Research in Pharmacy and Health Sciences 2026,12(1):277-283. e-ISSN: 2455-5258

REVIEW ARTICLE OPEN ACCESS

Floating Drug Delivery Systems: A Promising Approach for Prolonged Gastric Retention

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Received: 15 January, 2026
Accepted: 14 February, 2026

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Published by: OZZIE Publishers
Web: www.ozziepublishers.com

Abstract

Floating drug delivery systems have garnered a lot of attention in recent decades since they may address the drawbacks of standard drug delivery methods, such as frequent dosing, restricted bioavailability, etc., in comparison to the short stomach emptying time. A system that remains in the stomach for an extended period and delivers the active medication continuously is known as an optimal floating drug delivery system. These remain suspended in the gastric juice of the stomach. Increasing the drug's bioavailability and extending its pharmacological effects. This overview of gastroretentive and floating tablets was prepared to compile the latest research on the topic, as well as information on the floating tablets' principles, benefits, categorization, preparation, and assessment techniques of floating tablets. Creation and potential applications of floating tablets. The review focused on the types of floating medication delivery systems and the formulation aspect of effervescent floating drug delivery systems. The review aims to compile studies on this floating medication delivery system. The review discusses several factors that affect gastric retention (long duration) and provides details on the pharmaceutical formulation.

KEYWORDS: Gastro-Retentive, Floating Dosage Forms, Floating Tablets, Floating Microspheres, Gastric Floating, Buoyancy, etc.

1. INTRODUCTION

Oral dosage forms have been developed over the past four decades owing to their significant therapeutic advantages, including ease of administration, patient compliance, and flexibility in formulation. The development of innovative controlled drug delivery systems that enable sustained release of the active medication is a current trend. However, in controlled drug delivery, drug absorption is inadequate and highly variable among individuals due to physiological factors, such as gastrointestinal transit and gastric residence time (GRT) of the dosage forms. Gastroretentive technology is an approach to overcome this difficulty. With this method, the dosage form can remain in the gastrointestinal tract for several hours, thereby greatly prolonging the medication's gastric residence time. Long-term gastric retention increases the solubility of less-soluble medications in a high-pH environment, reduces drug waste, and increases bioavailability. It is also suitable for local administration of drugs to the stomach and the proximal small intestine[1,2].

The gastric residence time of drugs is further extended by gastroretentive mechanisms, allowing them to remain in the stomach for several hours. For less-soluble medications in a high-pH environment, prolonged gastric retention increases bioavailability, reduces drug waste, and increases solubility. It also has applications for local drug delivery to the stomach and proximal small intestines. Gastro retention helps ensure greater availability of new products, offering new therapeutic possibilities and substantial benefits for patients[3].

The stomach retention of dosage forms can be achieved through various mechanisms, such as floating, mucoadhesion, swellable systems, hydrodynamically balanced systems, sedimentation, expansion, and shape-change systems, among others. Out of all the approaches, flotation is the most convenient and effective method for stomach retention. Because gastroretentive floating drug delivery systems (GRFDDS) have a lower bulk density than the gastric medium, they can remain buoyant in the gastric medium for extended periods of time. While the system floats in the gastric contents, the medicine will be released continuously at the desired rate from the dosage form, thereby enhancing GRT. Due to an increase in the GRT of the dosage form, more of the drug may be released in the gastric area, thereby enhancing the bioavailability of the medication and improving control of interindividual variability in plasma drug concentrations[2].

To formulate a successful gastroretentive drug delivery system, several techniques are currently used, such as floating drug delivery systems, low-density systems, raft

systems incorporating alginate gel, bioadhesive or mucoadhesive systems, high-density systems, superporous hydrogel, and magnetic systems. The floating dosage formulations have been the most widely utilized of these. Floating drug delivery systems have a bulk density lower than that of gastric fluids and therefore remain buoyant in the stomach, without altering the gastric emptying rate, for an extended period[4].

Drug Candidates Suitable for FDDS

- Drugs that have a small absorption window in the GIT (e.g., Theophylline, L-DOPA, para- aminobenzoic acid, Furosemide, Riboflavin, Methotrexate)
- Drugs that are locally active in the stomach (e.g., Anti-ulcer medicines, Misoprostol, Antacids)
- Medications that are unstable in the colonic or intestinal environment, such as metronidazole, captopril, ranitidine HCl, and metformin HCl
- Drugs that affect normal colonic flora (e.g., antibiotics used for the eradication of Helicobacter pylori, such as tetracycline, clarithromycin, amoxicillin)

Drugs that display limited solubility at high pH values (e.g. diazepam, chlordiazepoxide, verapamil HCl, Furosemide)[5,6].

Advantages of floating drug

1. For medications intended for local action in the stomach, floating systems are beneficial, e.g., antacids.
2. Acidic compounds like aspirin create irritation on the stomach wall when they come in contact with it. Hence, FDDS may be effective for the administration of aspirin and other similar medicines.
3. The Floating systems are advantageous for medications absorbed through the stomach. Antacids and ferrous salts are examples.
4. Administration of prolonged-release floating dosage forms, tablets, or capsules will result in the disintegration of the drug in the gastric fluid. They dissolve in gastric juice and are available for absorption in the small intestine after stomach contents are emptied.
5. It is therefore envisaged that a medicine will be fully absorbed from floating dosage forms if it remains in the solution form even at the alkaline pH of the colon.
6. FDDS can stay in the stomach for a number of hours, extending the amount of time that certain medications are retained in the stomach.

DISADVANTAGES OF FLOATING DRUG DELIVERY SYSTEM

1. The medication compounds that are unstable in the acidic environment of the stomach are not good candidates for integration into the systems.

2. In these systems, food is typically necessary to extend the gastric emptying process.

3. Drugs with stability or solubility issues in the GIT should not use it.

4. The pharmaceuticals that experience the first pass effect and the drugs that are significantly absorbed throughout the gastrointestinal tract are the only desirable candidates.
5. The dosage form's level of hydration affects the tendency to float. To keep these tablets afloat, intermittent water administration is helpful[7,8].

Factors affecting gastric retention

The effectiveness of a dose form as a gastroretentive system is influenced by several parameters that determine its gastric retention time (GRT).

1. Density - GRT is a function of dose form buoyancy that is dependent on the density.
2. Size - Dosage form units with a diameter of more than 9.5mm are known to have an enhanced GRT.
3. Dosage form shape: Tetrahedron and ring-shaped devices with flexural moduli of 48 and 22.5 kilo pounds per square inch (KSI) are said to offer superior GRT. 90%-100% retention at 24 hours, in contrast to other forms.
4. Fed or unfed state- Under fasting settings, the GI motility is characterized by intervals of intense motor activity or the 1.5–2 hourly migrating myoelectric complex (MMC). The MMC removes undigested material from the stomach; if the formulation's administration time coincides with that of the MMC, the unit's GRT can be expected to be considerably reduced. However, in the fed state, MMC is delayed, whereas GRT is considerably longer [9].

Classification of FDDS
A. Effervescent FDDS

1. Gas-generating system

2. Volatile liquid containing system

B. Non-Effervescent FDDS

1. Colloidal gel barrier system
2. Bi-layer floating tablets
3. Microporous compartment system
4. Floating Beads/ Alginate Beads
5. Micro balloons/ Hollow Microspheres

C. Raft forming

A. Effervescent systems
1. Gas-generating system

A medication delivery system can be designed to float in the stomach by incorporating a floating chamber that may be filled with vacuum, air, or an inert gas. Gas-producing systems. These buoyant delivery methods utilise effervescence between carbonate/bicarbonate salts and citric/tartaric acid to produce CO_2, which becomes entrapped in the jellified hydrocolloid layer of the system, thereby reducing its specific gravity and causing it to float on water. A multiple-unit form of floating pills, which create CO2, has also been developed. The system comprises a sustained-release (SR) pill as the seed, surrounded by two layers. The inner layer is an effervescent layer containing sodium bicarbonate and tartaric acid. The outer layer comprises a

swellable membrane containing pVA, shellac, and other components.

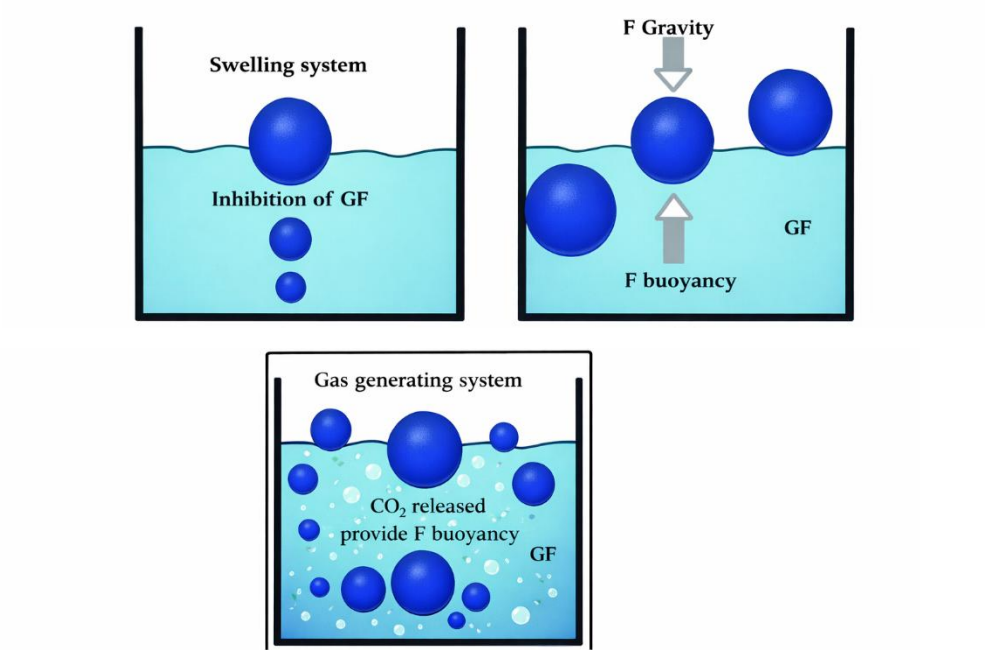

Figure no. 1: Formation of CO_2 in the gas generation system

2. Volatile liquid containing systems

These feature an inflatable chamber filled with liquid cyclopentane, which gasifies at body temperature, causing the stomach's chamber to expand. These systems are osmotically regulated, floating systems that incorporate a hollow, deformable unit. There are two chambers in the system, the first contains the medicine, and the second chamber contains the volatile liquid. 13. B. Non-effervescent Systems (Hydro dynamically balanced systems) unit dose forms, including one. These are single-unit dosage forms, containing one or more gel-forming hydrophilic polymers. Creating polymers that are hydrophilic. Hydroxypropylmethylcellulose (HPMC) is the most commonly used excipient; although hydroxyethylcellulose (HEC), hydroxypropylcellulose (HPC), sodium carboxymethylcellulose (NaCMC), agar, carrageen, or alginic acid are also used. The agar, carrageen, or alginic acid is also employed. The medicine and polymer are combined, and the mixture is often given as a gelatin capsule. The capsule is delivered in a gelatin capsule. The capsule immediately dissolves in the stomach fluid, and hydration and swelling of the surface polymers produce a floating mass. Drug release is controlled by the. Drug release is controlled by the formation of a hydrated boundary at the surface. Formation of a hydrated barrier near the surface. Continuous surface erosion allows water to penetrate into the inner layers, thereby maintaining surface hydration and buoyancy [10].

B. Non-effervescent Systems (Hydro dynamically balanced systems)

Unit dosage forms, containing one. These are single-unit dosage forms that contain one or more gel-forming hydrophilic polymers. Forming hydrophilic polymers. Hydroxypropylmethyl-cellulose (HPMC) is the most commonly used excipient; although hydroxyethylcellulose (HEC), hydroxypropyl-cellulose (HPC), sodium carboxymethylcellulose (NaCMC), agar, carrageen, or alginic acid are also used. Agar, carrageenan, or alginic acid is also used. The polymer is mixed with the drug and is usually administered in a gelatin capsule. The capsule is administered in a gelatin capsule. The capsule rapidly dissolves in gastric fluid, and hydration and swelling of the surface polymers produce a floating mass. Drug release is controlled by the. Drug release is controlled by the formation of a hydrated boundary at the surface. Formation of a hydrated boundary at the surface. Continuous erosion of the surface allows water to penetrate the inner layers, maintaining surface hydration and buoyancy. Incorporation of fatty. Incorporation of fatty excipients yields low-density formulations and density-modulated formulations, thereby reducing water penetration and erosion. Reduced penetration of water, reducing the erosion. Effective drug delivery depends on the balance between drug loading and the polymer's effect on the release profile[11,12].

1. Colloidal gel barrier systems: Such a system contains medication with hydrocolloids that gel and are supposed to float on the contents of the stomach. This prolongs GRT and optimises the amount of medication that reaches the absorption site in the solution state, facilitating absorption. This system combines a high level of one or more matrix-forming polymers, such as polycarbophil, polystyrene, and polyacrylate, with polysaccharides and gel-forming cellulose-based hydrocolloids, such as HPMC. When the system's hydrocolloid comes into contact with gastrointestinal fluid, it hydrates and forms a colloid gel barrier around its surface[13].

2. Bi-layer floating tablet

A bi-layer tablet contains two-layer one immediate release layer, which releases the initial dose from the system, while another sustained release layer absorbs gastric fluid, forming an impermeable colloidal gel barrier on its surface, and maintains a bulk density of less than unity, and thereby it remains buoyant in the stomach 13,12

3. Microporous compartment systems

This method involves enclosing a drug reservoir within a microporous compartment with pores extending along the top and bottom walls. To avoid any direct contact of the gastric surface with the undissolved drug, the periphery of the drug reservoir compartment is totally sealed.

The delivery system floats over the gastric contents in the stomach as a result of the flotation chamber's airtight closure, trapping air[15]. Gastric fluid enters through the aperture, dissolves the medication to the point that it cannot remain in the stomach, and then continuously moves the drug through the intestine in its dissolved state for absorption[16].

4. Alginate beads/Floating beads

Multi-unit floating dose forms have been developed using freeze-dried calcium alginate. Spherical beads approximately 2.5 mm in diameter can be formed by mixing a sodium alginate solution with an aqueous calcium chloride solution. After separation, the calcium alginate beads are rapidly frozen in liquid nitrogen and then freeze-dried at 400°C for 24 hours, yielding a porous structure that can sustain buoyancy for more than 12 hours. These floating beads have a longer residence time than 5.5 hours[17].

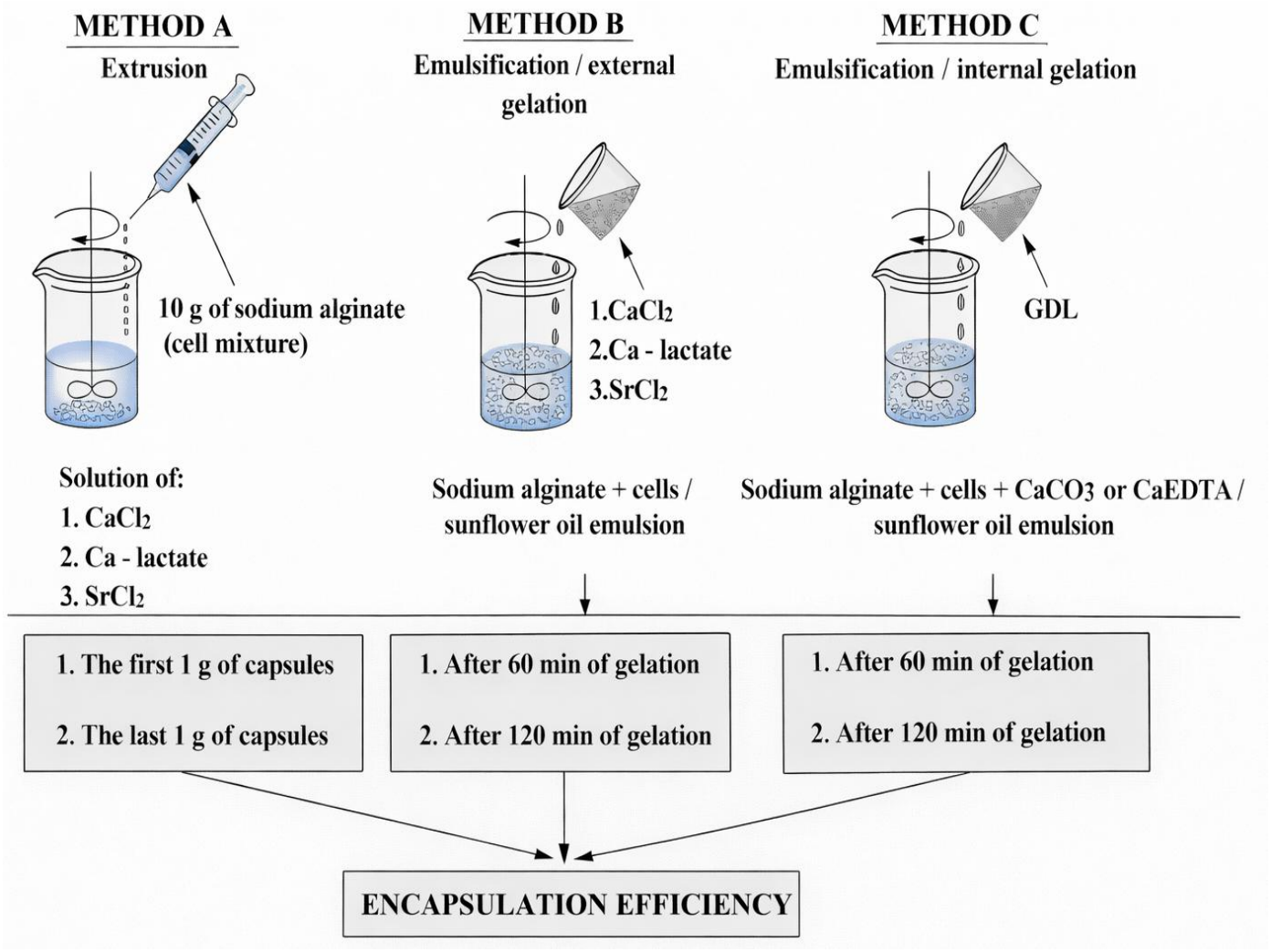

Figure no. 2: Alginate beads

5. Micro balloons/ hollow Microspheres

The Experts claim that hollow microspheres are the most advantageous buoyant system due to the core hollow region within the microsphere. A novel emulsion solvent Diffusion method was utilized to manufacture hollow microspheres that are loaded with medication in their external polymer shelf[13].

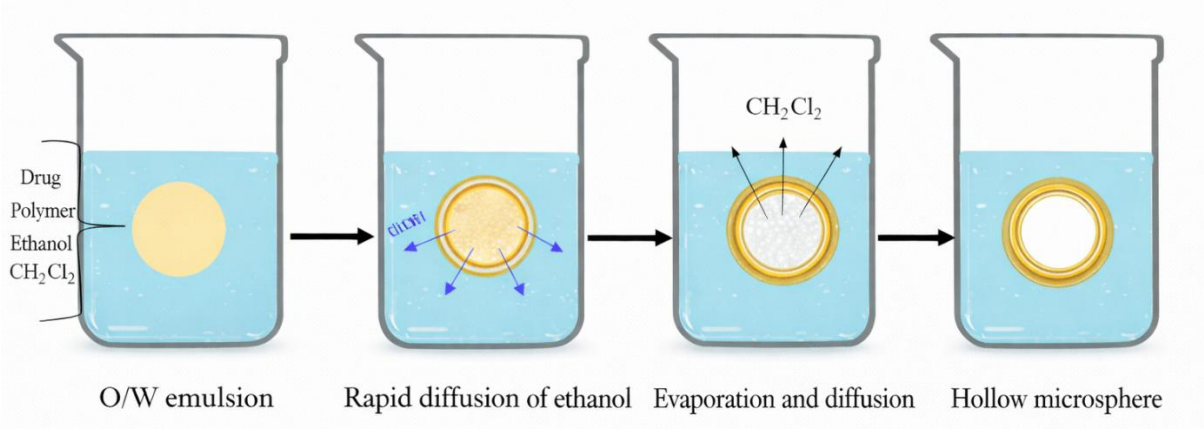

Figure no. 3: Hollow sphere formation

C. Raft Forming System

In this system, the gel-forming solution (e.g., a carbonate- or bicarbonate-containing sodium alginate solution) swells and forms a thick, cohesive gel upon contact with stomach fluid containing trapped CO_2 bubbles. Antacids, such as calcium carbonate or aluminium hydroxide, are generally included in formulations to reduce gastric acidity. Because raft-forming devices provide a covering for gastric fluids, they are also used to treat gastro-oesophageal reflux [19]. The production of a viscous, cohesive gel in contact with stomach fluid, in which the liquid expands in each section, forming a continuous layer known as a raft, is one mechanism of raft formation. Because of its low density and carbon dioxide generation, this raft floats on stomach fluids[14].

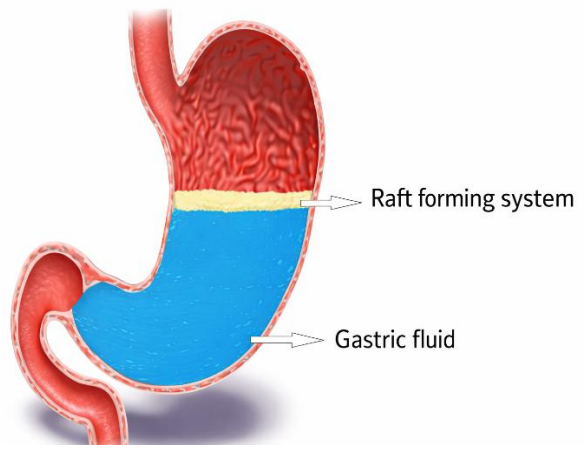

Figure no. 8: Raft forming system

Mechanism of floating systems

Various attempts have been made to retain the dosage form in the stomach to improve retention time. These attempts include developing floating dosage forms (gas-generating and swelling/expanding systems), mucoadhesive systems, high-density systems, and modified-shape systems for delayed gastric-emptying medications. Among them, the floating-dose forms have been most commonly used. Floating drug delivery systems (FDDS) have a bulk density lower than that of gastric fluids and therefore remain buoyant in the stomach, thereby delaying gastric emptying for a longer period. This results in an increased GRT and improved management of variations in plasma medication concentration. In addition to the minimum stomach content required to ensure proper application of the buoyancy retention principle, a minimum buoyancy force (F) is required to keep the dosage form reliably buoyant.

F = F buoyancy - F gravity = (Df - Ds) gv ---------- (1)

Where, F= total vertical force, Df = fluid density, Ds =object density, v = volume, g = acceleration due to gravity.15

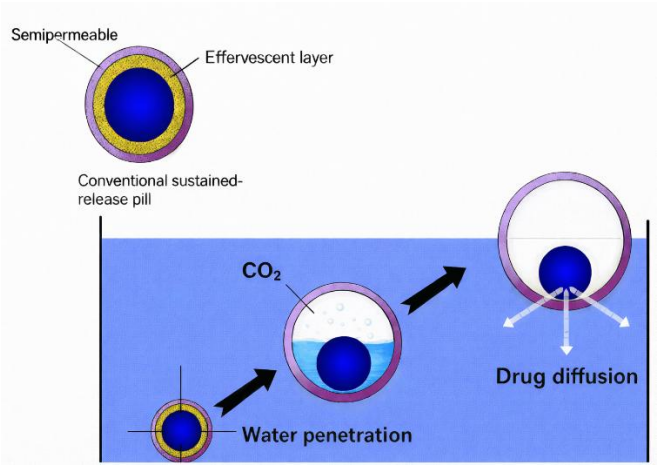

Figure no. 9: Mechanism of the floating drug delivery system

Applications of floating drug delivery system

1. Sustained drug delivery Hydrodynamically Balanced System (HBS) type dosage forms, which have a bulk density less than one, are relatively large in size and do not easily pass through the pylorus, releasing the drug over a prolonged period of time by retaining it in the stomach for several hours and by increasing the gastric residence time. The Madopar HBS formulation has been shown to release levodopa for up to 8 h in vitro, whereas the standard formulation released levodopa within less than 30 min[18].
2. Site-specific drug delivery. Floating drug delivery systems are particularly useful for drugs that are absorbed from the stomach or proximal small intestine, such as riboflavin and furosemide.

3. Minimized adverse activity in the colon. Retention of the drug in the stomach (HBS system) reduces the amount that reaches the colon, thereby preventing its undesirable effects there. This Pharmacodynamic aspect provides the rationale for GRDF Sciences' formulation of β-lactam antibiotics that are absorbed only from the small intestine and whose presence in the colon promotes the development of microbial resistance.
4. There are some cases in which the relative bioavailability of a floating dosage form is reduced as compared to a conventional dosage form, e.g., floating tablets of amoxicillin trihydrate have bioavailability reduced to 80.5% when compared with conventional capsules.

   In such cases, the reduction in bioavailability is compensated for by the advantages of FDDS; for example, patients with advanced Parkinson's disease experienced pronounced fluctuations in symptoms while receiving standard L-dopa. An HBS dosage form provided better control of motor fluctuations, although its bioavailability was reduced by 50-60% of the standard formulation[16,17].
5. *H. Pylori*, causative bacterium for peptic ulcers and chronic gastritis. Patients require a high local concentration of the drug at the site of infection, which is within the gastric mucosa. The floating dosage form, due to its buoyancy, remained in the stomach and maintained a high drug concentration there. A sustained liquid preparation of Ampicillin, using sodium alginate, was developed that spreads out and adheres to gastric mucosal surfaces and releases the drug continuously.
6. Floating drug delivery systems are particularly useful for drugs that are poorly soluble or unstable in intestinal fluids and acid-stable drugs and for those that undergo abrupt changes in their P H -dependent solubility due to pathophysiological conditions of the GIT, food, and age, e.g. floating system for furosemide leads to potential treatment of Parkinson's disease. Approximately 30% of the drug was absorbed following oral administration [19].

CONCLUSION

Floating pills are currently a highly successful approach to boost a drug's bioavailability, provide it with a continuous release, and minimize many of its undesirable side effects. It has been established that floating pills are an effective treatment for stomach retention. These systems offer a distinct benefit for medications that are largely absorbed from the upper gastrointestinal tract. Given our expanding knowledge of the physicochemical and pharmacological properties of medications, as well as formulation development, there is considerable scope for future growth in the design of optimal floating drug delivery systems.

Medication absorption in the gastrointestinal tract is highly variable, reflecting differences in physicochemical properties, as evidenced by a literature appraisal. The medication takes longer to absorb due to prolonged gastric retention of the dose form, attributable to FDDS. The purpose of gastroretentive floating drug delivery systems is to enhance the bioavailability and regulate drug delivery. To maximize molecular delivery and provide a practical approach to gastric retention, the floating medication delivery device improves gastric-retentive drug administration.

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