism responsible for the development of the raft. A continuous layer known as a raft is created when every component of the liquid swells. Stomach juices allow this raft to float because CO2 generation causes a low bulk density. Alkaline bicarbonate or carbonate, which produces CO2, and a gel-forming agent are the usual components of the system, which helps it become less dense and float over the stomach contents.[37]

When in contact with stomach contents, the system's gel-forming ingredient (such as alginic acid), sodium bicarbonate, and acid neutralizer create a foamy sodium alginate gel, or raft. As a barrier between the stomach and the esophagus, the raft that has so created floats on the gastric fluids and stops the reflux of the gastric contents, or gastric acid, into the esophagus.[3]

The raft system prescription contains sodium bicarbonate, calcium carbonate, sweetener, and alginic acid in addition to mannitol. The mixture of components was granulated and then treated with citric acid. The effervescence and aeration of the formulation lead the raft to develop and float. While the medication is floating on the contents of the stomach, it is gradually eliminated from the body at the proper rate. Once the drug has been discharged, any remaining medication is removed from the stomach. As a result, the gastro retention time is prolonged and changes in plasma medicine concentration are better managed.[38]

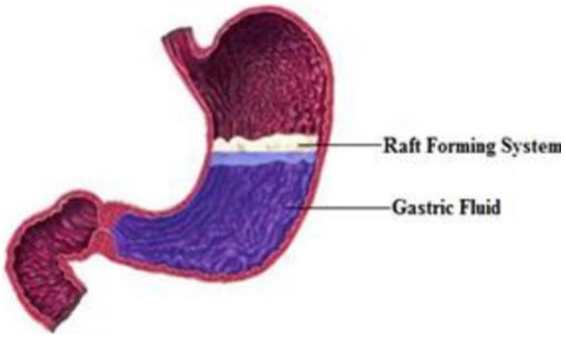

Fig 4: The design of the raft forming system.[39]

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The raft forming system's formulation is determined by the drug's physicochemical characteristics, the ailment that needs to be treated, the patient population, and the marketing strategy. Anatomical and physiological parameters include membrane transport and tissue fluid pH; physico-chemical considerations include molecular weight, lipophilicity, and molecular charge; formulation factors include pH, gelation temperature, viscosity, osmolarity, and spreadability.[38]

- The medication should be eliminated from the body gradually.
- The dosage form has to be strong enough to persevere the force of the stomach's peristaltic waves as well as the ongoing churning, grinding, and contractions of the stomach.
- Maintaining a specific gravity between 1.004 and 1.01 g/cm3 should be the goal.
- The dose form needs to be kept in the stomach for a lengthy time.
- Increased adherence from patients.
- Simple for the patient to administer.
- Following the medication's release, the apparatus ought to be effortlessly removed from the stomach.[11]

Table 2: Drug used for the raft forming system.[11]

CATEGORY	Drugs
Antacids	Aluminum hydroxide, Aluminum phosphate, Magnesium silicate, Magnesium hydroxide, Calcium carbonate.
H2 receptor Antagonist Proton Pump inhibitor	Cimetidine, Ranitidine, Loxatidine, Famotidine, Nizatidine, Omeprazole, Lansoprazole, Pantoprazole, Rabeprazole, Esomeprazole.
Anti-cholinergic	Oxyphenonium, Propantheline, Telezepine, Pirenzepine
Anti-helicobacter Pyloric drugs	Amoxicillin, Clarithromycin,Tetracycline, Metronidazole, Tinidazole, Colloidal bismuth

POLYMER USED IN THE FORMATION OF RAFT FORMING SYSTEM:

In floating drug delivery systems, the medication is distributed to specific parts of the gastrointestinal tract, like the stomach, using a variety of polymers. Combining synthetic and natural polymers, the drug delivery system that produces rafts is composed of. Poly (DL-lactic acid), Poly (DL-lactide-co-glycolide), Poly-caprolactone, HPMC, and other synthetic and natural polymers are used in the formulation development of the raft-forming drug delivery system. Xyloglucan, guar gum, gellan gum, pectin, and chitosan are examples of natural polymers.[40]

These qualities are what a polymer used for in situ gels should possess.

- Biocompatibility is a must.
- It ought to behave in a pseudoplastic manner.
- When the shear rate increases, the polymer should be able to increase viscosity.

Alginic acid :

Alginic acid is a polysaccharide that is a linear block copolymer, made up of β-D-mannuronic acid and α-L-glucuronic acid residues connected by 1, 4-glycosidic bonds. Brown seaweed and marine algae like Laminaria hyperborea, Ascophyllum nodosum, and Macrocystispyrifera have these unbranched polysaccharides.[41] Alginic acid-containing formulations have mucoadhesive qualities in addition to the capacity to create gel. It is biocompatible, nontoxic, hydrophilic, and biodegradable.It was discovered that when the cation's ionic radical is lower, alginates form compact structures. As di and trivalent metal ions are added to diluted aqueous solutions of alginates, successive glucuronic residues in the α-L-glucuronic acid blocks of the alginate chain work together to generate solid gels. In order to create a complexation with the free Ca2+ ions and release them only in the extremely acidic stomach environment, sodium citrate is added to the formulation.[42]

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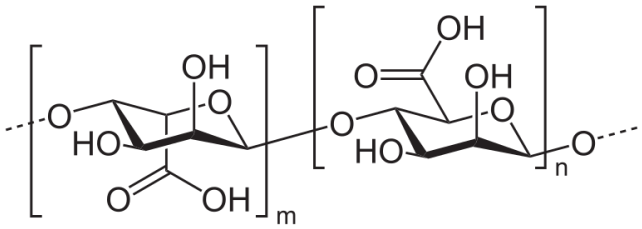

Fig 5: Structure of Alginic acid.[43]

Pectin :

An anionic polysaccharide derived from plants, pectin is typically collected from the cell walls of plants. Pectins are linear polymers mostly composed of 1, 2-linked L-rhamnose residues interspersed with α-(1-4)-linked D-galacturonic acid residues. Their molecular weight ranges from roughly 50,000 to 180,000 on average. When divalent ions, such as free calcium ions, are present, it easily gels in an aqueous solution and crosslinks the galacturonic acid chains in a way that is explained by the egg-box model.[41]

The principal advantage of using pectin in these compositions is its easy solubility in water, which eliminates the requirement for organic solvents in the blend. When pectin is consumed orally, it gels due to the divalent cations in the stomach. Complexed calcium ions may be present in the formulation intended to stimulate pectin gelation. The pectin solution can be mixed with sodium citrate to form a complex that contains most of the calcium ions included in the formulation. In this way, the formulation can be maintained in a fluid state (sol) until the complex decomposes in the acidic stomach environment and releases calcium ions, which leads to gelation.[44]

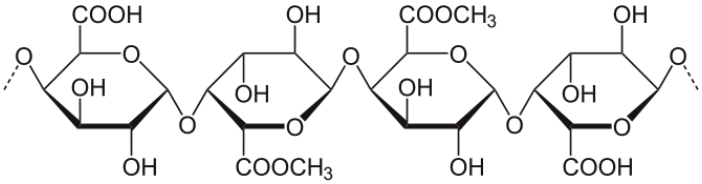

Fig 6: Structure of Pectin.[45]

Gellan Gum :

One α-L rhamnose, one β-D glucuronic acid, and two β-D glucuronic acid residues make up the tetra saccharide repeating unit of gellan gum, an anionic deacetylated exocellular polysaccharide. It is secreted by pseudomonas elodea, also known as Sphingomonas elodea. The polysaccharide's molecular structure includes a tetrasaccharide repeat unit made up of one glucuronic acid residue, one rhamnose residue, and two glucose residues.[38] Gellan gum causes in situ gelling that is either cation-induced or temperature-dependent.The polysaccharide's chemical structure includes a tetrasaccharide repeat unit made up of one glucuronic acid (GlcA), one rhamnose (Rha), and two glucose (Glc) residues. An assembly of these results in a tetrasaccharide repeat unit.[46]

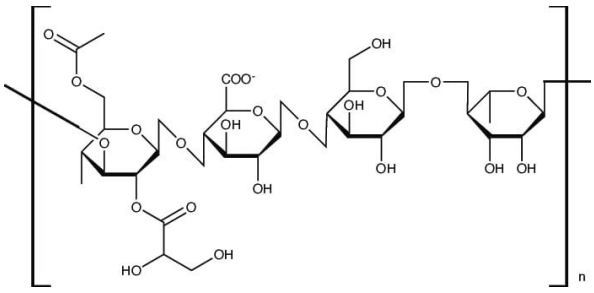

Fig 7: Structure of Gellan Gum.[47]

Xyloglucan :

Xyloglucan is a plant-based polysaccharide that is extracted from the seeds of tamarind plants. It consists of a (1–4)–β–D glucan backbone chain with partially substituted (1–6)–α–D xylose branches and a (1–2)–β–D-galacto xylose. The oligomers of hepta, octa, and nona saccharides—which differ in the quantity of galactose

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side chains they contain—compose xyloglucan. Even though xyloglucan does not form gel on its own, diluted solutions of the partially broken down xyloglucan caused by galactosidase exhibit a thermally reversible sol–gel transition upon heating.[38] Its possible use in oral administration takes advantage of the slow gelation period (several minutes) that is suggested,which would enable in situ gelation in the stomach after the oral administration of cold xyloglucan solution.[46]

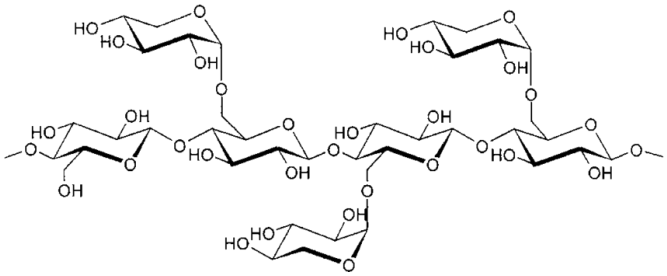

Fig 8: Structure of Xyloglucan.[48]

Chitosan :

A cationic polymer, chitosan is made up of copolymers of glucosamine and N-acetyl glucosamine, which are naturally occurring polymers that are produced by deacetylating chitin.[46] This polysaccharide is biocompatible, biodegradable, non-toxic, and has antibacterial and bioadhesive properties. When the pH of chitosan aqueous solution rises above 6.2, a hydrated gel-like precipitate is formed.[46]

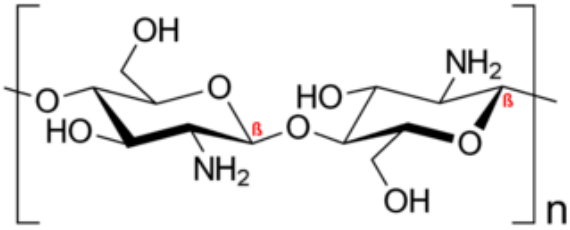

Fig 9: Structure of Chitosan.[49]

Carbopol:

The well-known pH-dependent polymer carbopol forms a low viscosity gel at alkaline pH levels but stays in solution at acidic pH levels. To give the carbopol solution viscosity, HPMC is used with carbopol. Polymer systems that precipitate in-situ due to pH changes include ethylene glycol, poly (methacrylic acid), carbopol system–hydroxyl propyl methyl cellulose system, and other water soluble polymers.[38]

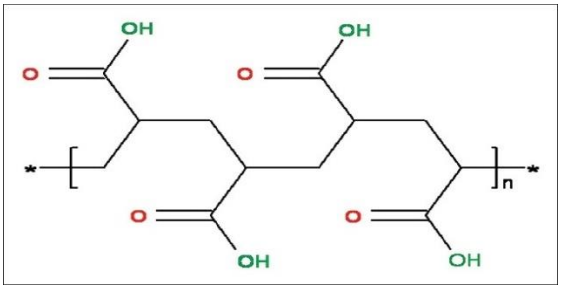

Fig 10: Structure of Carbopol.[50]

Advantages :

1. More drug release and improved bioavailability result from the low density viscous layer that the raft-forming machinery creates on the stomach contents.[38]
2. Introducing therapy once a day will increase patient compliance.
3. Improve therapeutic efficacy.
4. Easy to administer to a patient
5. It increases the contact time of drug at the site of maximum absorption (stomach).[11]

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Disadvantages :

1. For medications that have stability or solubility issues in the gastrointestinal tract, the floating method is impractical.
2. For these medicine delivery devices to function effectively and float, there needs to be a lot of fluid in the stomach—water, mainly.
3. Only those medications that undergo extensive first pass metabolism and are greatly absorbed throughout the gastrointestinal system are considered suitable candidates.
4. Certain medications found in the floating system irritate the stomach mucosa.[38]

II. CONCLUSION

In the stomach, raft-forming systems have demonstrated promise for extending medication release and enhancing localized drug delivery. Achieving the best possible drug delivery performance depends critically on the design of raft-forming systems.

In GRDDS, raft formulation has shown promise in improving medication delivery results.

Gastroretentive drug delivery systems (GRDDS) have shown promise in improving drug bioavailability and localized drug delivery.

- GRDDS can address challenges associated with conventional oral drug delivery, such as low bioavailability and rapid gastric empty in.

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