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Dr. Vijay Bahadur Maurya
Institute of Pharmacy, VBS Purvanchal University
Jaunpur, Uttar Pradesh, India

Corresponding Author:
Dr. Vijay Bahadur Maurya
Institute of Pharmacy, VBS Purvanchal University
Jaunpur, Uttar Pradesh, India

A review on gastroretentive drug delivery systems

Vijay Bahadur Maurya

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Abstract
Gastroretentive Drug Delivery Systems (GRDDS) are an innovative approach to enhance the bioavailability and efficacy of orally administered drugs that have a narrow absorption window, are unstable in the intestinal environment, or require localized action in the stomach. This review explores the principles, types, and advancements of GRDDS, including floating systems, mucoadhesive systems, expandable and swelling systems, and high-density formulations. These systems are designed to prolong gastric residence time, allowing for sustained drug release and better absorption. Various physiological factors such as gastric emptying rate, pH, and fed or fasted states influence the performance of GRDDS. The review also highlights the role of polymers and novel technologies in improving formulation stability and effectiveness. While GRDDS offer several advantages, including improved patient compliance, reduced dosing frequency, and targeted delivery, they also present formulation and physiological challenges that need to be addressed for optimal performance. Ongoing research is focused on overcoming these limitations through the development of smart polymers, responsive systems, and advanced drug carriers. In summary, GRDDS present a promising strategy in oral drug delivery, especially for drugs with specific absorption requirements, and continued innovation in this field is expected to expand their clinical application and therapeutic potential.

Keywords: Gastroretentive drug delivery systems, controlled-release formulations, floating systems, mucoadhesive systems, expandable and swelling systems, gastric residence time, polymers in drug delivery, targeted oral drug delivery, formulation challenges, innovative drug carriers

Introduction
Gastroretentive Drug Delivery Systems (GRDDS) have emerged as a promising solution to improve the efficacy and safety of medications, particularly those that exhibit a narrow absorption window in the gastrointestinal (GI) tract. These innovative systems are designed to prolong the gastric residence time of drugs, thereby enhancing their bioavailability and therapeutic outcomes [1].

The GI tract plays a pivotal role in drug absorption, with the stomach acting as a primary site for drug disintegration and dissolution. However, conventional oral dosage forms often pass quickly through the stomach, leading to variable absorption and reduced bioavailability, especially for drugs that are preferentially absorbed in the stomach or the upper part of the small intestine [2]. GRDDS overcome the limitation by retaining the drug delivery system in the stomach for an extended period, allowing for a controlled and sustained release of the active ingredient [3].

Advantages of Gastroretentive Drug Delivery Systems [4-6]
GRDDS offer several advantages over conventional dosage forms. They enhance drug absorption and bioavailability, reduce dosing frequency, and improve patient compliance by maintaining consistent therapeutic levels of the drug in the bloodstream. Additionally, they can minimize adverse effects by reducing the systemic exposure of drugs that are intended for local action in the stomach.

1. Enhanced Bioavailability
- **Prolonged Gastric Retention:** GRDDS extend the time a drug spends in the stomach, which can significantly improve the bioavailability of drugs that are absorbed primarily in the stomach or the upper part of the small intestine.

- **Improved Solubility:** For drugs with pH-dependent solubility, retaining the drug in the stomach's acidic environment can enhance its solubility and absorption.

2. Targeted Drug Delivery
- **Localized Action:** GRDDS are particularly beneficial for delivering drugs that act locally in the stomach. For instance, they can be used to treat gastric ulcers or Helicobacter pylori infections more effectively by maintaining higher local drug concentrations.
- **Reduced Systemic Side Effects:** By focusing the drug's action within the stomach, GRDDS can limit systemic exposure and potentially reduce side effects associated with the drug.

3. Controlled and Sustained Release
- **Extended Release Profiles:** GRDDS can be engineered to release drugs slowly over an extended period. This steady release can help maintain a constant drug concentration in the bloodstream, enhancing therapeutic efficacy.
- **Dosing Convenience:** The extended-release nature of GRDDS often translates into reduced dosing frequency, which can improve patient compliance and convenience.

4. Improved Patient Compliance
- **Less Frequent Dosing:** By maintaining therapeutic drug levels for longer durations, GRDDS reduce the need for multiple daily doses, which is particularly advantageous for chronic conditions requiring long-term treatment.
- **Patient-Friendly:** GRDDS are typically formulated as oral tablets or capsules, which are generally more acceptable to patients compared to other delivery routes like injections.

5. Versatility and Adaptability
- **Wide Range of Applications:** GRDDS can be adapted for various drugs, including those with narrow absorption windows, poor solubility in intestinal fluids, or those requiring a prolonged gastric presence.
- **Customization:** Various GRDDS designs, such as floating, mucoadhesive, or expanding systems, allow customization to meet specific therapeutic needs.

Disadvantages of gastroretentive drug delivery systems [7-9]
Despite their potential, GRDDS also present challenges, such as the need for precise control over the release rate and the development of systems that can withstand the dynamic environment of the stomach. Moreover, individual variations in gastric motility and pH can affect the performance of these systems.

1. Variability in gastric conditions
- **Influence of Gastric Motility:** The effectiveness of GRDDS can be significantly affected by variations in gastric motility. Factors such as the fed or fasting state, individual differences in gastric emptying times, and motility disorders can impact the system's performance.
- **Variable Gastric pH:** Differences in gastric pH, due to food intake, disease states, or age, can affect drug stability, solubility, and release characteristics.

2. Complexity in Formulation
- **Development Challenges:** Designing GRDDS that can consistently perform in the dynamic and harsh environment of the stomach is complex. Formulations must account for factors like swelling capacity, bioadhesion strength, and the ability to withstand gastric contractions.
- **Manufacturing Costs:** The sophisticated technology and materials required for GRDDS can increase production costs compared to conventional dosage forms.

3. Potential for Local Irritation:
- **Prolonged contact with gastric mucosa:** The extended presence of GRDDS in the stomach can sometimes lead to local irritation or damage to the gastric mucosa, particularly with systems that adhere to the stomach lining.
- **Unintended Retention:** In some cases, the prolonged retention of the drug delivery system might cause discomfort or pose risks of obstruction, especially in individuals with pre-existing gastrointestinal conditions.

4. Limited Drug Candidate
- **Specific Drug Properties Required:** Not all drugs are suitable for GRDDS. The drug needs to have a narrow absorption window in the upper GI tract, be stable in the acidic stomach environment, and ideally not cause irritation upon prolonged contact with the stomach lining.
- **Size and Dosage Constraints:** The size and dose of the drug can limit its compatibility with GRDDS, as the system must be small enough to be swallowed but large enough to avoid premature gastric emptying.

Approaches for Gastroretentive Drug Delivery Systems
Gastroretentive Drug Delivery Systems (GRDDS) are designed to maintain a therapeutic agent in the stomach for an extended period, optimizing drug absorption in the upper gastrointestinal (GI) tract. Various strategies have been developed to achieve gastroretention, each leveraging different physiological aspects of the stomach to extend the residence time of the drug [10].

1. Floating drug delivery systems (FDDS)
2. High density gastrointestinal delivery systems
3. Inflatable gastrointestinal delivery systems
4. Gastroadhesive systems

1. Floating drug delivery systems
Floating Drug Delivery Systems (FDDS) represent a significant advancement in the realm of gastroretentive drug delivery. These systems are engineered to remain buoyant in the stomach's gastric fluid, providing prolonged gastric retention, which enhances drug absorption and therapeutic efficacy for drugs that are preferentially absorbed in the upper part of the gastrointestinal (GI) tract or are less soluble in the intestinal environment [11].

The fundamental principle behind FDDS is to maintain the drug delivery system at a level in the stomach where it can remain buoyant and resist gastric emptying for extended periods. This is achieved through various design approaches:
- **Density-Based Buoyancy:** FDDS typically have a density lower than the gastric fluids (about 1.004 g/cm³). This allows them to float on the surface of the

stomach contents. The systems can either be inherently low-density or designed to generate gas that reduces their density upon contact with gastric fluids [12].

- **Swelling and Gel Formation:** Upon reaching the stomach, some FDDS swell and form a gel barrier around the core. This barrier traps the gas generated within the system or maintains a low-density structure, ensuring buoyancy. The gel matrix controls the drug release, providing a sustained delivery profile [13].

Types of floating drug delivery systems: Based on the mechanism of buoyancy and two distinctly different technologies have been utilized in the development of FDDS.

a. Non-Effervescent FDDS
b. Effervescent FDDS

a. Non-Effervescent Floating Drug Delivery Systems: Non-effervescent Floating Drug Delivery Systems (FDDS) are a class of gastroretentive drug delivery systems designed to enhance the retention of drugs in the stomach by leveraging the buoyancy provided through the use of swellable and gel-forming hydrophilic polymers. Unlike effervescent systems, non-effervescent FDDS do not rely on gas generation to achieve flotation but rather on the intrinsic properties of the polymers used.[14]

Mechanism of Action [15]

- **Hydration and Swelling:** Upon contact with gastric fluids, the hydrophilic polymers absorb water and swell to form a gel layer. This layer entraps the drug and forms a low-density matrix that floats on the gastric contents.
- **Gel Matrix Formation:** The gel matrix acts as a barrier to drug release, allowing for a controlled and sustained release of the drug as the system remains buoyant.
- **Buoyancy Maintenance:** The swollen gel matrix keeps the system less dense than the gastric fluids, ensuring that it remains at the surface of the stomach contents and is retained for a longer duration.

Types of Non-Effervescent FDDS [16-18]: Non-effervescent FDDS can be categorized based on their design and the materials used. The common types include single-unit and multiple-unit systems, each offering specific advantages.

A. Single-Unit Systems: Single-unit systems are typically in the form of tablets or capsules that swell and form a gel barrier to achieve buoyancy.

- **Floating matrix tablets:** The drug and hydrophilic polymers are blended into a single tablet. Upon contact with gastric fluids, the polymers hydrate and form a gelatinous layer that provides buoyancy and controls the drug release. Commonly used polymers include hydroxypropyl methylcellulose (HPMC), carbopol, and ethyl cellulose.
- **Capsule-Based Systems:** Capsules are filled with a blend of drug and hydrophilic polymers. Upon ingestion, the capsule shell dissolves, and the polymers inside swell to form a floating mass that remains buoyant in the stomach. These systems can be designed for immediate or controlled release.
- **Floating Alginate Beads:** These are formed by ionotropic gelation of sodium alginate with calcium chloride. The beads swell upon contact with gastric fluids and remain buoyant due to the low-density gel structure formed by alginate.

B. Multiple-Unit Systems: Multiple-unit systems consist of smaller units like pellets, beads, or microspheres that can distribute uniformly throughout the stomach, offering more predictable drug release and reducing the risk of localized irritation.

- **Floating Microsphere:** Floating microspheres are small, hollow or porous particles, usually ranging from 1 to 1000 micrometers in diameter. They are engineered to float on the gastric fluids due to their low density, which is achieved through the incorporation of hydrophilic polymers that swell and form a buoyant gel matrix upon contact with gastric fluids. This buoyancy allows the microspheres to stay in the stomach for extended periods, leading to sustained drug release.
- **Floating Beads:** Beads are typically made using natural polymers like alginate, which can swell and form a buoyant structure. They can be loaded with the drug and hydrophilic polymers that swell upon hydration to maintain buoyancy.
- **Granules and Pellets:** These are small, discrete particles that contain the drug and a blend of hydrophilic polymers. Upon ingestion, they hydrate and swell to form a floating mass that provides a controlled release of the drug.

B. Effervescent Floating Drug Delivery Systems [19]: Effervescent systems are a type of gastroretentive drug delivery system that utilize gas-generating agents to achieve buoyancy in the stomach. These systems typically contain a combination of carbonates or bicarbonates (such as sodium bicarbonate) and organic acids (such as citric acid or tartaric acid). When these components react, they generate carbon dioxide (CO_2) gas. The evolution of gas reduces the density of the dosage form, allowing it to float on the surface of the gastric contents and thereby prolonging gastric residence time. An alternative design involves the incorporation of a matrix containing a volatile liquid component. Upon exposure to body temperature, this liquid evaporates, producing gas that contributes to the system's buoyancy. These effervescent systems further classified into two types.

- Gas generating systems
- Volatile liquid/vacuum systems
- **Gas generating systems:** These buoyant delivery systems utilize effervescent reactions between Carbonate/bicarbonate salts and citric/tartaric acid to liberate CO_2, which gets entrapped in the jellified hydrocolloid layer of the systems thus decreasing its specific gravity and making it to float over gastric content [20].
- **Single Layer Floating Tablets or Hydrodynamically Balanced System (HBS):** These systems are formulated by thoroughly mixing carbon dioxide-generating agents with the drug within a matrix tablet. The resulting dosage form has a lower bulk density than gastric fluids, enabling it to float on the stomach contents and resist gastric emptying for an extended period. As the tablet remains buoyant, the drug is gradually released at a controlled rate, ensuring sustained delivery. Once the drug is completely released, the residual matrix is eventually expelled from the stomach. This mechanism prolongs gastric residence time and allows for more consistent plasma

drug concentrations, minimizing fluctuations and improving therapeutic effectiveness [21].

- **Bilayer Floating Tablets:** These are also compressed tablet containing two layer i.e. (1) Immediate release layer (2) Sustained release layer.
- **Multiple Unit Type Floating Pills:** These systems are composed of sustained-release pellets, often referred to as "seeds," encased within two distinct layers. The inner layer contains effervescent agents, while the outer layer consists of a swellable polymeric membrane. Upon exposure to a dissolution medium at body temperature, the system initially sinks due to its density. However, the effervescent reaction within the inner layer generates carbon dioxide (CO_2), which becomes trapped within the swollen structure as the outer membrane expands. This entrapment of gas decreases the system's overall density, causing the pills to swell and rise, eventually floating like balloons in the gastric environment. This floating behavior enhances gastric retention and supports prolonged drug release [22].
- **Ion exchange resin:** Ion-exchange resins, a type of multiple-unit oral floating dosage system, have been developed to prolong the gastric residence time of drug formulations. This system consists of beads containing a drug-resin complex, which are preloaded with bicarbonate ions and subsequently coated with a hydrophobic polymer. Upon reaching the stomach, the chloride ions present in the gastric fluid are exchanged with the bicarbonate and drug ions from the resin. This ion-exchange reaction leads to the generation of carbon dioxide (CO_2), which becomes entrapped within the polymer-coated beads. The accumulation of CO_2 decreases the density of the beads, enabling them to float in the gastric environment, thereby enhancing gastric retention and enabling sustained drug release.[23]
- **Volatile liquid containing system**: The gastric retention time (GRT) of a drug delivery system can be extended by incorporating an inflatable chamber containing a volatile liquid, such as ether or cyclopentane, which vaporizes at body temperature, causing the chamber to inflate within the stomach. This inflation reduces the system's density, allowing it to float and remain in the gastric environment for a prolonged period. Additionally, the device may include a bioerodible plug composed of materials like polyvinyl alcohol or polyethylene, which gradually dissolves over time. Once the plug erodes, it releases the trapped gas, leading to the deflation of the chamber. This controlled collapse facilitates the eventual exit of the system from the stomach, ensuring safe and timely removal after the desired drug release has been achieved [24].

2. High density system gastrointestinal delivery systems

This approach involves the development of high-density drug delivery systems, designed to have a density greater than that of normal gastric fluids (approximately 1.004 g/mL). These formulations are typically prepared by coating the drug onto a dense core or by blending it with heavy, inert materials such as iron powder, zinc oxide, titanium dioxide, or barium sulfate. The resulting pellets or tablets can be further coated with a diffusion-controlled membrane to regulate drug release. While this method effectively prolongs gastric retention by preventing premature emptying, it presents certain limitations. Manufacturing challenges arise, particularly when incorporating a high drug load, as the dense materials may interact with gastric fluids, potentially affecting drug stability and release profiles. Additionally, ensuring uniformity and buoyancy control in large-scale production can be technically complex [25].

3. Inflatable Gastrointestinal Delivery Systems

In these systems, an inflatable chamber is incorporated, containing a volatile liquid, such as ether, which vaporizes at body temperature, causing the chamber to inflate within the stomach. The system is designed by loading the inflatable chamber with a drug reservoir, which may consist of the drug itself or a drug-impregnated polymeric matrix, and then encapsulating the entire assembly in a gelatin capsule. Upon oral administration, the gelatin capsule dissolves in the gastric environment, releasing both the inflatable chamber and the drug reservoir. As the liquid ether vaporizes, the chamber inflates, enabling the system to float in the gastric fluid, thereby retaining the drug reservoir in the stomach and prolonging gastric residence time for sustained drug release [26].

4. Gastroadhesive or Mucoadhesive systems [27]

Mucoadhesive drug delivery systems utilize polymers that can stick to the gastric mucosal lining, thereby extending the residence time of the dosage form in the gastrointestinal tract. This adhesion to the mucus gel layer makes these polymers highly effective excipients in gastroretentive drug delivery systems (GRDDS). The polymers used can be of natural origin, such as sodium alginate, gelatin, and guar gum, or semi-synthetic, like hydroxypropyl methylcellulose (HPMC), carbopol, and sodium carboxymethyl cellulose. The interaction between these polymers and the mucosal membrane can occur through various mechanisms: hydration, bonding, or receptor-based adhesion. In hydration-mediated adhesion, hydrophilic polymers absorb moisture, becoming sticky and enabling attachment to the mucosa. Bonding-mediated adhesion involves either physical interlocking or chemical bonding, which may include ionic or covalent bonds and Van der Waals forces between the polymer and the mucus layer. Receptor-mediated adhesion occurs when certain polymers interact specifically with receptors found on gastric cells. Depending on their nature, these polymers can carry a positive (cationic), negative (anionic), or neutral charge.

- **Hydration-mediated adhesion:** Certain hydrophilic polymers have the tendency to imbibe large amount of water and become sticky, thereby acquiring bioadhesive properties. The prolonged gastroretention of the bio/muco-adhesive delivery system is further controlled by the dissolution rate of the polymer [28].
- **Bonding-mediated adhesion:** Adhesion of polymers to mucus/epithelial cell surface involves varying bonding mechanism. Physical or mechanical bonds can result from deposition and inclusion of the adhesive material in the crevices of the mucus. Secondary chemical bonds, contributing to bioadhesive properties, consist of dispersive interactions (i.e. Vander Walls interactions) and stronger specific interaction, which include on the cell surface. The receptor mediated hydrogen bonds. The hydrophilic functional groups responsible for forming hydrogen bonds are the hydroxyl (OH) and the carboxylic groups (COOH) [29].
- **Receptor-mediated adhesion:** Certain polymers have the ability to bind to specific receptor sites events serves as a potential approach in bio/muco-adhesion,

hence enhancing the gastric retention of dosage forms. Certain plant lectins, like tomato lectins interact specifically with the sugar groups present in mucus or on the glycocalyx [30].

Conclusion

Gastroretentive drug delivery systems (GRDDS) represent a significant advancement in oral pharmacotherapy, especially for drugs with narrow absorption windows, low solubility in alkaline pH, or those that act locally in the stomach. This review highlights various GRDDS approaches such as floating systems, bioadhesive systems, swelling and expandable systems and high-density systems, each offering unique mechanisms to prolong gastric residence time and enhance drug bioavailability. The success of these systems depends on multiple physiological and formulation factors including gastric motility, density, size, and patient-related variables.

Although GRDDS present numerous advantages such as reduced dosing frequency, improved patient compliance, and targeted drug release, they also face challenges such as unpredictable gastric emptying and variability among individuals. Recent advancements in polymer science and nanotechnology continue to overcome some of these limitations, offering more reliable and efficient delivery platforms. In conclusion, GRDDS hold substantial promise in optimizing oral drug delivery and therapeutic outcomes, especially for drugs requiring extended gastric retention. Continued research and development in this field will further enhance their effectiveness and expand their applicability across various therapeutic areas.

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