

FLOATING GASTRORETENTIVE DRUG DELIVERY SYSTEM: A COMPREHENSIVE REVIEW OF FORMULATION STRATEGIES, EVALUATION METHODS AND RECENT ADVANCES

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Abstract

Advanced pharmaceutical formulations called Gastroretentive Drug Delivery Systems (GRDDS) are intended to increase a drug's therapeutic efficacy and bioavailability by prolonging its residence duration in the stomach. For medications that are poorly absorbed in the lower gastrointestinal tract or need extended stomach retention for maximum efficacy, this approach is very helpful. By using a variety of mechanisms, including buoyancy, swelling, and bioadhesion, to extend stomach retention, GRDDS overcomes the drawbacks of traditional drug delivery techniques. Improved bioavailability for medications with a limited window of absorption, increased patient compliance as a result of fewer doses, and tailored local action for ailments like peptic ulcers are some of the main benefits. Drugs that operate locally in the stomach, are mostly absorbed in the stomach, or are poorly soluble in alkaline pH are examples of GRDDS possibilities. Different GRDDS techniques, including high-density systems, mucoadhesive systems, and floating systems, provide a variety of methods for achieving extended stomach residence. GRDDS devices, which use cutting-edge materials and technology like hydrogels and magnetic systems, are currently available for treating gastroesophageal reflux disease and peptic ulcers. With continued research concentrating on increasing drug bioavailability, lowering side effects, and boosting patient compliance, GRDDS has bright future prospects. The ultimate goal of this field's ongoing development is to transform pharmaceutical care and therapeutic results by optimizing drug distribution, offering focused therapies, and addressing the shortcomings of conventional dosage forms.

Keywords - Gastro retentive Drug Delivery Systems, bioavailability, therapeutic efficacy.

How to cite this article: Thorat. V. G.^{1*} Jain. A. K.. FLOATING GASTRORETENTIVE DRUG DELIVERY SYSTEM: A COMPREHENSIVE REVIEW OF FORMULATION STRATEGIES, EVALUATION METHODS AND RECENT ADVANCES. Int J Drug Deliv Technol. 2026;16(86s):356-362. DOI: 10.25258/ijddt.16.86s.41.

Introduction

Oral drug delivery system is most widely preferred method because of its flexibility in formulation, convenience of administration, and patient compliance. Oral dosage formulations have advanced significantly from instantaneous release to site-specific delivery. Any drug delivery system's objective is to deliver a therapeutic dosage of the medication to the right location in the body in order to quickly reach and then sustain the intended drug concentration¹.

In order to address physiological challenges such as short gastric residence periods (GRT) and unexpected gastric emptying times (GET), technological efforts have been made in pharmaceutical research and development of rate-controlled oral drug delivery systems. Gastroretentive drug delivery systems (GRDDS) are dosage forms that can be held in the stomach. By constantly releasing the drug for an extended amount of time before it reaches its absorption site, GRDDS can enhance the regulated administration of medications with an absorption window, guaranteeing its optimal bioavailability².

Without providing any control over medication administration, conventional oral dose forms release a particular drug concentration into the systemic circulation. Drug release is provided by controlled-release drug delivery systems (CRDDS) at a set, consistent, and regulated rate. For oral CRDDS to be successful, the drug must be well absorbed throughout the gastrointestinal tract (GIT), ideally by passive diffusion, to guarantee ongoing absorption of the released medication. Although there are minor differences between different dose forms, a single unit typically takes three to four hours to pass through the GIT³.

Not every drug candidate is absorbed evenly across the GIT, which is a significant barrier to oral controlled medication administration. Certain medications are either only absorbed in a specific area of the GIT or are absorbed differently in distinct GIT segments. These medications are referred to as having an absorption window, which indicates the main area of absorption in the GIT. Because of physiological, physicochemical, or biochemical reasons, there is an absorption window. An important factor in a drug's

absorption is its pH-dependent solubility and stability level. A medication must be stable and soluble in order to pass through the biological barrier, and when it passes through the GIT, its pH will fluctuate between 1 and 8.⁴

Physiology of Stomach-

Three anatomical areas make up the stomach. Figure 1 shows the fundus, body, and pylorus. While the distal portion (Pylorus) is the primary site of mixing motions and functions as a pump to propel gastric contents for gastric emptying during both fed and fasting stages, the proximal stomach, which is made up of the fundus and body, serves as a reservoir for ingested materials.

Fig.,1 – Stomach

Histology of Stomach –

There are four fundamental layers that make up the stomach wall. Mucous surface cells are a layer of simple columnar epithelial cells that make up the mucosa's surface. Additionally, epithelial cells extend into the lamina propria, where they produce columns of secretory cells known as gastric glands and numerous tiny pathways known as gastric pits. The stomach lumen receives secretions from the gastric glands after passing through the gastric pits. Mucous neck cells, chief cells, and parietal cells are the three types of exocrine gland cells found in the glands that discharge their contents into the stomach lumen.

The GIT is constantly moving. The two motility patterns involved in food digestion are the digestive mode and the interdigestive (or fasting) mode. An interdigestive sequence of electrical events that cycle through the stomach and small intestine every two to three hours is what defines the fasting state.⁵

Gastrointestinal Motility Patterns Affecting Dosage Form Retention -

GI motility patterns that influence how long dosage forms are retained. The intricate structure and function of the gastrointestinal tract, including variations in acid levels, bile salts, enzyme composition, and the mucosal surface for absorption, greatly affect the release, breakdown, and uptake of orally given medications. There are two separate types of gastrointestinal (GI) motility and secretion, which match the fasted and fed conditions. The fasted condition is linked to several recurring events, often known as the Migrating Myoelectric Complex (MMC), which governs GI motility patterns. The MMC consists of alternating periods of activity and rest, and can be split into basal (Phase I), preburst (Phase II), and burst (Phase III) stages

Phase I, the quiescent period, lasts between 30 and 60 minutes and is marked by the absence of secretory, electrical, and contractile activity.

Phase II shows intermittent activity for 20–40 minutes, during which contractile movements

increase in both frequency and amplitude. Bile enters the duodenum during this phase, while gastric mucus secretion occurs in the later part of Phase II and throughout Phase III.

Phase III is defined by strong, large, and regular contractions, known as housekeeper waves that clear undigested food and persist for 10–20 minutes.

Phase IV is the transitional period of 0–5 minutes between Phases III and I.⁶

Floating drug delivery systems (FDDS) -

From a technological standpoint, the floating system makes sense and is simple to define when taking into account the various ways for developing GRDDS. Because these systems function independently of changes that occur during the process of stomach emptying, they lessen oscillations in medication bioavailability. Various strategies are used to support the system's buoyancy. Based on its floating process, FDDS can be divided into effervescent and non-effervescent systems.

- 1) **Effervescent system** - This system of FDDS consists of swellable polymers along with carbon dioxide (CO₂) or other organic acids (citric and tartaric acid) entrapped in swollen hydrocolloids of formulation which acts as effervescent component. Incorporation of gas within the formulation helps in reducing the density and makes the system to buoyant over the gastric fluid⁷.
- 2) **Gas generating system** - Drugs and polymers are combined with gas forming agents in gas generating systems, and the mixture is crushed into matrix tablets. Effervescence is created when carbonate or bicarbonate salts react with citric or tartaric acid to form CO₂, which is trapped in a jellified polymer layer and lowers the formulation's specific gravity while keeping it afloat over the stomach fluid. One, two, or more layers can be present in such a matrix tablet⁸.
- 3) **Volatile liquid / vacuum containing system-**
Inflatable GRDDS : In such systems liquids like ether and cyclopentane were incorporated in inflatable chamber which gasify due to body temperature and helps the chamber to float over the stomach.
Intragastric osmotically controlled drug delivery system : The system is made up of biodegradable capsule consists of osmotically controlled drug delivery device and inflatable support. A hollow polymeric bag of inflatable support will form to float over the stomach⁹.
- 4) **Non-effervescent system -**

During formulation, non-effervescent systems use one or more cellulose hydrocolloids, polysaccharides, which are highly swellable and gel-forming polymers, instead of gas-forming agents. The hydration of the polymer in the gastric fluid and the formation of a colloidal gel barrier cause the dosage form to float. There are numerous methods for creating non-effervescent FDDS.

Hydrodynamically balanced system (HBS) / colloidal gel barrier system : The HBS system is a single-unit dosage form having gel-forming hydrophilic polymer of one or more type. Hydroxypropyl methylcellulose (HPMC) is basically used apart from hydroxyethylcellulose (HEC), sodium carboxymethylcellulose (NaCMC), hydroxypropylcellulose (HPC), agar, carrageenan polymers¹⁰.

Microporous system : Porous materials due to their unique characteristics of stable porous structure, high surface area, changeable pore sizes and good surface properties comprises new category in delivery system. During the development of FDDS such material plays an important role, especially to improve solubility of drugs having poor water solubility¹¹.

Alginate beads : A floating system can be created using both synthetic and natural hydrophilic polyionic polymers such as alginate. Alginate is primarily utilized due to its non-toxic and biocompatible properties when ingested. It also provides safeguarding for the mucous membranes found in the upper GIT¹².

Hollow microspheres / microballoon : These consist of multiple unit floating systems with a density below 1 g/cm³ that exhibit immediate buoyancy. The hollow microspheres (microballoons) are empty particles with a spherical shape¹³.

Need of the study –

The oral route is the most preferred method of drug administration due to its simplicity, convenience, and patient compliance. However, many orally administered drugs suffer from poor bioavailability due to short gastric residence time and limited absorption in the upper gastrointestinal (GI) tract. Drugs that are primarily absorbed in the stomach or proximal small intestine, or those that are unstable or poorly soluble in alkaline pH, require innovative delivery systems to maximize their therapeutic potential.

The floating gastroretentive drug delivery system (FGDDS) offers a promising approach by prolonging the gastric residence time of the drug formulation, thus allowing better absorption, controlled release, and improved bioavailability. Floating systems are particularly beneficial for drugs with narrow absorption windows, local action in the stomach, or those degraded in the intestinal environment.

There is a need to develop such advanced drug delivery systems to enhance the effectiveness of oral therapy. By formulating and evaluating a floating system, this research aims to address limitations of conventional dosage forms, improve drug therapeutic efficacy, and potentially reduce dosing frequency, leading to better patient compliance and treatment outcomes.

This area of research remains highly relevant in the field of pharmaceutical sciences, with significant potential for clinical application and innovation.

Advantages of FDDS -

- Prolonged gastric retention time- The main advantage of this approach is that the floating systems keep the drug in the stomach for a long period¹³.
- Enhanced bioavailability of drugs with narrow windows- Drugs absorbed mainly in the stomach or upper small intestine have longer time to be absorbed which results in increased bioavailability. This is applicable for drugs unstable in intestinal fluids and poorly soluble at alkaline pH¹³.
- Lower frequency of dosing and improved patient compliance- Sustained release means that drugs with short half-lives are given less frequently, resulting in better compliance¹⁴.
- Delivery to the stomach, site-specific. Useful for local action e.g. peptic ulcer treatment, antacids and gastro-esophageal reflux.
- More stable levels in the plasma. Controlled release decreases fluctuations in drug concentration and can minimize adverse activity in the colon. Less irritation of the mucosa. Controlled slow release of irritant¹⁴.
- Less doses, better patient compliance. Sustained release can give short half life drugs less often and improve compliance¹³.
- Site specific delivery to the stomach. Helpful in local action e.g. in treatment of peptic ulcer, antacids and gastro-esophageal reflux¹⁵.

- More stable plasma levels. Controlled release reduces fluctuations in drug concentration and may lessen adverse activity in the colon¹⁵
- Less mucosa irritation. Slow, controlled release of irritant drugs (e.g. aspirin) Reduces direct contact with gastric wall¹⁶
- Easy to manufacture. Conventional equipment can be used to make floating forms¹⁶

Disadvantages of FDDS -

- Needs lots of stomach fluid to float. The system should be suspended in a sufficient amount of stomach fluid so a higher intake of water is recommended with these dosage forms¹⁷
- Not for all medications. Poor candidates are drugs that are unstable in acid, poorly soluble in gastric fluids (e.g. phenytoin) or irritating to the gastric mucosa (e.g. NSAIDs such as aspirin).¹⁸
- Unpredictable gastric retention; Gastric motility, pH, food intake, posture and co-administered drugs influence floatation and release and buoyancy cannot always be predicted.¹⁸
- Gastric emptying varies widely. Emptying is an all or nothing process so the retention time can be highly variable between patients and doses.¹⁹
- Position dependent. In the supine position (e.g. sleeping), contractile waves may sweep the floating form away, so patients are discouraged from taking it immediately before bedtime²⁰
- Cost and formulation problems. Floating systems can be difficult to formulate and expensive to manufacture²¹
- Side effects to look out for. Some systems may cause nausea and vomiting.²¹

Preparation methods of various floating dosage forms -

Tablets (single-unit, effervescent or non-effervescent)

Direct compression is the most common and simplest method. The drug, matrix-forming polymer (HPMC, sodium alginate, guar/xanthan gum), gas-forming agent (sodium bicarbonate) and acid (citric/tartaric) are blended and compressed directly on a rotary tablet press. A typical example is mitiglinide floating matrix tablets made with HPMC K15M plus sodium alginate and sodium bicarbonate, which stayed buoyant for 12 h.²² The same technique is used for effervescent floating tablets, where an effervescent mixture of sodium bicarbonate and citric acid provides buoyancy.

Wet granulation is used when the powder blend doesn't flow or compress well: powders are mixed with a binder solution to form granules, dried, sized, lubricated, and compressed.

Melt granulation (binder melts during mixing) is a variant for heat-sensitive or poorly flowing systems.²³

Microspheres / microballoons (multiple-unit)

Emulsion solvent evaporation is the standard method. The drug and polymer (ethyl cellulose, cellulose acetate, HPMC, Eudragit) are dissolved in an organic solvent, emulsified in an aqueous phase (O/W, O/O, or W/O/W double emulsion), and the solvent is evaporated, leaving hollow, buoyant microspheres. In the gabapentin study, the O/O single-emulsion method with ethyl cellulose gave near-100% encapsulation efficiency and up to 98% buoyancy. A related **quasi-emulsion solvent diffusion** technique is used for floating microsponges.

Ionotropic gelation is used for alginate beads: sodium alginate and drug are dropped into a calcium chloride solution, where cross-linking forms gel beads; CO₂-generating agents can be added to make them float.²⁴

Advanced / continuous methods

Hot-melt extrusion (HME): drug, matrix polymer (HPMC, hydroxypropyl cellulose) and sodium bicarbonate are extruded as a melt; the bicarbonate decomposes to CO₂, which expands the extrudate into porous foam pellets that float immediately with zero lag time. It also converts crystalline drug into an amorphous dispersion, improving solubility, and pellets maintained buoyancy for over 12 h. HME is a continuous, solvent-free alternative to spray drying and roll spinning.²⁵

3D printing (fused deposition modeling): floating tablets are printed layer-by-layer from a drug-loaded filament, allowing precise control of internal geometry and density, as demonstrated for famotidine floating tablets.²⁶

Raft-forming systems

These are prepared simply as a liquid or suspension: alginic acid and sodium bicarbonate (plus drug) are dispersed in water; on reaching the acidic stomach they form a floating gel raft.²⁶

Emerging platform technologies

- **Floating-mucoadhesive hybrids.** Combining buoyancy with mucoadhesion is now the exciting area of research. It is focused on

solving two problems with just floating systems. These problems are reliance on the amount of fluid in the stomach. Not knowing when the system will leave the body. A new study from AAPS PharmSciTech worked on improving floating-mucoadhesive tablets. They used a 3² design. This approach led to buoyancy. The tablets stayed afloat without stopping for, than 24 hours. They also had a release pattern that followed Higuchi-type diffusion.^{27,28}

- **Floating bilayer tablets.** Bilayer architectures combine an immediate-release layer that works quickly with a floating sustained-release layer that provides lasting effects. New developments in this area include nanostructured bilayer systems, polymers that react to changes, in the environment ultra-low-density matrices, 3D printing and computer-assisted formulation modeling.²⁹
- **Floating in-situ gels and raft systems.** These are made as low-viscosity liquids. Low-viscosity liquids turn into a floating gel when they meet fluid so they avoid the buoyancy problems of solid single-unit tablets. In 2026 a review, in the Journal of Biomaterials Science looked at floating raft systems. The review said biopolymer-based floating raft systems are a relevant strategy. The strategy creates low-density gels that stay in the stomach for a long time.^{30,31}
- **Nanotechnology integration.** Buoyant tablets containing drug nanospheres were created for cefditoren pivoxil. These nanosphere-loaded tablets provided control over drug release through diffusion. The batch, with a 1:1 ratio of nanospheres and guar gum showed the buoyancy and the most consistent release profile. Reviews also highlight floating nanoparticles, microcapsules and nanocomposite hydrogels as areas of research.^{32,33}
- **Supramolecular organogels.** I read a 2026 Gels study that made supramolecular organogels. These cinnarizine supramolecular organogels could float in stomach fluid for the duration of the release test. The researchers used in-silico simulation to predict how the drug would travel through the body. This new method that uses simulation offers a way to keep medicines in the stomach longer.³⁴
- **QbD, DoE, and AI-driven design.** Factorial designs and Design-of-Experiments optimization are now common in floating-system development. Recent reviews point to stimuli- polymers, AI-driven design and theranostics as important areas for future work. These topics are getting attention because they offer new ways to improve systems. Scientists are looking at these areas to find solutions. The

focus is, on how to create materials and devices. These are the directions that experts think will shape the future.³⁵

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