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Gastro retentive drug delivery system: A review

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Abstract
Gastro retentive drug delivery systems (GRDDS) have garnered significant attention in recent years due to their potential to enhance therapeutic efficacy and patient compliance by prolonging gastric residence time and optimizing drug release kinetics. This review provides a comprehensive overview of the latest advancements in GRDDS, focusing on formulation strategies, design principles, and evaluation methodologies. Various approaches such as floating systems, mucoadhesive systems, expandable systems, and magnetic systems are discussed in detail, highlighting their mechanisms of action and applications in targeted drug delivery. Furthermore, recent innovations in materials science and formulation technologies have enabled the development of novel GRDDS with improved biocompatibility, stability, and controlled release profiles. The review also addresses challenges associated with GRDDS, including physiological variability, drug stability, and regulatory considerations, and proposes potential strategies to overcome these obstacles. Additionally, the clinical relevance of GRDDS in the treatment of various gastrointestinal disorders and their future prospects in personalized medicine and targeted therapy are explored. Overall, this review aims to provide valuable insights into the current state-of-the-art in GRDDS research and its implications for the advancement of drug delivery science.

Keywords: GRDDS, floating system, stomach physiology, factor affects gastric retention, classsification of GRDDS.

Introduction
One of the most commonly used routes of drug administration is the oral route. In recent times, oral controlled-release drug delivery systems have gained significant attention in the pharmaceutical field due to their ability to enhance the therapeutic effectiveness of drugs while also improving patient compliance. Gastro-retentive drug delivery is an effective approach designed to extend the residence time of a drug in the stomach, enabling targeted drug release at a specific site for either local or systemic therapeutic effects. These formulations are capable of staying in the stomach for extended periods, thereby significantly increasing the drug's gastric retention time. By releasing the drug in a controlled manner within the stomach, they ensure a steady and continuous supply of the drug to its primary absorption site in the gastrointestinal tract. Gastro-retentive drug delivery systems (GRDDS) are designed to retain the drug delivery system in the stomach or the upper part of the small intestine until the complete release of the drug. These systems are developed by utilizing the principles of controlled release (CR) and delayed gastric emptying.

Stomach
The stomach is situated just below the diaphragm, in the upper left region of the abdominal cavity. Its volume varies depending on how much it is stretched, and it can expand up to approximately 1500 ml after a meal. Once the stomach empties, it shrinks back to a resting volume of about 25-50 ml.

Structure and Function of Stomach
The human gastrointestinal tract is anatomically divided into three primary sections: the fundus, the neck, and the antrum. The upper portion, known as the fundus, serves as a storage area for undigested food. In contrast, the antrum functions like a pump, playing a key role in mixing the stomach contents and propelling them toward the intestines for further digestion.

Physiology of Stomach

Stomach is divided into three parts

1. Body
2. Fundus
3. Pylorus

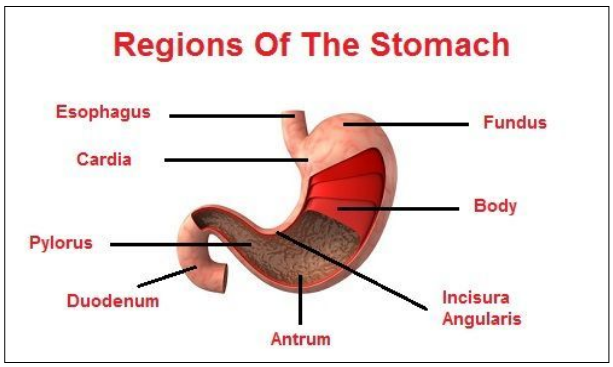


Fig 1: Regions of the Stomach

Advantages Of GRDDS

1. It has been utilized in the treatment of peptic ulcer disease.
2. Commonly applied for drugs with a narrow therapeutic index to reduce dosing frequency.
3. Enhances the bioavailability of certain medications.
4. Suitable for drugs that are typically unstable in intestinal fluids.
5. Helps provide sustained drug release to maintain optimal therapeutic levels within the desired therapeutic window.

Disadvantages of GRDDS

- Drugs that are unstable in highly acidic conditions, poorly soluble in gastric acid, or irritating to the stomach lining are not suitable for formulation as gastroretentive drug delivery systems (GRDDS).
- Floating Drug Delivery Systems (FDDS), a type of GRDDS, require a sufficient amount of fluid in the stomach to float and function effectively. Therefore, increased water intake is necessary when taking this type of dosage form.

Requirements for GRDDS

Requirements for Designing a Gastro-Retentive Drug Delivery System (GRDDS)

1. Medications that exert their effects locally in the stomach, such as antacids and agents used to treat *Helicobacter pylori* (e.g., Misoprostol).
2. Drugs that are primarily absorbed in the stomach, like Amoxicillin.
3. Compounds with poor solubility in intestinal fluids, including Furosemide, Diazepam, and Verapamil.
4. Drugs with a narrow absorption window, such as Cyclosporine, Methotrexate, and Levodopa.
5. Medications that are rapidly absorbed in the gastrointestinal tract**,** like Metronidazole and Tetracycline.
6. Drugs that are unstable or degrade in the colon**,** including Ranitidine and Metformin HCl.
7**.** Medications that disrupt normal colonic microflora, such as antibiotics used to treat *H. pylori* infections.

Current Trends in GRDDS

1. Dual working system

These systems operate based on mechanisms such as floating, bioadhesion, and swelling. A dual-function system that combines these principles could significantly enhance the therapeutic efficacy of the drug. Such a system would effectively address the limitations associated with using bioadhesive, swelling, or floating approaches individually.

2. Floating osmotic system

"Pulsatile drug delivery systems release drugs rapidly and completely after a predetermined lag time. However, due to this delay, there is a risk that the system may be eliminated from the body before the drug is released."

Factors Affecting Gastroretentive Retension

1. Density: The gastric residence time (GRT) of an oral dosage form is influenced by its buoyancy, which depends on its density. If the dosage form has a density lower than that of gastric fluids, it tends to float, thereby increasing its GRT.

2. Size: "A dosage form with a diameter of 7.5 mm has been reported to have a longer gastric residence time (GRT) compared to one with a diameter of 9.9 mm."

Suitable Drug Candidates For GRDDS

1. **Acts locally in the stomach**

Exerts its effects directly within the stomach.

2. **Primarily absorbed in the stomach**

Mainly taken up through the stomach lining.

3. **Poorly soluble at an alkaline pH**

Has low solubility in basic (alkaline) environments.

4. **Absorbed rapidly from the stomach**

Quickly taken up by the stomach.

5. **Degrade in the colon**

Breaks down in the colon.

Need for GRDDS

- Conventional oral drug delivery is commonly used in the pharmaceutical field to treat various diseases. However, it comes with several limitations, the most significant being lack of site-specificity.
- Certain drugs are absorbed only at specific sites in the gastrointestinal tract. These drugs need to be released directly at the target site, or in a manner that ensures the maximum drug concentration reaches the desired location.
- As a result, the pharmaceutical industry is increasingly focusing on the development of site-specific drug delivery systems to enhance therapeutic effectiveness and reduce side effects.

Limitations of Techniques of Gastric Retension

To ensure improved predictability and reproducibility of floating drug delivery systems under extreme gastric conditions, several challenges must be addressed:

1. Achlorhydria and Swellable Systems: In patients with achlorhydria, the effectiveness of swellable systems becomes questionable. These systems must exhibit rapid swelling behavior, achieving full expansion well before

gastric emptying occurs to ensure proper retention and drug release.

2. Bioadhesion and Mucus Turnover: The efficiency of bioadhesive systems in the acidic stomach environment is debatable due to the high turnover rate of gastric mucus. Furthermore, the retention of high-density systems in the antrum region of the stomach remains uncertain under the influence of migrating motor complex (MMC) waves.

3. Unsuitability for Certain Drugs: These systems are not appropriate for drugs that may cause gastric irritation or lesions, such as non-steroidal anti-inflammatory drugs (NSAIDs). Additionally, they offer limited benefits for drugs that are unstable in acidic environments or those absorbed throughout the gastrointestinal tract, as compared to conventional dosage forms.

4. Mucus Renewal and Adherence: The continuous renewal of gastric mucus results in inconsistent and unpredictable bioadhesion, limiting the reliability of mucoadhesive drug delivery approaches.

Biological Factors

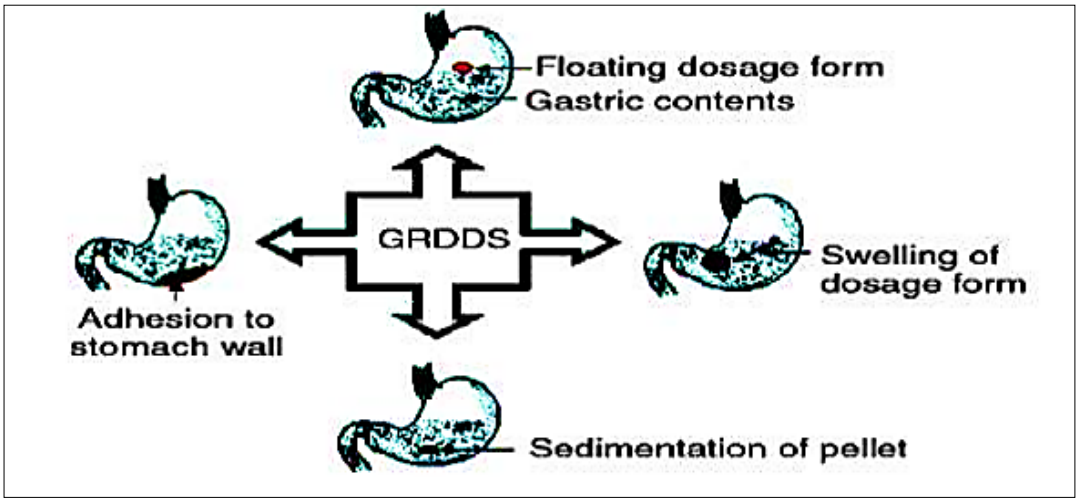
1. Age: "Individuals over the age of 65 typically show prolonged gastric residence times for the dosage forms.

2. Gender: research shows that gender has a notable impact on gastric emptying time and luminal pH, with women experiencing slower gastric emptying compared to men.

3**. Disease state:** Different diseases can influence the gastric retention time (GRT) of medications in various ways. For example, patients with Parkinson's disease often experience prolonged GRT and may commonly suffer from constipation.

Classification of GRDD

1. High density systems
2. Expandable system
3. Super porous hydrogels
4. Mucoadhesive or bioadhesive systems
5. Magnetic system
6. Dual working systems
7. Floating systems



1. High-Density Systems

This method involves designing dosage forms with a density greater than that of the stomach contents, which is approximately 1.004 g/ml. To achieve this, the drug is coated or combined with heavy, inert substances like iron powder, zinc oxide, titanium dioxide, or barium sulfate. These materials increase the overall density of the formulation, helping it remain in the stomach for a longer period.

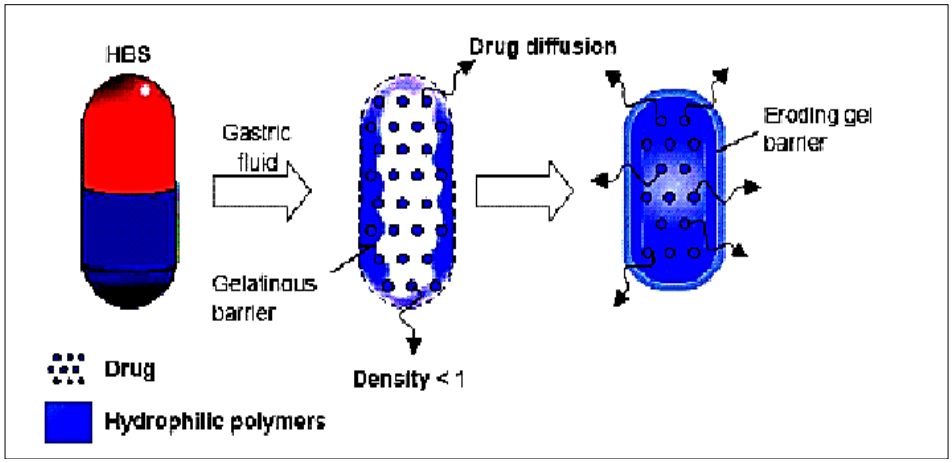
2. Swellable and Expandable Systems: A dosage form can remain in the stomach without being affected by gastric transit if it expands to a size larger than the pyloric sphincter. However, patient compliance is a key consideration for all types of dosage forms. Therefore, the dosage form must initially be small enough to be easily swallowed and should not cause gastric obstruction as it expands or accumulates.

3. Super Porous Hydrogels

These swellable systems differ significantly from conventional hydrogels. Traditional hydrogels absorb water slowly, often requiring a long time to reach their equilibrium swelling state. This delay can lead to premature evacuation of the dosage form before it fully expands. In contrast, super porous hydrogels have a pore size greater than 100 µm, allowing them to swell to their full size within a minute. This rapid swelling is due to capillary action, as water is quickly drawn in through a network of interconnected open pores.

4. Floating Systems (Hydro-dynamically Balanced Systems - HBS)

These systems are designed to have a lower density than gastric fluids, allowing them to float on the stomach contents without altering the natural gastric emptying process. By remaining buoyant for an extended duration, they enable the drug to be released gradually at a controlled rate. This leads to prolonged gastric retention time and helps minimize fluctuations in drug levels.

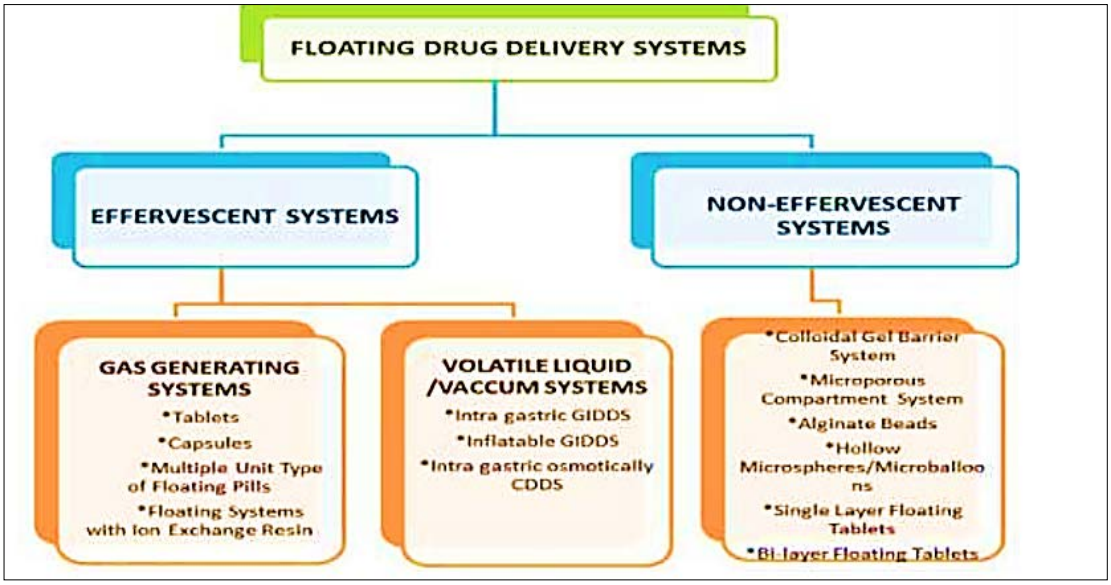


Principles of HBS15

The gel barrier regulates how quickly fluid enters the device, which in turn governs the rate at which the drug is released.

- It should possess adequate structural integrity to develop a unified gel-like barrier.
- It must retain a density that remains less than that of the stomach contents.

Classification of Floating Drug Delievery System

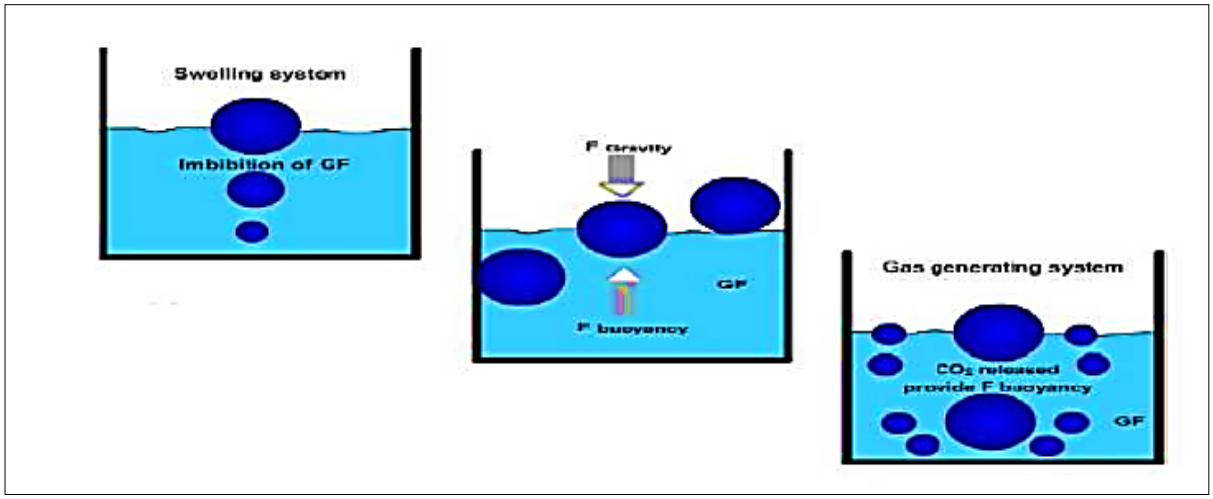


Non-effervescent FDDS

One method of creating floating dosage forms involves thoroughly blending the drug with a gel-forming hydrocolloid. When this mixture reaches the stomach, it absorbs gastric fluid, swells, and keeps its shape while maintaining a lower density than the surrounding fluid. The air that becomes trapped in the swollen polymer helps the dosage form float. Additionally, the gel structure serves as a drug reservoir, allowing the drug to be released gradually through controlled diffusion from the gel barrier.

Effervescent FDDS

These systems remain buoyant in the stomach by using matrices made from swellable polymers like Methocel or natural polysaccharides such as chitosan. They also incorporate effervescent agents like sodium bicarbonate combined with citric or tartaric acid, which generate gas upon contact with gastric fluid. Alternatively, some formulations include liquid-filled chambers that release gas when exposed to body temperature, aiding in floatation. Floating dosage forms that utilize an in situ gas-generating mechanism typically offer enhanced buoyancy and improved drug release profiles. However, adjusting the drug release characteristics can sometimes affect the floating ability. Therefore, during formulation development, it may be necessary to independently control buoyancy and drug release behavior to achieve optimal performance.



Conclusion

In light of recent developments, it can be concluded that gastroretentive drug delivery systems represent a valuable strategy for improving the bioavailability of drugs that are poorly absorbed and primarily absorbed in the upper gastrointestinal tract. By prolonging the drug's retention in this region, these systems enhance absorption and optimize therapeutic effectiveness. Advancements in delivery technology will enable the development of more effective gastro-retentive drug delivery systems, improving the administration of drugs that undergo extensive first-pass metabolism, have low bioavailability, or a narrow absorption window. Our review of the literature indicates that gastro-retentive drug delivery provides significant advantages for drugs with poor bioavailability by restricting their absorption to the upper gastrointestinal tract. This targeted approach enhances drug absorption and increases overall bioavailability. Ultimately, a gastro-retentive drug delivery system maximizes therapeutic outcomes for patients.

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