

DESIGN AND DEVELOPMENT OF FLOATING DRUG DELIVERY SYSTEMS FOR ENHANCED GASTRIC RETENTION

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Abstract

Gastro retentive floating drug delivery systems (GRFDDS) are designed to prolong the residence time of dosage forms in the stomach, thereby improving the bioavailability of drugs that are preferentially absorbed from the upper gastrointestinal tract. These systems remain buoyant in gastric fluid without affecting the normal gastric emptying rate, allowing sustained and controlled drug release. Floating drug delivery systems are particularly beneficial for drugs with a narrow absorption window, low solubility at high intestinal pH, or those intended for local action in the stomach. GRFDDS are mainly classified into effervescent and non-effervescent systems. Effervescent systems generate gas upon contact with gastric fluid, reducing density and enabling floatation, whereas non-effervescent systems rely on swellable polymers to maintain buoyancy. Various polymers such as hydroxypropyl methylcellulose, chitosan, and sodium alginate are commonly used in formulation development. The advantages of GRFDDS include improved therapeutic efficacy, reduced dosing frequency, enhanced patient compliance, and minimized drug fluctuations. However, factors such as gastric motility, fed or fasted state, and formulation variables influence system performance. Overall, gastro retentive floating drug delivery systems represent an effective approach for enhancing oral drug delivery and are widely explored in modern pharmaceutical research.

Keywords: Gastro retentive drug delivery system (GRDDS), Floating drug delivery system (FDDS), Gastric retention time (GRT), Low density systems, Floating lag time, Sustained release, Controlled release, Hydrodynamically balanced system (HBS), Effervescent floating systems.

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1. INTRODUCTION

Oral administration is considered the most convenient and widely preferred route for introducing drugs into the systemic circulation. In recent years, considerable attention has been directed toward oral controlled-release drug delivery systems, as they enhance therapeutic efficacy, improve patient compliance, provide formulation versatility, and simplify dosing schedules. Nevertheless, drugs that are rapidly absorbed from the gastrointestinal tract (GIT) and have short biological half-lives are quickly eliminated from the bloodstream [1].

The oral route of drug administration has gained wide acceptance because of its distinctive advantages, including cost-effectiveness, ease of administration, improved patient compliance, and the availability of diverse dosage forms. Among the various approaches used to prolong gastric residence time (GRT), floating drug delivery systems (FDDS) are one of the most widely employed strategies [2]. After the drug is

released, the residual dosage form is eventually emptied from the stomach. Consequently, gastric residence time (GRT) is increased and fluctuations in plasma drug concentration are more effectively controlled [3]. However, this approach is associated with several physiological limitations, such as variable and unpredictable gastric emptying, the presence of a specific absorption window in the upper small intestine for many drugs, and a short overall gastrointestinal transit time of approximately 8–12 hours [4].

In recent years, oral dosage forms designed for gastric retention have attracted considerable attention because they provide better control over the timing and location of drug release, leading to improved therapeutic effectiveness [5].

2. PHYSIOLOGY OF STOMACH GRDDS

Success of gastro retentive drug delivery systems (GRDDS) largely depends on a clear understanding of gastric physiology and the gastric emptying process.

The human stomach is anatomically divided into three main regions: the fundus, body, and antrum (pylorus). After a meal, the stomach typically holds about 1.5 L of content, while during the inter digestive state its volume varies between 250–500 mL. Gastric motility differs between fed and fasting states and follows alternating active and resting cycles known as the migrating motor complex (MMC). Each MMC cycle lasts approximately 90–120 minutes and consists of four distinct phases [6, 7].

Conventional oral dosage forms are widely employed in the pharmaceutical field for disease treatment; however, they present several limitations, particularly the lack of site-specific drug delivery. Some drugs are absorbed only at specific regions of the gastrointestinal tract and therefore require release at a predetermined location to ensure maximum therapeutic availability.

Gastro retentive drug delivery is one such strategy, in which the dosage form is retained in the stomach and the drug is gradually released in a controlled manner into the stomach, duodenum at the desired site.

Components of Floating Drug Delivery Systems

The formulation of floating drug delivery systems (FDDS) involves several functional excipients, each contributing to buoyancy, stability, and controlled drug release:

Hydrocolloids: Hydrophilic polymers, either synthetic or naturally derived, that swells in gastric fluid to form a gel barrier and help maintain floatation.

Polymers: Various polymers are widely used to develop floating formulations by controlling swelling and drug release. Common examples include HPMC K4M, HPMC K15M, polyethylene glycol, polycarbonate, sodium alginate, PVA, PVP, Eudragit, Carbopol, methyl methacrylate, and acrylic polymers [8].

1. Importance of GRDDS In The Field Of Pharmaceutics

Immediate-release oral dosage forms are widely used for disease management, but their absorption often occurs only at specific regions of the gastrointestinal tract. The limitations associated with these conventional formulations have led to the development of gastro-retentive drug delivery systems. These systems prolong the retention of the dosage form in the stomach, enabling controlled and targeted drug release at desired such as the stomach, thereby improving therapeutic effectiveness [9].

2. Classification of Gastro Retentive Floating Drug Delivery System [10].

3. Approaches of GRFDDS

Floating drug delivery systems (FDDS), also called hydrodynamically balanced systems, are designed to prolong gastric residence time and improve optimal drug bioavailability. Buoyancy in the stomach is achieved by reducing the bulk density of the dosage form compared with gastric fluid.

6. High-density systems: In GRDDS, density plays a significant role in gastric retention. High-density systems rely on increased weight to remain in the

stomach; therefore, the dosage form density must exceed that of gastric contents (approximately 1.004 g/mL).

6.1. Low-density systems: Another strategy for prolonging gastric retention is to design dosage forms with density lower than gastric fluid. Such formulations remain buoyant, allowing continuous drug release, thereby increasing gastric residence time and improving bioavailability.

6.2. Mucoadhesive and bio adhesive systems: Mucoadhesive or bio adhesive systems prolong gastric retention by adhering to the mucosal surface of the stomach. These formulations employ adhesive polymers that maintain the dosage form at a specific site for an extended duration, enabling targeted drug delivery.

6.3. Swelling systems: In swelling (expandable or plug-type) systems, the dosage form enlarges upon contact with gastric fluid to a size larger than the pyloric opening, preventing its passage into the intestine. Suitable excipients are used to achieve sustained and controlled drug release [11].

7. Factors Affecting of GRFDDS

7.1 Size and shape: Dosage forms with a diameter greater than 7.5 mm generally exhibit longer gastric residence time (GRT) compared to smaller units. Tetrahedral and ring-shaped devices, possessing suitable flexural strength (about 48 and 22.5 KSI), demonstrate superior retention in the gastrointestinal tract, achieving nearly 90–100 % retention after 24 hours.

7.2 Caloric content: A protein-rich meal can prolong gastric residence time by approximately 4–10 hours.

7.3 Density: For floating systems, the dosage form density should be lower than that of gastric contents (≈ 1.004 g/mL).

7.4 Volume of gastrointestinal fluid: The stomach normally contains 25–50 mL in the resting state. Larger fluid volumes promote faster emptying, and fluids at body temperature empty more rapidly than colder or hotter liquids.

7.5 Age: Elderly individuals, especially those above 70 years, generally exhibit longer gastric retention time, with notable inter- and intra-subject variability [12].

7.6 Mechanism of Floating Drug Delivery System

Various strategies have been explored to retain dosage forms in the stomach for prolonged periods. These include co-administration of gastric emptying–delaying agents and the development of floating, mucoadhesive, high-density, and modified release dosage forms. To evaluate floating behavior, a specialized apparatus has been reported for determining floating force kinetics. The device continuously measures the force required to keep the dosage form submerged as a function of time. This method assists in optimizing floating drug delivery systems by ensuring stability and persistence of buoyant force, thereby minimizing variations in intragastric floating performance.

The net vertical force acting on the dosage form is expressed as:

$$F = F_{\text{buoyancy}} - F_{\text{gravity}} = (D_{\text{f}} - D_{\text{s}}) g v \quad [13].$$

8.1 Effervescent systems

Effervescent floating systems are further categorized into the following type:

a. Gas-generating systems: In these systems, carbon dioxide (CO₂) is produced through the reaction between sodium bicarbonate and organic acids such as citric acid or tartaric acid.

Typically, the formulation consists sustained-release tablet surrounded by a structure. The inner effervescent layer contains sodium bicarbonate and tartaric acid responsible for gas generation, outer layer is swellable polymeric membrane that controls expansion allowing the system to over gastric contents.

b. Volatile Liquid Containing Systems: Volatile liquid containing systems are gastroretentive dosage forms designed with an inflatable chamber that encloses a volatile liquid such as ether or cyclopentane. At body temperature, the volatile liquid vaporizes, producing gas that inflates the chamber within the stomach.

- Intra-Gastric Floating Gastrointestinal Drug Delivery System: This system consists of a flotation chamber containing a vacuum or an inert, non-toxic gas to ensure buoyancy.

- Inflatable Gastrointestinal Drug Delivery System: In this approach, the inflatable chamber contains a volatile liquid such as ether, which vaporizes at body temperature and causes the system to expand within the stomach [14].

8.2 Non-Effervescent Systems: Non-effervescent gastroretentive drug delivery systems are designed to maintain prolonged gastric residence time without the generation of carbon dioxide. These systems generally rely on swelling, bioadhesion, or low-density materials to achieve buoyancy.

a. Hydrodynamically Balanced System (HBS): A hydrodynamically balanced system consists of a drug formulation incorporated within gel-forming hydrocolloids.

b. Microballoons (Hollow Microspheres): Microballoons, also known as hollow microspheres, are spherical particles characterized by the absence of a solid core [15].

3. EXCIPIENTS INCORPORATED IN DIFFERENT FLOATING DOSAGE FORM [16].

Various excipients are incorporated into floating drug delivery systems to achieve buoyancy, controlled drug release, stability, and desired therapeutic performance. The commonly used excipients include the following:

- Effervescent Agents: Effervescent agents are included to generate carbon dioxide when they react with gastric fluid, thereby reducing the density of the dosage form and promoting floatation.

- Release Rate Retardants: Certain excipients are added to slow down the drug release rate and maintain

sustained therapeutic levels. Materials such as talc, dicalcium phosphate, and magnesium stearate are commonly used as release-retarding agents.

4. PHARMACOKINETIC AND PHARMACODYNAMIC ASPECTS OF FLOATING DRUG DELIVERY SYSTEM

The objective of this section is to outline the pharmacokinetic and pharmacodynamic considerations that support the rational selection of drugs suitable for Floating Drug Delivery Systems (FDDS). These aspects help determine whether FDDS would provide therapeutic advantages for a specific drug candidate.

10.1 Pharmacokinetic Aspects of Floating Drug Delivery Systems

- Absorption Window: Floating drug delivery systems are particularly beneficial for drugs that possess a narrow absorption window in the upper gastrointestinal tract.

- Enhanced First-Pass Biotransformation: Sustained drug delivery from floating systems may also influence pre-systemic metabolism. When a drug is continuously presented to metabolic enzymes, first-pass metabolism may increase compared to bolus administration [17].

10.2 Pharmacodynamic Aspects of Floating Drug Delivery Systems

Floating Drug Delivery Systems (FDDS) influence not only the pharmacokinetic profile of a drug but also its pharmacodynamic response.

- Reduced Fluctuations in Drug Concentration: Compared to immediate-release dosage forms, floating systems provide continuous and controlled drug input, resulting in relatively stable plasma drug concentrations within a narrow therapeutic range.

- Improved Selectivity in Receptor Activation: Maintaining consistent plasma drug levels also enhances selectivity in receptor activation. Certain drugs interact with multiple receptor subtypes at different concentration ranges [18].

5. EVALUATION TESTS FOR GRDDS

Evaluation of GRDDS involves both in vitro and in vivo studies to assess buoyancy, drug release behavior, physicochemical properties, and biological performance.

7.1 Floating Lag Time: Floating lag time is defined as the time required for a dosage form to rise to the surface of the dissolution medium after being placed in it. This parameter is usually measured during in vitro dissolution testing and indicates the efficiency of buoyancy of the formulation.

7.2 Moisture Content, Ion Exchange Capacity, and Particle Size: The particle size of ion-exchange resin systems can be determined using techniques such as sieve analysis (sieve shaker), laser diffraction, and Coulter counter analysis.

7.3 Drug–Excipient Interaction Studies: Drug–excipient compatibility studies are conducted to evaluate possible physicochemical interactions. These studies can be performed using analytical techniques such as Fourier Transform Infrared (FT-IR) spectroscopy,

Differential Scanning Calorimetry (DSC), and High-Performance Liquid Chromatography (HPLC).

7.4 Swelling Index: The swelling index measures the extent of expansion of the dosage form in simulated gastric fluid (SGF) at 37°C. The dosage form is removed at predetermined time intervals, and changes in dimensions (thickness or diameter) are recorded to evaluate the swelling behavior over time.

7.5 Water Uptake Study: Water uptake is an indirect measure of the swelling characteristics of swellable matrix systems. The dosage form is periodically removed from the medium, and its weight gain is measured over time [19].

The percentage water uptake (WU) is calculated using the formula:

$$WU = \frac{(W_t - W_0)}{W_0} \times 100$$

Where: W_t = Weight of the dosage form at time t

W_0 = Initial weight of the dosage form

This parameter reflects the hydration capacity of the formulation.

7.6 Entrapment Efficiency: Entrapment efficiency (percentage encapsulation efficiency) determines the amount of drug successfully incorporated into multi-particulate systems. It is calculated by lysing the washed micro-particulates and analyzing the released drug content according to pharmacopeial standards.

The percentage entrapment is calculated using the formula:

$$\% \text{ Entrapment} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

This parameter indicates the efficiency of drug loading.

7.7 In Vivo Evaluation Tests

Radiographic (X-ray) Studies: X-ray imaging is widely used to monitor the gastric retention of dosage forms. A radio-opaque marker such as barium sulfate is incorporated into the formulation to visualize its position in the gastrointestinal tract [20].

6. ADVANTAGES AND DISADVANTAGES OF GRFDDS

Gastro retentive Drug Delivery Systems (GRDDS) offer several therapeutic benefits, particularly for drugs absorbed in the upper gastrointestinal tract. However, they also present certain limitations that must be considered during formulation design.

12.1 Advantages

Enhanced Bioavailability: GRDDS can significantly improve the bioavailability of certain drugs. For example, controlled-release gastro retentive formulations of riboflavin have demonstrated higher bioavailability compared to conventional controlled-release polymeric systems. **Sustained Drug Delivery and Reduced Dosing Frequency:** Controlled-release gastro retentive formulations provide prolonged and gradual drug input, which may produce flip-flop pharmacokinetics in drugs with short biological half-lives [21].

12.2 Disadvantages

Despite their advantages, GRDDS have certain limitations:

- Drugs that are unstable in acidic gastric conditions (e.g., erythromycin) are not appropriate candidates.
- Drugs that irritate the gastric mucosa or cause ulceration when retained for prolonged periods (e.g., NSAIDs, aspirin) should be avoided [22].

7. Applications of Floating Drug Delivery System (FDDS)

Floating Drug Delivery Systems offer significant therapeutic advantages, particularly for drugs exhibiting poor bioavailability due to a narrow absorption window in the upper gastrointestinal tract. By prolonging gastric residence time and maintaining the dosage form at the preferred absorption site, FDDS enhance drug absorption and overall therapeutic efficacy. The major applications are discussed below.

7.1 Sustained Drug Delivery

Hydrodynamically balanced systems (HBS) are capable of remaining in the stomach for an extended duration, thereby enabling sustained drug release [23].

7.2 Site-Specific Drug Delivery

Floating systems are particularly beneficial for drugs that are primarily absorbed from the stomach or proximal small intestine. By ensuring prolonged localization in the upper gastrointestinal tract, FDDS improve therapeutic outcomes for such drugs.

7.3 Enhanced Bioavailability

Floating controlled-release gastro retentive formulations have been shown to significantly improve bioavailability compared to conventional controlled-release polymeric formulations. Multiple physiological factors related to absorption and transit collectively influence the overall magnitude of drug absorption [24].

8. LIMITATIONS OF GRDDS [25].

Despite their therapeutic advantages, Gastro retentive Drug Delivery Systems (GRDDS) have several limitations that restrict their applicability to certain categories of drugs. These limitations are outlined below:

- Stability and Solubility Constraints:** GRDDS are not suitable for drugs that exhibit instability or poor solubility within the gastrointestinal tract. Such physicochemical limitations may compromise the effectiveness of prolonged gastric retention.
- Gastric Irritation:** Drugs that irritate the gastric mucosa or cause local discomfort are undesirable candidates for gastro retentive systems. Prolonged retention in the stomach may exacerbate mucosal irritation or damage.
- Requirement of Adequate Gastric Fluid:** Floating dosage forms generally require administration with a full glass of water to ensure proper buoyancy.

Adequate gastric fluid volume is essential for optimal floating behavior and system performance.

9. CHALLENGES AND CONSIDERATIONS IN FLOATING DRUG DELIVERY SYSTEM

Although Floating Drug Delivery Systems (FDDS) provide several therapeutic benefits, certain practical and physiological challenges must be addressed to ensure optimal performance.

Requirement of Adequate Gastric Fluid: The effectiveness of floating systems depends on the presence of sufficient gastric fluid to allow proper hydration, swelling, and buoyancy of the dosage form.

- **Risk of Dose Dumping:** There is a potential risk of dose dumping if the floating system fails to maintain buoyancy or undergoes premature disintegration.

- **Patient-Related Variability:** Physiological factors such as body posture, age, gastric motility, disease state, and individual variability in gastric emptying time can significantly influence the performance of floating system [26].

10. FUTURE DIRECTIONS OF GRFDDS

Gastro retentive Floating Drug Delivery Systems (GRFDDS) continue to advance as a promising strategy for enhancing the bioavailability of drugs characterized by a narrow absorption window, poor aqueous solubility, in the intestinal environment. Ongoing research focuses on improving gastric retention, achieving precise control of drug release, and minimizing physiological variability that affects system performance.

10.1 Development of Advanced Polymers

Future formulation strategies emphasize the use of biodegradable and biocompatible polymers with superior swelling capacity and floating characteristics.

10.2 Integration of Novel Technologies

The incorporation of innovative technologies is expected to significantly improve GRFDDS performance.

Three-dimensional (3D) printing offers opportunities for designing personalized floating tablets with controlled density, geometry, and drug release profiles. Combination Gastro retentive Systems

Development of dual- or multi-mechanism gastro retentive systems represents another promising direction. Examples include combinations such as floating with mucoadhesive properties, floating with expandable systems, or floating with high-density systems.

10.3 Targeted and Localized Drug Delivery

Future GRFDDS formulations are being designed for targeted therapy of gastric disorders, including *Helicobacter pylori* eradication, gastric ulcers, and gastric cancer.

10.4 Improved In Vitro–In Vivo Correlation (IVIVC)

Efforts are underway to develop advanced in vitro models that better simulate gastric motility, pH variations, and physiological conditions.

10.5 Application to Emerging Drug Candidates

GRFDDS show strong potential for Biopharmaceutics Classification System (BCS) Class II and IV drugs, which exhibit poor solubility.

10.6 Commercial and Regulatory Advancements

Future progress also depends on successful scale-up strategies for industrial manufacturing and commercialization.

11. CONCLUSION

The development of Gastro retentive Floating Drug Delivery Systems (FDDS) represents a significant advancement in overcoming the limitations associated with conventional oral drug delivery. By prolonging gastric residence time and enabling controlled drug release, these systems enhance therapeutic effectiveness and improve patient outcomes.

Gastro retentive systems offer notable advantages, including improved bioavailability and regulated drug administration. The buoyancy-based approach provides a relatively simple and effective method for achieving extended gastrointestinal retention and sustained drug release. In particular, non-effervescent floating systems have emerged as promising strategies for achieving reliable in vitro buoyancy and prolonged gastric retention.

Furthermore, GRDDS can enhance the solubility of drugs that exhibit poor solubility in alkaline environments, maintain consistent therapeutic plasma levels by minimizing fluctuations, and extend effective drug action.

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