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Gastroretentive Drug Delivery Systems: A Comprehensive Review on Floating Tablet Technology

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ABSTRACT

Gastroretentive drug delivery systems (GRDDS) have emerged as an advanced approach to overcome the limitations of conventional oral dosage forms by prolonging gastric residence time and improving drug bioavailability. The objective of these systems is to remain buoyant in gastric fluid for extended periods, allowing controlled release of drugs and enhanced absorption of medications with limited absorption windows. Floating tablets achieve buoyancy using low-density excipients, such as gas-generating substances like sodium bicarbonate, or swellable polymers like hydroxypropyl methylcellulose (HPMC). Formulation strategies generally employ polymeric matrices, effervescent components, or coating technologies to regulate release kinetics and enhance stability. Evaluation parameters, such as floating lag time, total floating duration, and in vitro and in vivo correlation, are essential for assessing system performance. GRDDS can improve the therapeutic efficacy of medicines used in gastrointestinal disorders and those requiring localized gastric delivery. Despite significant advancements, variability in gastric motility and physiological factors limit the reproducibility and scalability of formulations. This review consolidates current progress and identifies future directions for optimized gastroretentive floating tablet technology.

Keywords: Gastroretentive drug delivery system, Floating tablet, Buoyancy, bioavailability, Polymer, Sustained release, gastric retention.

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INTRODUCTION

Oral formulations are becoming more well-known among the different formulations designed for human use. However, in most cases, traditional oral delivery systems have low bioavailability due to rapid gastric emptying, enzymatic breakdown in the gastrointestinal tract, pH variations along the digestive pathway, poor intestinal mucosa permeability, and significant first-pass metabolism. [2, 3] Gastroretentive formulations (GRDDS) are innovative formulations that extend the duration medications remain in the stomach, thereby increasing bioavailability and therapeutic efficacy. It's a unique approach to pharmaceutical formulation that aims to overcome challenges related to drug delivery in the GIT. These formulations aim to increase the duration of drug retention in the stomach, enhancing controlled release and improving bioavailability. [1]

Rationale and Objectives of GRDDS

1. To provide prolonged, controlled drug release[13]
2. To improve patient compliance[14]
3. To enhance first pass metabolism[12]
4. To provide local action.[15]
5. To enhance bioavailability [12]

Advantages [4, 5]

1. Enhanced Bioavailability and Prolonged Gastric Retention: GRDDS increases the amount of time a drug remains in the stomach, significantly improving the degree to which a drug is absorbed mainly in the stomach and proximal small intestine.
2. Improved Solubility: Retaining drugs with pH-dependent solubility in the stomach's acidic environment can boost their solubility and absorption.
3. Precision drug delivery and Localized Action: GRDDS are particularly useful in delivering medications that produce their action, particularly in the stomach. For example, they are useful for the treatment of stomach ulcers or Helicobacter pylori infections more efficiently by maintaining higher local concentrations of medication.
4. Controlled and Sustained Release Extended-Release Profiles: GRDDS can be designed to release drugs gradually over a longer time frame. By maintaining a consistent drug concentration in the bloodstream, this gradual release can improve therapeutic efficacy.
5. Enhanced Adherence to Treatment Less Frequent Dosing: GRDDS minimizes the requirement for numerous daily doses by sustaining therapeutic drug levels for extended periods, giving considerable benefits in the management of chronic diseases requiring long-term treatment.

6. Adaptability and Versatility: GRDDS can be modified for various types of drugs, such as those requiring prolonged gastric presence, those with narrow absorption windows, or drugs that have poor solubility in intestinal fluids. 7. Customizations: A variety of GRDDS designs, including expandable, mucoadhesive, and floating systems, allow for customization to satisfy specific therapeutic requirements.

Disadvantages [6, 7]

1. May irritate the gastric mucosa
2. Not ideal for drugs having low acid solubility.
3. Unsuitable for drugs that are unstable in acidic environments.
4. Unsuitable for drugs that are absorbed selectively in the colon.
5. Floating drug delivery systems require adequate fluid in the stomach for floating and functioning effectively.

Factors affecting the gastroprotective system

1. **Density:** Density affects dosage form buoyancy, which in turn affects gastric retention time (GRT). The dosage form's density (1.004 gm/ml) must be less than the contents of the stomach.[16]]
2. **Dosage form size and shape:** Dosage forms with a diameter greater than the pyloric sphincter's diameter remain in the stomach area because they cannot be impacted by the gastric emptying process or pass through the stomach contents into the intestine.[17]
3. **Meal type and calorie content:** Feeding non-digestible polymers or fatty acid salts can alter the gut motility to resemble the fed state, decreasing the pace of emptying of the stomach and extending the rate of drug release. A protein- and fat-rich meal can enhance buoyancy by 4–10 hours. [12]
4. **Gender:** Regardless of height, weight, or body surface, men's mean ambulatory GRT is lower (3, 4 hours) than that of women of similar age and racial background(4, 6 hours). [18]
5. **Fed or unfed condition:** Every 1.5 to 2 hours, periods of high levels of motor activity have been seen in the GI motility during fasting. The Migrating Motor Complex (MMC) removes stomach contents that remain undigested. If the formulation and MMC timing overlap, the unit's GRT can be very short; nevertheless, during the fasting state, MMC is delayed, and GRT is longer.

Suitable drug candidates GRDDS

1. Drugs that act locally in the stomach, such as misoprostol, antacids, and drugs for H. pylori.[18]
2. Drugs having a limited absorption window in the gastrointestinal tract (GIT), such as furosemide, para-aminobenzoic acid, and L-DOPA.[19]
3. Drugs that are unstable in the environment of the intestines or colon, such as metronidazole, captopril, and ranitidine HCl.[19]
4. Drugs that disrupt normal colonic microorganisms, such as antibiotics that act against Helicobacter pylori.[19]
5. Drugs having poor solubility in alkaline pH, such as verapamil, diazepam, and furosemide[12]

Different Classes of GRDDS

The different classes of GRDDS explore the various strategies employed to extend the residence time of a formulation within the stomach. These systems are categorized based on the mechanism they employ. [Table 1]

Table 1: Different classes of gastroretentive drug delivery systems.

Main Class	Sub Class	Mechanism
Floating System	Effervescent	When effervescent floating systems are exposed to gastric fluids, they produce carbon dioxide, which is then trapped in a polymeric matrix to reduce density and provide buoyancy for prolonged gastric retention.[8][Figure.1]
	Non-Effervescent	Non-effervescent systems utilize swellable hydrophilic polymers that, when in contact with gastric fluid, form a gel-like matrix that traps air within the swollen structure.[18]
	Raft System	When mono or divalent cations are present, the polymer draws in and retains water, swells, to form in situ gel layers that float on top of the gastric fluid and are known as rafts.[8][Figure.2]
High-Density System	Single and multi-unit	By having densities higher than that of gastric fluids, high-density systems can achieve gastric retention. Due to this, they sink and remain in the bottom portion of the stomach, where they prolong gastric residence and resist peristaltic motions.[10][Figure.3]
Mucoadhesive System		Designed to adhere to the mucous membrane of the stomach and prolong the gastric residence time of drugs. This method involves incorporating the drug into a synthetic or natural mucoadhesive polymer that adheres to the mucosal lining.[8] [Figure.4]
Swelling / Expandable Systems		When these formulations come into contact with the gastric fluids, they enlarge. This enlargement prevents early transit through the gastrointestinal tract and mechanically promotes retention.[11][Figure.5]
Magnetic Systems		Utilizes magnetic attraction between an external magnet positioned over the stomach and a dosage form that contains magnets. By

anchoring the formulation close to the stomach wall, this interaction increases bioavailability and prolongs gastric residence. However, patient compliance is decreased when an external magnet is required.[11][Figure.6]

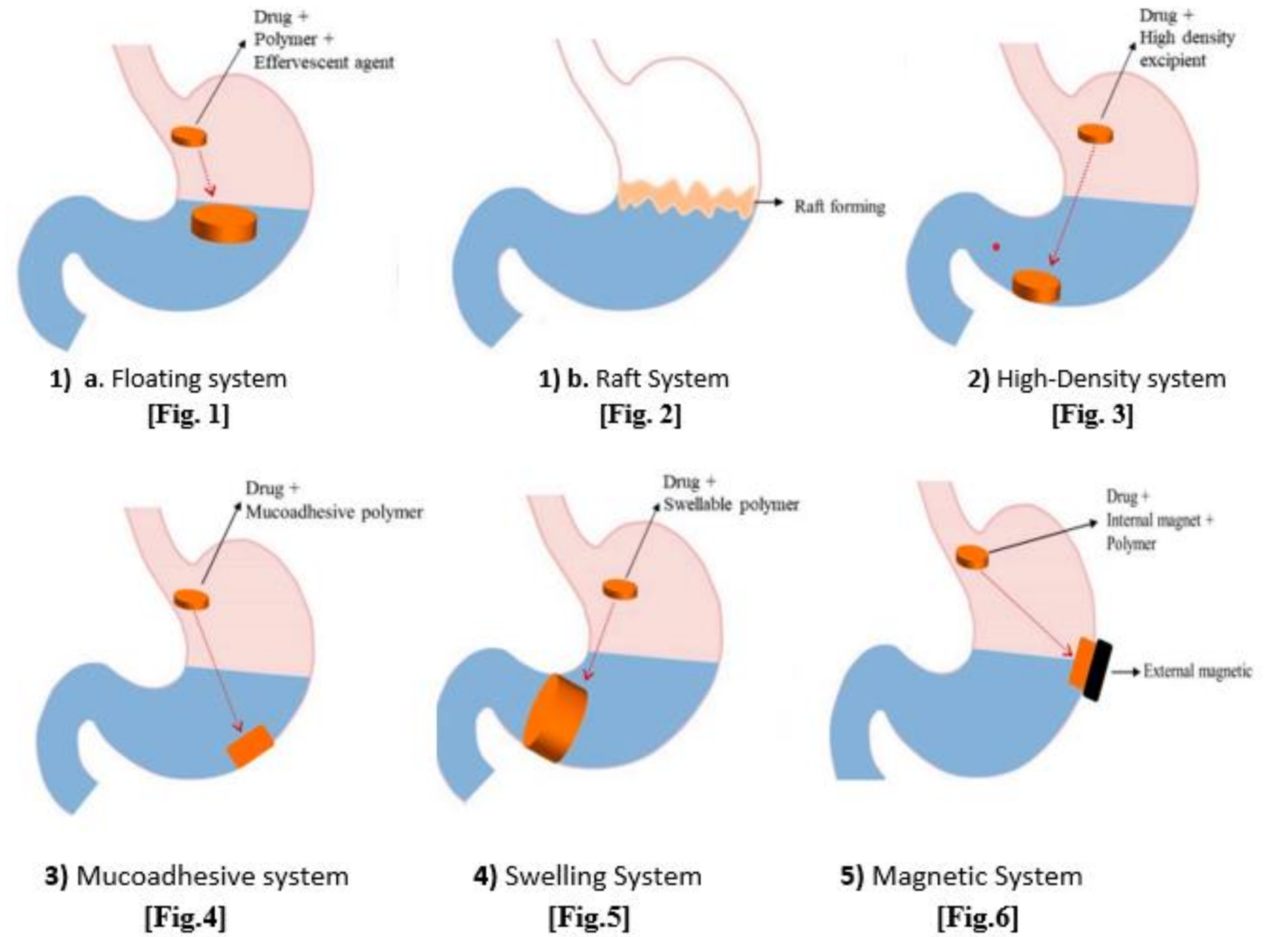


Figure 1-6: Overview of Major Gastro-retentive drug delivery System[8]

FLOATING DRUG DELIVERY SYSTEM

FDDS are designed with a density lower than gastric fluids. This allows them to remain buoyant in the stomach for a longer period without interfering with the gastric emptying rate. While floating on the stomach contents, the medicine is gradually released from the system at the desired rate. Following drug release, the remaining system is gradually cleared from the stomach, which increases the gastric residence period.[20] FDDS can be classified as follows. [21]

A. Single Unit Dosage Systems [21]

- Non-effervescent Systems (balanced systems)
- Effervescent Systems (Gas-generating Systems)

B. Multiple Unit Dosage Systems [21]

- Non-effervescent Systems (balanced systems)
- Effervescent Systems (Gas-generating Systems)

- Hollow Microspheres

C. Raft Forming Systems [21]

A Single Unit Dosage Systems

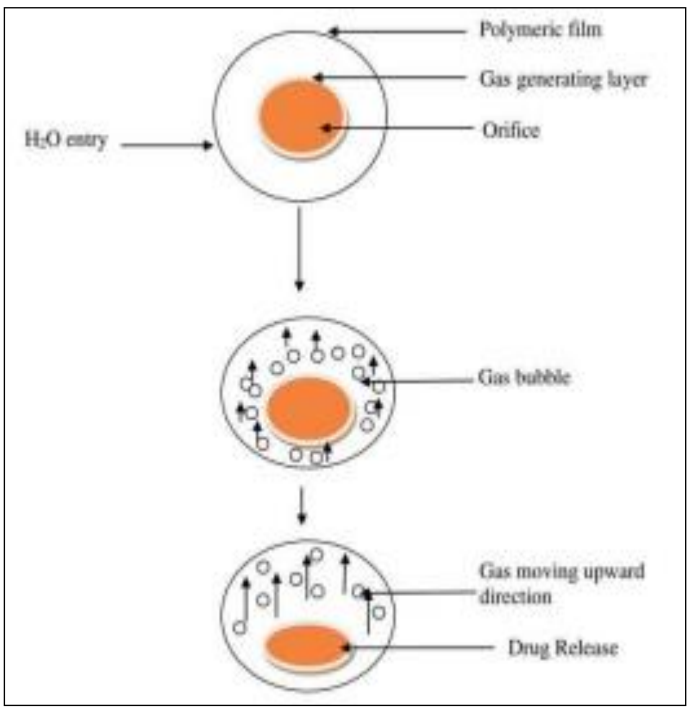
Single-unit dosage forms are the simplest to develop, but there is a possibility that their therapeutic effects might end too quickly due to their all-or-none emptying from the GIT, which can result leading to variable drug absorption and possible local irritation because of the large amount of medication delivered at a particular region of the GI tract. [23]

1. Effervescent FDDS

Effervescent FDDS can be categorized into the following systems.

Gas-Generating Systems: These are matrix forms of systems made from swelling polymers such as chitosan and methylcellulose, and effervescent substances including citric acid, sodium bicarbonate, and tartaric acid. They're designed such that CO2 is produced when they come into contact with acidic gastric contents [Figure. 7], and get lodged in swollen hydrocolloids, giving the doses buoyancy. [24]

Volatile liquid-containing system: These systems contain an inflatable chamber filled with a liquid, such as ether or cyclopentane, that converts into gas at body temperature, causing the chamber to inflate in the stomach. These systems are designed to manage floating through osmotic regulation. They contain a hollow, defined unit, and they consist of two chambers in the system: the first containing the therapeutic agent, along with the second housing the volatile system. [18]



[Figure. 7] Mechanism of Floating using Co2 libratopn[22]

2. Non-effervescent FDDS

Non-effervescent FDDS utilize matrix-forming polymers such as polycarbonate, polymethacrylate, and polystyrene, as well as hydrocolloids that can gel or swell into cellulose. They may follow any of the following principles.

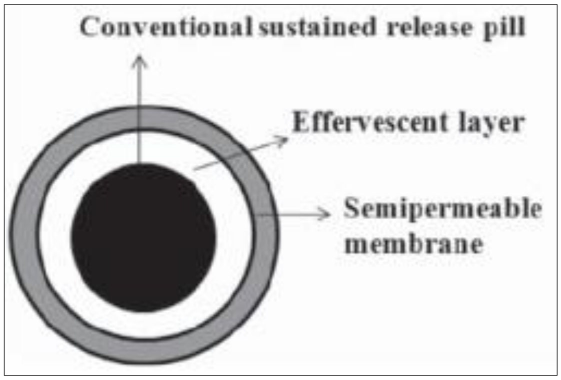
Hydrocolloid Systems (Gel-forming): This approach uses drug formulations combined with gel-forming polymers such as PEO or HPMC, which help the dosage form stay afloat in gastric fluids. Because their overall density is lower than that of stomach contents, these delivery systems can float on the surface for a lengthy period of time without interfering with the regular gastric emptying process. As they continue to float, the drug is gradually and efficiently released at the desired rate.[18]

Microballoons: These are spherical vacant particles that, when in contact with gastric fluids, hydrate to produce gel barriers made of colloidal particles that determine the pace at which fluids diffuse through the dosage form and allow a slow, controlled release of the drug. Continuous hydration maintains the stability of the gel layer, while the air retained within the swollen polymer matrix lowers the overall density, thereby providing sufficient buoyancy to the microballoons.[25,26].

Microporous compartment: In this design, the drug reservoir is enclosed in a microporous compartment with apertures on both the upper and lower surfaces. A floating chamber filled with trapped air keeps the dosage form buoyant in the gastrointestinal fluids. When stomach contents enter through these pores, the drug dissolves and travels to the stomach and upper section of the small intestine, where absorption occurs. [18]

B. Multiple unit dosage form

These forms may be an appealing alternative because studies indicate decreased variability in drug absorption among and within subjects, along with a reduced chance of dose dumping. Several multiple-unit floating systems were developed employing concepts like multiple-unit air compartment systems, hollow microspheres generated using an emulsion-based solvent diffusion approach, and beads made using the emulsion gelation process. Another method for planning multiple-unit FDDS is to employ effervescent and swellable polymers. [29][Figure.8]



[Figure. 8] Multiple units of oral FDDS [29]

C. Raft forming systems

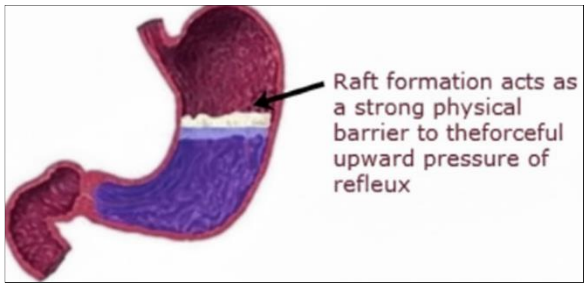


Figure. 9: Formation of a Floating Raft Layer functioning as a barrier preventing gastric contents like HCl and enzymes from refluxing into the oesophagus.[29]

The process of raft formation begins with the formation of a viscous, cohesive gel when the system comes into contact with gastric fluids. Each part of the liquid swells, forming a continuous layer known as a raft, which then floats on top of the stomach contents, because of the decrease in the bulk density caused by the production of CO2[Figure.9]. Typically, the system includes a gel-forming ingredient (e.g., alginic acid), sodium bicarbonate, and an acid neutralizer, which, when in contact with gastric fluids, forms a foamy sodium alginate gel (raft).[27]

RECENT ADVANCEMENTS AND EMERGING TECHNOLOGIES

3D Printing Approaches in FDDS

3D printing is emerging as a promising technique for manufacturing floating gastroretentive systems, since it enables precise control of geometry, internal structure, dose, and release rate. This flexibility can be used to customize designs, which may help to overcome many of the limitations of conventional FDDS, allowing for both controlled drug release and patient-specific therapy. [29, 28]

Several printing technologies used are:[28]

- FDM – Fused Deposition Modeling
- SSE – Semi-Solid Extrusion

- SLA – Stereolithography
- SLS – Selective Laser Sintering
- DLP – Digital Light Processing

FDM is known for its ability to produce complex, low-density structures essential for buoyancy. Recent research has focused on hybrid systems in which an FDM-printed scaffold serves as the floating mechanism while a conventional drug-loaded core or capsule delivers the active ingredient. Such designs have made possible pulsatile systems, sustained-release platforms, and multifunctional devices. Additionally, placing the drug in the core prevents exposure to FDM's high temperatures, making the method appropriate for thermolabile pharmaceuticals and formulations needing high drug loading, areas where completely printed matrices have limits. Research further reveals that scaffold architecture, including infill, wall thickness, and internal channels, shows a significant effect on buoyancy and drug release behavior, emphasizing the importance of structural design in optimizing 3D-printed FDDS.[28]

Shin et al. developed a 3D-printed gastro-floating device consisting of two sealed side chambers that act as air pockets to maintain buoyancy and a center cavity designed to contain a standard sustained-release tablet. The central compartment is comprised of small apertures ("windows") that allow gastric fluid to enter and drugs to disperse out. [Figure. 10] This structural design enabled longer floating, while the inserted tablet controlled the release profile. [30]

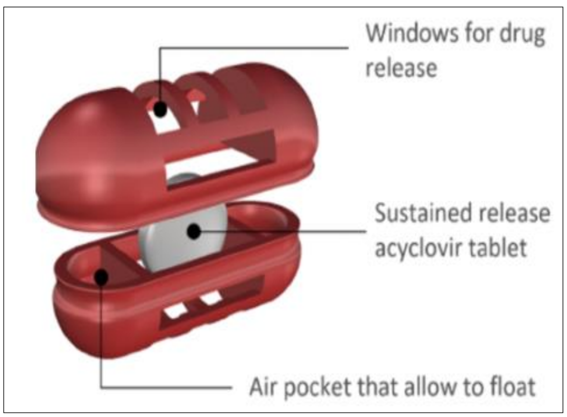


Figure. 10: 3D-Printed Gastroretentive Floating Capsule Design[30]

Hybrid and Combination Systems

A clear example of a hybrid FDDS is the system developed by Belgamwar and Surana[31], which combines floating, swelling, and bioadhesive mechanisms into a single platform. The formulation employed novel effervescent agents, citroglycine and disodium glycine carbonate, to achieve buoyancy, while polymers like crosspovidone, psyllium husk, and HPMC K15Mprovided the swelling and bioadhesive properties required to keep the dosage form in the stomach for an extended period. The system delivered extended release of the drug for more than12 hours, indicating how combining various gastroretentive techniques can enhance the general performance when compared to single-mechanism designs. [31]

Smart and In-situ Systems

The in-situ gel dosage form is liquid before administration, but it transforms to a gel that floats on the gastric contents when it is exposed to them. These gel transformations can be caused by any of the following mechanisms: [32, 33]

pH-responsive floating systems

- Contain polymers that swell or gel only at gastric pH.
- Maintain buoyancy and modulate release only under acidic conditions.

Temperature-responsive floating systems

- Liquid formulations that convert to a buoyant gel at body temperature.
- Used for local gastric delivery with controlled release.

Enzyme-responsive systems (emerging concept)

- Use polymers that degrade or alter properties upon contact with gastric enzymes to adjust drug release.

Floating in situ gel drug delivery systems can be used to deliver various drugs, which are used either for their systemic or for their local effects in the GIT. [32, 33]

POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Floating Drug Delivery Systems (FDDS) rely primarily on polymers for buoyancy, controlled drug release, and gastrointestinal stability. These Polymers can be classified into three types: natural polymers, semi-synthetic polymers, and synthetic polymers. Each category has distinct qualities that contribute to the performance of FDDS.

Natural Polymers:

Natural gums (derived from plants) are hydrophilic carbohydrate polymers with high molecular weights. They are often insoluble in organic solvents such as hydrocarbons and ether. Gums are either water-soluble, absorb water and swell, or disperse in cold water to form a viscous solution or jelly. Natural polymers are biodegradable, biocompatible, non-toxic, economically feasible, and environmentally sustainable. [29]

Table 2: Examples of Natural Polymers and Their Properties

Polymer	Source	Key Properties	Role in FDDS
Alginate [43,44]	Brown seaweed	Gel-forming, mucoadhesive	Forms a gel matrix, helps buoyancy via swelling
Chitosan [43,29]	Shells of crustaceans	Swelling, bioadhesive	Enhances mucoadhesion,

			controlled release
Xanthan gum[29]	Fermentation of glucose by Xanthomonascampestris	Thickening, swelling	Increases viscosity, sustains release
Carrageenan [43]	Red seaweed	Gel-forming, hydrophilic	Matrix-forming agent for sustained release

Semi-synthetic Polymers

Natural polymers that undergo chemical modification are called semi-synthetic polymers. They are mostly cellulose derivatives, frequently used for their versatile swelling, viscosity, and matrix-forming. [43]

Table 3: Examples of Semi-synthetic Polymers and Their Properties

Polymer	Source	Key Properties	Role in FDDS
Hydroxypropyl methylcellulose (HPMC)[43,29]	Modified cellulose	Swelling, mucoadhesion, forms films,	Controls drug release via gel barrier
Hydroxypropyl cellulose (HPC)[43]	Modified cellulose	Film-forming, swelling	Sustained release and buoyancy
Sodium carboxymethyl cellulose (NaCMC)[43]	Modified cellulose	Hydrophilic, swelling	Matrix formation and mucoadhesion

Synthetic Polymers

Synthetic polymers consist of a wide range of materials engineered for specific characteristics such as hydrophobicity, stability, and responsiveness to gastric pH or enzymes. They are typically used for coatings, scaffolds, or matrix formers in FDDS. [43,44]

Table 4: Examples of Synthetic Polymers and Their Properties

Polymer	Key Properties	Role in FDDS
Polyvinyl alcohol (PVA)[43,44]	Hydrophilic, film-forming	Matrix former improves stability
Polyethylene oxide (PEO)[43,44]	Hydrophilic, swelling	Provides controlled release, swelling matrix
Carbomers (Carbopol)[43,44]	High viscosity, swelling	Provides controlled release, swelling matrix

EVALUATION PARAMETERS FOR FLOATING TABLETS

Pre-compression Parameters

Table 5: Pre-compression Parameters

Parameter	Details	Equation
Angle of repose	Defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane. The fixed funnel approach was used. A funnel is positioned with its tip at a certain height 'h above a flat horizontal platform on which a graph paper is laid. Powder is carefully poured through a funnel until the tip of the conical pile touches the funnel's tip. [35]	Angle of repose Ø = tan -1 (h/r)

Bulk density	It represents the ratio of a powder's mass to its bulk volume. A precisely weighed amount of powder is transferred into a graduated measuring cylinder using a funnel, and the resulting volume is recorded, referred to as the initial bulk volume. It is expressed in gm/ml. M = mass of the powder Vo = bulk volume of the powder.[34]	Bulk density=M/Vo
Tapped density	10 g of powder is added to a clean, dry 100 ml measuring cylinder and tapped 100 times at a consistent height, and the tapped volume is measured. Expressed in gm/ml. M = mass of the powder Vt = final tapping volume of the powder[34]	Tapped density=M/Vt
Carr's Index	Used as an important parameter to evaluate the flow behavior of the powder. It is indirectly related to the relative flow property rate, cohesiveness, and particle size. ρo = Bulk density g/ml, ρt = Tapped density g/ml[34,35]	$= \frac{\rho t - \rho o}{\rho t} x100$
Hausner's Ratio	It is calculated by dividing the tapped density by the bulk density.[34]	Hausner's Ratio= Tapped density / Bulk density

Post-Compression Parameters

a) Hardness: For the Determination of tablet hardness, A random sample of twenty tablets from each batch of formulations is taken to determine hardness using a Monsanto-type hardness tester.[22]

b) Weight variation: Twenty tablets are randomly selected and weighed accurately; the average weight of the pills is calculated. The variation of each individual's weight from the average weight is then determined. [22]

c) Friability test: This was measured by weighing 26 tablets after dusting and placing them in a Roche friabilator at 25 rpm for four minutes, as per the Indian Pharmacopoeia (IP). The total remaining weight of the pills after dusting was recorded, and the percentage of friability was calculated using the equation below.

% Friability = Initial wt. of tablets – Final wt. of tablets / Initial wt. of tablets × 100

The acceptable Friability of tablets= < 1%[22]

In vitro buoyancy study

Two key buoyancy characteristics are evaluated in the context of floating drug delivery. The first is Floating Lag Time (FLT), also known as Buoyancy Lag Time (BLT), which shows how long it takes for the dosage form to float to the top of the surface after being deposited into the gastric medium. The second is Total Floating Time (TFT), which refers to how long the dose form remains buoyant.

In-Vitro Drug Release

Release Kinetics Models: [36, 37]

- Zero-order
- First-order
- Higuchi
- Korsmeyer-Peppas (n value)
- Hixson- Crowel

In-Vivo Studies

1. X-ray method: It helps in the tracking of the dosage forms within the gastrointestinal tract and enables the prediction and correlation of stomach emptying time and dosage form passage. The incorporation of a radio-opaque substance into the formulation allows it to be viewed using X-rays.[21,24]
2. Gamma scintigraphy: During the manufacturing of the dosage Form, a small amount of a stable isotope, such as Sm, is added. Incorporating this γ-emitting radionuclide in a formulation enables indirect external observation with a γ-camera or scinti-scanner. In γ-scintigraphy, the radionuclide emits γ-rays that are focused on a camera to monitor the dosage form's location in the Gastrointestinal tract. [38, 21]

APPLICATION OF FLOATING DRUG DELIVERY SYSTEMS

1. Sustained drug Delivery: Because FDDS can remain in the gastrointestinal tract for an extended period of time, the drug can be released over a long period of time. For example, sustained-release floating capsules containing nicardipine hydrochloride were designed and tested in vivo. The formulation was compared with commercially available MICARD capsules, which were tested in rabbits. Plasma concentration time curves showed that sustained-release floating capsules had a longer administration period (16 hours) than regular MICARD capsules (8 hours).[39]
2. Antimicrobials (e.g., amoxicillin, levofloxacin): FDDS formulations provide rapid floating and prolonged gastric retention, allowing for sustained release and localized delivery in the stomach, which improves the elimination of resistant Helicobacter pylori infections.[40]
3. Peptic Ulcer Therapy: FDDS bilayer or floating formulations prolong gastric residence time, improve gastric retention, protect the drug from gastric acid degradation, improve bioavailability, reduce drug waste, and allow for localized, sustained drug release precisely at the site of the ulcer, making them a more effective and convenient treatment option for peptic ulcer diseases. [41,42]

4. Targeted Drug Delivery: Such systems are especially effective for medications that can only be absorbed from the stomach or the proximal region of the small intestine. Furosemide, for example, is absorbed predominantly by the stomach and then through the duodenum. [39]

CONCLUSION

Gastroretentive drug delivery systems have revolutionized oral drug therapy by significantly prolonging gastric retention and enhancing the systemic availability of drugs with narrow absorption windows. Floating tablets remain a preferred approach due to their simplicity, adaptability, and ability to provide controlled and sustained drug release.

The use of advanced polymers has been instrumental in optimizing buoyancy and release kinetics, while emerging technologies such as 3D printing have enabled precise, customizable, and complex dosage forms. Additionally, hybrid systems that combine floating with mucoadhesive, swelling, and smart in situ gelation mechanisms have further enhanced gastric retention and therapeutic efficacy. These innovations collectively improve patient compliance and broaden the applicability of gastroretentive systems. As research continues to evolve, floating tablets are poised to become a cornerstone in the development of efficient, patient-friendly, and targeted oral drug delivery platforms.

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