**Int. J. Sci. R. Tech., 2025 2(5)**
A Multidisciplinary peer-reviewed Journal
www.ijsrtjournal.com [ISSN: 2394-7063]

*Original Article*

# A Review on Gastro Retentive Drug Delivery System (GRDDS)

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## ABSTRACT

The gastroretentive Drug Delivery System (GRDDS) is a novel method of oral medication administration that tackles significant issues with traditional systems. way to take drugs since it is convenient, patient-compliant, and flexible. Traditional oral drug delivery techniques, however, frequently encounter gastrointestinal (GI) tract restrictions, including insufficient drug release, diminished efficacy, and the requirement for frequent dosing. In order to address these issues, GRDDS extends the gastric residence time (GRT) of medications, allowing them to remain in the stomach for a longer period of time. By providing controlled, sustained drug release, improving drug absorption, and improving targeted distribution within the stomach, this extended GRT increases therapeutic efficacy and lowers the frequency of dose. This review examines the fundamentals, varieties, and advantages of GRDDS, highlighting how it can optimize drug release, boost bioavailability, and enhance overall therapy results.

**Keywords:** Gastro Retentive Drug Delivery System, GRT, optimize drug release, boost bioavailability

## INTRODUCTION

The oral route is the most widely used administration method for systemic as well local activity. Most likely, at least 90% of all medications are administered orally. Among the medications administered orally, the solid dose form is the most favored product class. Because it is easy to swallow, painless, and adaptable to many kinds of medications, the oral route is the one that is most frequently given. Traditional drug delivery methods are unable to address the problems caused by the gastrointestinal tract, including insufficient drug release, reduced dose efficacy, and frequent dose requirements. Consequently, the development of GRDDS may result from the inability of traditional drug delivery methods to keep medications in the stomach. These systems have various advantages, including the capacity to target delivery in the stomach, improve drug absorption, and boost the therapeutic efficiency of medications by prolonging the gastric residence time (GRT) of dose forms in the stomach for several hours. Furthermore, GRDDS can improve controlled drug delivery by releasing the medication continuously for a long time at the appropriate rate and to the appropriate absorption site until the drug is fully released from the dosage form.

**• Gastro can retentive drug delivery system:**

Gastroprotective drug delivery systems (GRDDS) are dosage forms that can be stored in the stomach. Because it increases the bioavailability of the drug by prolonging the stomach's retention time, decrease drug waste, and increase the solubility of drugs with lower solubility in a high pH environment, the gastro retentive drug delivery system (GRDDS) has emerged as the most popular drug delivery system of today. The gastric retentive (GR) system may also be advantageous for medications that act locally in the stomach or have poorer stability in the lower GI tract. One kind of controlled release drug delivery system that can stay in the gastrointestinal tract for a long time while changing the GIT's motility and gastric emptying time is the gastro-retentive system.

**• An Ideal drug delivery system should possess two main properties:**

1) There should only be one dose given during the period of treatment.

**Relevant conflicts of interest/financial disclosures**: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

2) The location of action should receive the active medication directly.

A controlled-release drug delivery device that can be held in the stomach is called a gastro-retentive drug delivery system. By releasing the drug for a considerable amount of time before the absorption window, they can aid in the optimization of oral controlled administration of medications with a "absorption window," guaranteeing superior bioavailability. Both when fasting and when eating, the stomach empties. But there are differences in the two states' migratory trends. A short stomach residence duration and an inconsistent gastric emptying rate are two issues with oral controlled release dosage forms, per gastric emptying studies.

**• Need For GRDDS:**

Although conventional dosage forms are most frequently used to treat a variety of ailments, they have a number of significant drawbacks, including the fact that they are not site-specific; many medications are only absorbed at a certain location or must be released at a targeted site in order to provide the most effect and get beyond these issues. GRDDS is intended to provide regulated medication delivery to particular locations, such as the stomach, bowel, colon, and duodenum.

**• Stomach Anatomy and Physiology:**

The stomach is a J-shaped organ that is situated in the upper left quadrant of the abdomen. The stomach is separated anatomically into three primary areas:

- The fundus or fundic area
- The stomach body
- The pylorus, or pyloric area.

The average adult human stomach measures 30.5 cm in length and 15.2 cm in width, with a 1.5L capacity. It serves as both a mixing and digestion chamber and a reservoir for food that has been consumed. The rugae, which are noticeable wrinkles in the stomach's inner mucosal lining, enable the stomach to grow up to 50 times its empty volume. Understanding stomach physiology and the associated gastric emptying process is essential for GRDDS success. The fundus, body, and antrum (pylorus) are the three anatomical regions that make up the human stomach's structure. The stomach's volume ranges from 250 to 500 ml during the inter-digestive periods, with an average of 1.5 l following a meal. The antrum serves as the main location for the mixing process, while the portion composed of the fundus and body serves as a repository of any undigested material. The antrum, which is the lowest portion, propels the stomach emptying process. A key factor in the gastric residence period of the ingested contents is the pylorus, which separates the stomach from the duodenum.

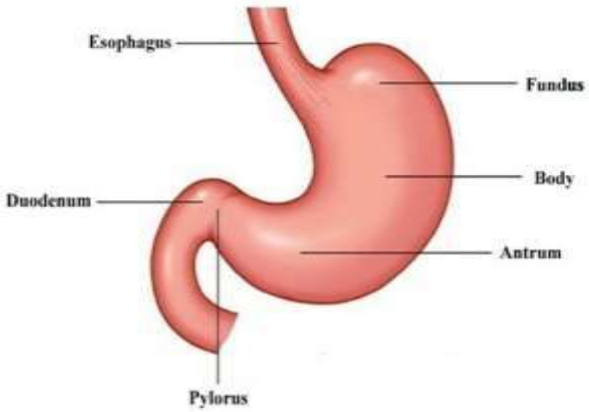



Fig. 1 – Diagram of human stomach.

**• Functions of Stomach:**

Among the stomach's functions are the following:

1) Short-term storage to give the pepsins and other digestive enzymes time to work
2) Chemical digestion: proteins are broken down into polypeptides by pepsins.

3) Mechanical breakdown: the stomach's three smooth muscle layers allow it to function as a churn, adding gastric juice and causing the contents to liquefy. Parasympathetic nerve stimulation has enhanced gastric motility and output.
4) Restricts absorption of alcohol, water, and certain lipid-soluble medications. 5) The hydrolytic acid in gastric juice offers a non-specific defense against microorganisms. Ingestion of stomach irritants, such as chemicals or bacteria, can cause vomiting.
6) Iron preparation for absorption: Iron salts, which are necessary for iron absorption in the small intestine, are dissolved in the stomach's acidic environment.
7) The terminal ileum produces and secretes the intrinsic factor required for vitamin B12 absorption.
8) Control of the stomach contents' transit into the duodenum. The pylorus pushes tiny jets of stomach contents through the duodenum's pyloric sphincter when the chyme is sufficiently liquefied and acidified. Normally, the sphincter is closed, which stops chime from flowing backward into the stomach.

**• Gastric motility and emptying of food:**

When you eat and fast, your stomach empties. Gastric emptying is how medications move from the stomach into the small intestine. An electro-mechanical activity known as the migration myoelectric complex (MMC) is a feature of the gastric emptying process. The stomach and small intestine go through four stages of this sequence of events that happen every 1.2 to 2 hours:

1. Stage I (the foundational stage)
2. Stage II (stage prior to detonation)
3. Stage III: The stage of epidemic

4. Step IV Stage I: This is a 30- to 60-minute period of rest during which there are no contractions.

Stage II: There are sporadic contractions. The tension progressively rises as the stage goes on and lasts for roughly 20 to 40 minutes. Very tiny particles and gastric juice start to be evacuated later in this stage.

Stage III: This phase lasts roughly 10 to 20 minutes and is characterized by brief, strong distal and proximal stomach contractions (4–5 contractions per minute). The contents of the stomach are swept to the small intestine by these contractions, which are also referred to as "housekeeper waves."

Stage IV: This brief transitional phase lasts roughly 0 to 5 minutes. Between the final portion of the third stage and the remainder of the first stage, the contraction subsides.

**• Ideal Drug Characteris Tics for GRDDS:**

1. Medication that acts locally in the stomach, such as antacids and medications for H. Pylori, such as misoprostol
2. Medications such as amoxicillin, calcium supplements, chlordiazepoxide, and cinnarizine that are mostly absorbed in the stomach and upper gastrointestinal tract.
3. Medicines with low solubility at alkaline pH, such as furosemide, diazepam, verapamil HCL, chlordiazepoxide, etc.
4. Medication with a limited window of absorption in the gastrointestinal tract, such as levodopa, methotrexate, cyclosporine, riboflavin, and para aminobenzoic acid, among others.
5. Medications that the GI tract absorbs quickly. such as tetracycline and metronidazole.
6. Medication that breaks down or becomes unstable in the colon. such as metformin HCl, ranitidine HCL, captopril, and metronidazole.
7. Medication that disrupts natural bacteria in the colon, such as medicines against Helicobacter pylori and amoxicillin trihydrate.

**• GRDDS is useful for such drugs by improving their:**

• Bioavailability
• Treatment effectiveness
• Potential dosage reduction
• Keeping the therapeutic level steady for an extended length of time, which lessens its variability.
• Cutting down on drug waste.
• Low-soluble medications are more effectively soluble in high pH conditions.

**• Advantages of Gastroretentive Drug Delivery Systems:**

• Improved bioavailability When riboflavin CR-GRDF is administered instead of non-GRDF CR polymeric formulations, the bioavailability of the

former is greatly increased. Numerous processes that are connected to the drug's absorption and passage through the gastrointestinal tract work together to affect how much of the medicine is absorbed.

1. GRDDS helps to sustain a medication's therapeutic level over time.
2. The drug's pharmacologic efficacy has increased.
3. The frequency of dosing is decreased.
6. Chronotherapy can make advantage of this system.
7. Offers an action specific to a site.
9. Because the medicine stays in the stomach for a longer amount of time, unwanted action in the colon can be avoid.

Because the body's counteractivity is decreased, this system operates more efficiently [18].

**• Disadvantages of Gastroretentive Drug Delivery Systems:**

1. Not appropriate for medications with low acid solubility. For instance, phenytoin
2. Not appropriate for medications that become unstable in an acidic environment. For instance, erythromycin
3. Slow-release medications that irritate the stomach or create sores. For example, NSAIDs and aspirin
4. Medication that enters the colon preferentially. For instance, corticosteroids
5. Medication that passes through the GIT equally well. For instance, nifidipine and isosorbide dinitrate
6. To float and function properly, floating medicine delivery systems need a high stomach fluid level.
7.Causing G.I irritation [18].

**• Factors affecting gastric retention time of the dosage form:**

**• Size:** Doses with a diameter greater than 7.5 mm have a longer stomach residence duration than those with a diameter of 9.9 mm.

**• Shape of the dose form:** the tetra hedron resided in the stomach for longer period than other devices of similar size. Compared to single unit dosage forms, multiple unit formulations allow for a greater margin of safety against dosage form failure, allow co-administration of units with different release profiles or containing incompatible substances, and exhibit a more predictable release profile with negligible performance impairment from unit failure.

**• Caloric content:** A meal heavy in fat and protein can raise GRT by 4–10.

**• Density:** The buoyancy of the dose form determines GRT, and the dosage form influences the stomach emptying rate as well.The floating property of the dosage form requires a density of less than 1.0 gm/cm3, whereas high density systems sink to the bottom of the stomach. Dosage forms with a density lower than the gastric contents can float to the top.

**• Age:** GRTs for the dose forms are typically longer in people over 65.

**• Gender:** Wang et al. found that women have slower rates of gastric emptying than males, and that gender can have a substantial impact on luminal pH and gastric emptying time.

**• Type of food:** The stomach's motility pattern can be changed by administering fatty acid salts or indigestible polymers like cellulose, starch, and polydextrose. This is because delaying the MMC slows down the stomach's emptying rate and prolongs digestion.

**• APPROACHES FOR GRDDS:**

The following are the several methods developed for creating a dose form that will result in an acceptable gastric retention and release inside the gastric region:

**A. Floating drug delivery system (FDDS):**

Another name for floating medication delivery systems is low density systems. There are several types of floating medication delivery systems:

**1.Effervescent system:**

- Volatile liquid containing system
- Gas generating system:

**2.Noneffervescent system:**

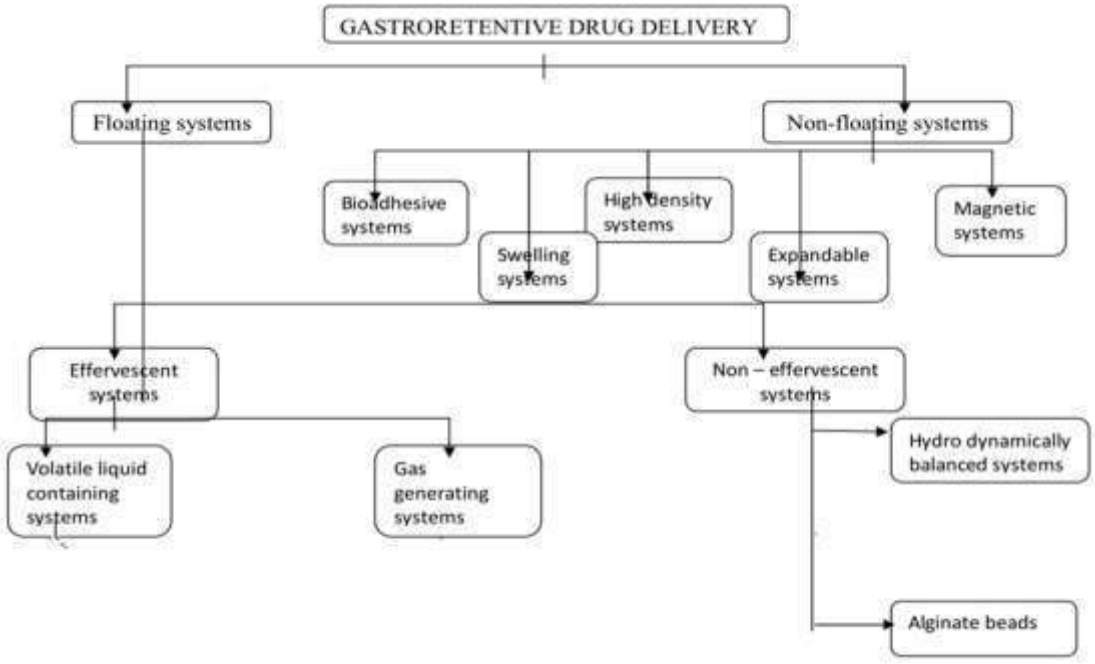
- Hydrodynamcally balanced system
- Alginate beads

**B. Non-floating system:**

Different processes keep these gastro-retentive drug delivery systems in the stomach, even if they don't float there.

Non-floating system is further divided into.

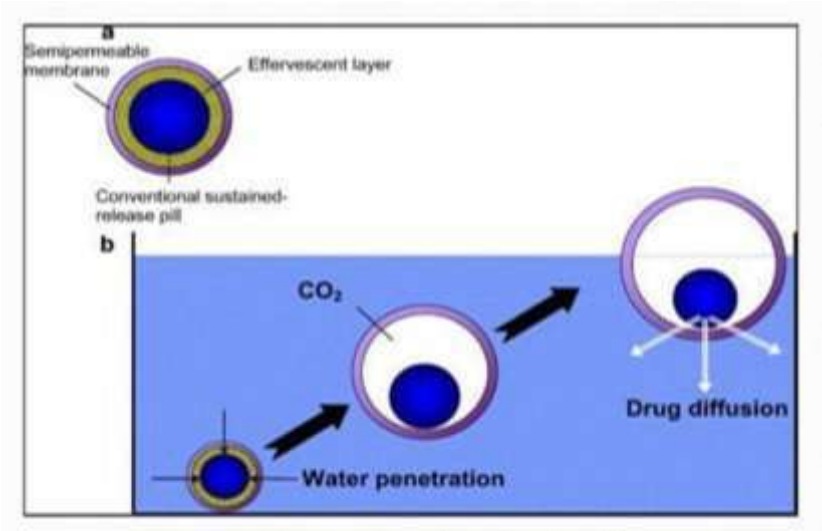
1.High density drug delivery system.
2.Bioadhsive or mucoadhesive system.
3. Magnetic system.
4. Swelling System
5. Expandable System
6. Raft forming system:




**A. Floating drug delivery system (FDDS):**

Low-density systems with enough buoyancy to float over the contents of the stomach and stay buoyant in the stomach for an extended amount of time without influencing the gastric emptying rate are known as floating systems or dynamically regulated systems. As a result, the variations in plasma drug concentration are better controlled and the stomach retention period is extended. Granules, powders, capsules, tablets, laminated films, and hollow microspheres have all been used to create a variety of buoyant systems.

**1.Effervescent floating system:**




Gas generating system:schematic monolayer drug delivery system

Such systems are developed using a variety of effervescent producing chemicals and swellable polymers. They are designed so that CO2 is released and entangled in swollen hydrocolloids upon coming into touch with the acidic stomach material, giving the measurement dosage forms their lightness. The medication delivery device floats in the stomach when it is filled with air, vacuum, or an inert gas. A natural dissolvable (organic) solvent, such as ether or cyclopentane, can volatilize to bring gas into the floating chamber. Alternatively, CO2 can be provided due to a floating response between organic acids and carbonate-bicarbonate salts. To enable the unrestricted release of a thin floatable system from the stomach, these devices contain a hollow deformable unit that alternates between a collapsed and an extended configuration before returning to the collapsed position after a predetermined amount of time. For the best gas production, the ratio of citric acid to sodium carbonate should ideally be 1:0.76.

- **Volatile liquid containing system:**

Two chambers make up this type of system, which is separated by a movable, pressure-responsive bladder. The volatile liquid is in the second chamber, while the medication is in the first. A liquid (like ether or cyclopentane) that gasifies at body temperature and causes the stomach chamber to inflate can be used to fill an inflatable chamber and maintain the GRT of a medication delivery system.The device may additionally incorporate a bioerodible plug made of polyethylene, polyvinyl alcohol, etc. that slowly dissolves and causes the inflated chamber to release gas and collapse after a certain period of time, enabling the inflatable systems to be automatically ejected from the stomach.As the device inflates, the drug is continuously discharged from the reservoir into the stomach fluid.

- **Gas generating system:**

Creating gas bubbles is another way to achieve floatability. CO2 can be created when carbonates or bicarbonates are mixed with acid, either the natural acid of the stomach or an acid that has been coformulated as tartaric or citric acid. According to reports, the optimal stoichiometric ratio for gas production between sodium bicarbonate and citric acid is 0.76:1. An approach is to use a matrix that traps liquids, which at body temperature transform into a gas. Both single-unit and multi-unit systems have been subjected to these techniques.

**2. Non-effervescent system:**

In non-effervescent systems, tablets or capsules contain a high concentration (20–75% w/w) of one or more gel-forming, highly swellable, cellulosic hydrocolloids (such as sodium carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose [HPMC], and hydroxyethyl cellulose), polysaccharides, or matrix-forming polymers (such as polycarbophil, polyacrylates, and polystyrene). When these gel formers, polysaccharides, and polymers come into contact with stomach fluid, they hydrate and create a colloidal gel barrier that regulates the rate at which fluid enters the device and, in turn, the release of the medicine. The hydration of the adjacent hydrocolloid layer preserves the gel layer as the dosage form's external surface dissolves. The air that the expanded polymer traps reduces the dosage form's density and gives it hope.

- **Hydrodynamically balanced gel systems:**

The creation of hydrodynamically balanced systems requires the addition of a high concentration (20–75% w/w) of gel-forming hydrocolloid to the medication, which keeps the medication afloat above the stomach contents. Alginic acid, hydroxypropyl methyl cellulose, ethyl cellulose, and other gel-forming cellulose hydrocolloids may be present in these systems." Additionally, matrix-forming polymers such polyacrylate and polycarbophil are present. These systems create a colloid gel barrier around their surface when they come into touch with stomach juices, causing the hydrocolloid to hydrate. A hydrodynamically balanced system of metformin has been created as a single unit floating capsule using different polymers such as HPMC K4M and ethyl cellulose. Gamma scintigraphic studies showed that the formulations remained buoyant for six hours. It was also noted that the drug release from the optimized HBS formulations could be sustained for a longer amount of time, with Cmax and Tmax being 76.97% in seven hours as opposed to 97.21% in three hours in immediate release capsules

- **Alginate beads:**

Multi-unit floating dose forms have been developed using freeze-dried calcium alginates. Dropping sodium alginate solution into an aqueous solution containing calcium chloride can create spherical beads with a diameter of roughly 2.5 mm. Air is used to separate and dry these beads. An aporous system is created as a result, which keeps the stomach afloat.

- **Advantages of FDDS:**

• Increases patient adherence by lowering dosage frequency.
• The medication is released in a regulated manner over an extended period of time.
• Drug release to the stomach can be accomplished site-specifically.
• Better absorption of pharmaceuticals that are exclusively soluble in the stomach.
• Uniform drug release and no chance of dose dumping with single unit floating dosages, such microspheres.

**B. Non-floating system**

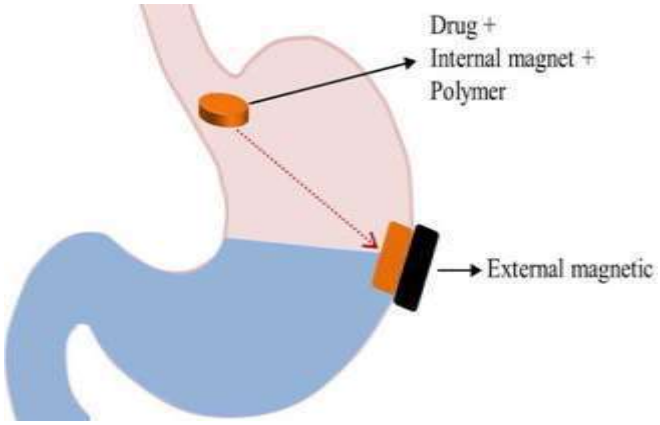
**1. High Density (Sinking) Drug Delivery System:**

This dosage form is made by coating the medicine on a heavy core or by combining it with inert substances like iron powder, barium sulfate, zinc oxide, and titanium oxide. This way, the formulation's density is higher than that of the typical gastric content.Their density might reach 1.5–2.4 gm/cm3. However, no formulation has been marketed, and the system's efficacy in humans has not been noted.

**2.Bio-adhesive Systems:**

The fundamental basis of these systems is bio-adhesive polymers, which attach to mucous and non-mucous membranes, such as the surface of the epithelium and mucin. The term muco-adhesion refers to bio-adhesion that is limited to the mucosa's surface. The most common ligand for accurate bio-adherence is lecithin. Non-specific bio-adhesion is dependent on the system's polymer quality. Alginates, polystyrene, sodium hyaluronate, chitosan, polyacrylates, and polylactic acid are a few polymers that are said to be bio-adhesive in nature. They are said to have a bioadhesive nature.

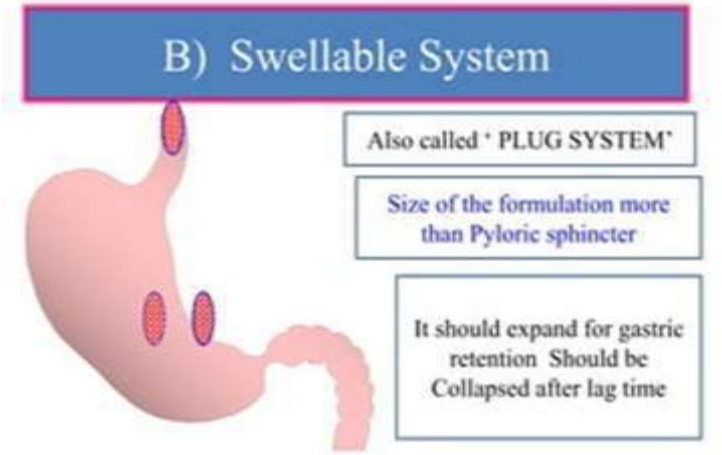
**3. Magnetic systems:**




The magnetic attraction force between two magnets serves as the foundation for magnetic systems. The combination of API, excipients, and a tiny amount of magent is used to create the formulated dosage form. By covering the stomach with an external magnet, the dose form is drawn toward the gastric wall once it reaches the stomach. Both the stomach residence duration and bioavailability are increased as a result.

It was discovered that an external magnet with a strength of 1700 G could hold magnetic granules in the stomach areas for longer than two hours. The positioning of the external magnet is magnetic systems' main drawback. Comparing it to other GRDDS techniques, it is discovered to have extremely low patient compliance.

**4. Swelling System:**

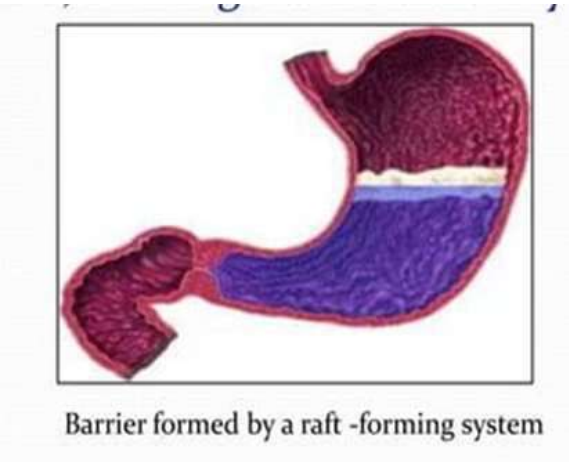



Stomach contents are absorbed by swelling systems in order to enlarge. Other names for them are highly porous hydro gels and swelling-controlled systems. The system cannot access the small intestine due to the pyloric sphincter's enlargement. The medication is released over time as the system expands and weakens.

**5. Expandable System:**

Physical-chemical crosslinking of the hydrophilic polymer network is responsible for the widespread swelling of these polymers. By preventing the polymer from dissolving, these cross-links maintain the dosage form's physical integrity. The amount of swelling and its duration are determined by the degree of cross-linking between the polymeric chains. When crosslinking is high, the system's ability to expand is slowed down and its structural integrity is maintained for a longer amount of time. Conversely, a low level of cross-linking results in significant swelling, which is swiftly followed by the dissolution of the polymer. To prevent swelling and disintegration, the proper amount of cross-linking is required. The swelling system will eventually disintegrate when the membrane bursts from continuous expansion or loses its structural integrity as a result of abrasion or erosion-induced mechanical weakness. Three configurations are typically the foundation of extendable GRDFs: A compact, folded shape that allows for adequate oral intake. The enlarged stomach, which results from swelling, prevents the pyloric sphincter from working. After the GRDF releases its active ingredient and permits evacuation, a smaller version is received in the stomach, negating the need for retention. The expansion can be accomplished via Swelling system.

**6. Raft forming system:**


Barrier formed by a raft -forming system

The administration of antacids and medications for gastrointestinal infections and illnesses has drawn a lot of interest in raft-forming systems. This type of GRDDS is induced by the production of a viscous gel in contact with gastric fluids, which results in the formation of a continuous layer known as RAFT on

top of the gastric fluids due to the low bulk density caused by the formation of CO2. A gel-forming substance (such as alginic acid) and alkaline bicarbonates, or carbonates that produce CO2, are typically included in this system's ingredients to make it less thick and float on the stomach juices. Antacids like calcium carbonate or aluminum hydroxide are also frequently included in formulations to lessen stomach acidity. By creating a barrier between the stomach and the esophagus, the raft that is generated floats on the gastric fluids and stops the reflux of the gastric contents into the esophagus. It is typically used to treat gastroesophageal reflux disease.

- **Future Perspectives Of GRDDS:**

In the pharmaceutical sector, one of the biggest problems is the GRT of the traditional dosage form, particularly for medications that are absorbed from the upper intestine. The creation of GRDDS will aid in overcoming the limitations of the traditional dosage form, while more research is required to address these issues. The single system technique has been used in numerous research on GRDDS to date, including those including mucoadhesive, expandable, and floating systems. GRDDS has a bright future ahead of it. GRDDS has several potential applications to enhance medication delivery to the stomach with more study and development. The following are GRDDS's future perspectives:

• **Increased drug bioavailability:** By shielding medications from enzymes or stomach acid, GRDDS can increase the bioavailability of medications. Osmotic systems, mucoadhesive systems, or floating systems can all be used for this.

• **Extended drug release:** By limiting the medication's premature release, GRDDS can be employed to prolong the drug's release period. Both magnetic and osmotic methods can be used for this.

• **Targeted drug delivery:** Medications can be administered to a particular area of the stomach using GRDDS. Magnetic or bioadhesive methods can be used for this.

• **Less side effects:** GRDDS can be used to transport medications to a specific area in the stomach or stop them from being absorbed too quickly, which can lessen unwanted effects

• **Better patient compliance:** By making GRDDS easier to use and more comfortable, patient compliance may increase. GRDDS, for instance, can be transformed into more easily swallowed chewable pills or capsules.

• A variety of disorders could be better treated with the help of GRDDS, a promising new technology. With further study and advancement, GRDDS has the potential to completely transform how medications are absorbed in the stomach. The following obstacles must be overcome for GRDDS to reach its full potential:

• **Stability:** GRDDS must remain stable in the hostile stomach environment. This can be difficult because enzymes and stomach acid break down a lot of the polymers and other components used in GRDDS.

• **Biocompatibility:** GRDDS must be biocompatible, which means the stomach lining shouldn't be harmed. Given how sensitive the stomach lining is, this is crucial.

• **Manufacturing:** GRDDS must be produced in an economical manner. This presents a problem because GRDDS frequently call for specific tools and methods.

• **Clinical trial:** To prove their safety and effectiveness, GRDDS must be put to the test in clinical trials. To make sure that GRDDS are safe and effective for human usage, this is a time-consuming and costly procedure.

## CONCLUSION:

Gastro-retentive drug delivery systems (GRDDS) play a crucial role in enhancing the therapeutic efficacy of drugs that require prolonged gastric retention. The ability of GRDDS to maintain drug levels within the therapeutic window for extended periods allows for improved bioavailability and reduced dosing frequency. Through mechanisms such as floating, swelling, and bioadhesion, these systems can effectively prolong the residence time of medications in the gastric environment. This review highlights the various technologies employed in

GRDDS, including formulations based on polymers, hydrogels, and other innovative materials. Each approach has its own set of advantages and challenges, necessitating careful consideration of factors such as drug properties, patient variability, and the specific therapeutic objectives. When it comes to improving the therapeutic efficacy of medications that need prolonged gastric retention, gastro-retentive drug delivery systems (GRDDS) are essential. Better bioavailability and fewer doses are made possible by GRDDS's capacity to keep medication levels within the therapeutic window for prolonged periods of time. These systems can successfully extend the duration of a drug's residence in the stomach environment by means of processes like floating, swelling, and bioadhesion. The several technologies used in GRDDS are highlighted in this review, including formulations based on hydrogels, polymers, and other cutting-edge materials. Every strategy has pros and downsides of its own, requiring careful evaluation of variables including medication characteristics, patient variability, and the particular treatment goals. The intricacy of formulation design, the impact of food intake, and patient-to-patient variation in stomach retention are some of the issues that persist despite the progress made in GRDDS. Future studies should concentrate on resolving these issues by creating GRDDS that are more patient-centered and predictable, making use of cutting-edge materials, and implementing innovative fabrication methods. For a variety of therapeutic uses, GRDDS have great potential to transform drug delivery, especially for medications with localized gastric action or low bioavailability. To fully utilize GRDDS in enhancing patient outcomes, more research and development in this area are necessary.

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HOW TO CITE: Mayur Pawar*, Rushikesh Patkal, Pratiksha Bhalekar, Omkar Karad, A Review on Gastro Retentive Drug Delivery System (GRDDS), Int. J. Sci. R. Tech., 2025, 2 (5), 73-84. https://doi.org/10.5281/zenodo.15328412