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Review Article

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A COMPREHENSIVE REVIEW ON FLOATING DRUG DELIVERY SYSTEMS FOR PROTON PUMP INHIBITORS: FORMULATION STRATEGIES AND QUALITY EVALUATION

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ABSTRACT

Proton pump inhibitors (PPIs) are widely used for the treatment of acid-related gastrointestinal conditions; however, their effectiveness is constrained by marked instability in acidic and humid environments, rapid degradation in gastric fluid, and absorption restricted primarily to the upper intestine. These limitations make conventional delayed-release formulations highly dependent on gastric emptying, resulting in inconsistent drug exposure. Floating drug-delivery systems (FDDS), a prominent category of gastroretentive drug-delivery systems (GRDDS), provide a valuable solution by extending gastric residence and maintaining a protective internal environment suitable for stabilizing PPIs and delivering them in a controlled manner. This review compiles current scientific advancements relevant to FDDS design for PPIs, covering the influence of gastric physiology, polymer properties, buoyancy mechanisms, pH-modulating components, and modern manufacturing technologies. Novel fabrication approaches-including 3D printing, hot-melt extrusion, super-porous hydrogel systems, and floating-mucoadhesive hybrids are critically discussed for their potential to enhance both stability and release performance of PPI formulations. Updated regulatory considerations aligned with the latest IP, USP-NF, and ICH requirements are also highlighted. Special focus is given to formulation strategies and evaluation methods for floating omeprazole tablets. Overall, this review provides a contemporary and comprehensive foundation for designing, optimizing, and quality-assessing floating dosage forms intended for improved PPI

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delivery.

KEYWORDS

Proton Pump Inhibitors, Floating Drug-Delivery Systems, Gastroretentive Systems, Buoyancy Mechanisms.

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INTRODUCTION

Proton pump inhibitors (PPIs) such as omeprazole, pantoprazole, esomeprazole, rabeprazole and lansoprazole are widely used for the management of acid-related disorders, including gastroesophageal reflux disease and peptic ulcer disease [1]. Despite their efficacy, PPIs exhibit extreme acid-lability, moisture sensitivity, and short plasma half-lives, all of which complicate their oral delivery. Conventional delayed-release formulations rely on enteric coatings to protect PPIs from gastric degradation, but these systems are highly dependent on gastric emptying patterns and often show variable absorption [2].



Figure 1.Floating Drug Delivery

Gastroretentive drug-delivery systems (GRDDS) have emerged as an important alternative for improving the pharmacokinetics of PPIs by prolonging gastric residence time [1,3]. One of the example of Effervescent floating systems (as shown in figure 1) one of the Among GRDDS approaches, floating drug-delivery systems (FDDS) are especially advantageous because they maintain buoyancy in gastric fluid regardless of nutritional state [3,4]. Their prolonged residence near the duodenum-the primary PPI absorption window-supports more predictable and controlled drug release, while the dosage form can incorporate alkalizers that stabilize PPIs against acid-catalyzed degradation [2].

Recent advances in pharmaceutical materials and processing technologies have significantly expanded FDDS design options. Techniques such as 3D printing [5-9], hot-melt extrusion [10], super-porous hydrogels [11,12], and hybrid floating-mucoadhesive systems [13] enable precise modulation of density, porosity, swelling behavior, and release kinetics. Updated quality-control requirements in the latest IP, USP-NF, and ICH guidelines provide additional regulatory direction [14-17].

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MATERIALS AND METHODS

Literature Search

A comprehensive search of PubMed, Scopus, ScienceDirect, Web of Science, and Google Scholar was performed using keywords related to *FDDS, GRDDS, PPIs, omeprazole, buoyancy mechanisms, polymers,* and *gastroretentive formulations*.

Inclusion& Exclusion Criteria

Peer-reviewed English articles relevant to floating systems, polymer selection, PPIstability, and regulatory guidelines were included. Non-English papers,duplicates, abstracts without full text, and irrelevant studies were excluded.

Screening& Study Selection

Titles and abstracts were screened first, followed by full-text evaluation. Only studies meeting relevance and quality requirements were selected.

Data Extraction

Key study information-materials, methods, formulation strategies, evaluation parameters, buoyancy performance, and stability data-was systematically extracted and organized.

Analysis & Thematic Synthesis

Extracted data were categorized thematically to identify trends, formulation challenges,technological advancements, and gaps in FDDS development for PPIs.

Quality Assessment

Selected studies were evaluated for methodological rigor, clarity of experimental design, analytical validation, and compliance with pharmacopoeial (IP, USP-NF)and ICH standards.

Compilation& Writing

Findings were compiled into structured sections and synthesized to form a coherent narrative relating FDDS principles to omeprazole floating tablet development.

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RESULTS

Overview of gastroretentive drug-delivery systems (GRDDS)

GRDDS are designed to prolong gastric residence time and enhance drug delivery to the upper gastrointestinal (GI) tract. They include four primary categories:

1. Floating systems (FDDS) - Low-density systems that float on gastric fluid.
2. Bioadhesive systems - Adhere to gastric mucosa.
3. Expandable or unfolding systems - Increase size to prevent passage through pylorus.
4. High-density systems - Sink and remain in the stomach due to weight.

FDDS have gained the most attention due to simpler manufacturing, superior patient acceptability, and broad compatibility with drugs requiring localized gastric delivery, such as PPIs [3,2].

Biopharmaceutical challenges of proton pump inhibitors

PPIs face several inherent challenges that complicate effective oral delivery.

- **Acid-catalyzed degradation**
  PPIs are weakly basic prodrugs that undergo rapid degradation at gastric pH values (1-2.5), forming inactive sulfenamide derivatives [2,18]. Omeprazole, for instance, degrades almost completely within minutes in acidic fluid [2]. FDDS enable localized pH control to protect the drug.
- **Moisture sensitivity**
  PPIs are highly susceptible to hydrolytic degradation in the presence of moisture during manufacturing, packaging, and storage [4]. Alkalizing and moisture-adsorbing excipients such as sodium bicarbonate and magnesium oxide are often required [2,4].
- **Narrow absorption window**
  PPIs are primarily absorbed in the duodenum and proximal jejunum, making rapid gastric emptying problematic [2,18]. Floating systems improve delivery consistency by prolonging gastric retention [1,2].
- **Short plasma half-life**
  PPIs have plasma half-lives of less than 2 hours, despite their prolonged pharmacodynamic effect [4]. Controlled-release FDDS help modulate drug release and plasma concentrations more consistently.

Why floating drug-delivery systems are preferred

Given the significant limitations associated with PPIs-such as acid-catalyzed degradation, moisture sensitivity, a narrow absorption window, and rapid gastric emptying-floating drug-delivery systems (FDDS) present a particularly advantageous approach for enhancing their oral delivery. FDDS remain buoyant on gastric contents, enabling prolonged gastric residence and reducing the likelihood of expulsion by the strong peristaltic waves of the migrating motor complex [3,4]. Unlike expandable or high-density systems, FDDS involve simple polymeric matrices or effervescent mechanisms and therefore avoid risks of gastric obstruction or complex manufacturing challenges. Their reliable performance in both fasted and fed states, coupled with the ability to incorporate alkalizers for microenvironmental pH control, makes FDDS especially well-suited for stabilizing PPIs and supporting controlled release near the duodenal absorption window [2,3].

Principles and types of floating drug-delivery systems

FDDS achieve buoyancy either by generating gas (effervescent systems) or by entrapping air within a swollen polymeric matrix (non-effervescent systems).

- **Effervescent floating systems**

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These systems incorporate gas-formers such as sodium bicarbonate with organic acids (citric or tartaric acid), which release CO? upon contact with gastric fluid. The gas becomes entrapped within hydrated polymer networks such as HPMC, carbopol, or alginate, reducing the system's density [4,19].

- **Non-effervescent floating systems**
  These formulations rely on swellable polymers-HPMC, PEO, xanthan gum, sodium alginate-to absorb gastric fluid and expand, forming a low-density matrix that remains buoyant [4,18]. They are particularly suitable for PPIs due to improved stability.
- **Floating microspheres (hollow microballoons)**
  Prepared using solvent diffusion or evaporation, these multi-unit systems provide excellent buoyancy and controlled release due to their low-density, porous internal structure [4,18].
- **Floating matrix tablets**
  Simple to manufacture and widely used for PPIs, these tablets incorporate hydrophilic polymers, gas-formers, and pH-modifiers to maintain buoyancy and achieve sustained release [2,4].
- **Floating-mucoadhesive hybrid systems**
  These systems combine low density with mucoadhesive polymers to enhance retention even under strong gastric motility [13].

Materials and polymers for FDDS tailored to PPIs

Table 1. Material and Polymers

Polymer	Role in FDDS	Advantages	Refs
HPMC (K4M/K15M/K100M)	Gel formation, controlled release	Predictable viscosity	[2,4,20]
Carbopol	Swelling, floating support	Strong gel matrix	[4]
PEO	High swelling & viscosity	Good matrix integrity	[2,4]
Sodium alginate	Gelation, buoyancy	Biocompatible	[4]
Guar gum, pectin	Hydrogel formation	Fast swelling (super-porous)	[11-12]
Eudragit RS/RL	Controlled permeability	Used in microspheres	[4]

Formulation approaches for PPIs in floating systems

1. Microenvironmental ph modulation

PPIs degrade rapidly in acidic environments, so many floating systems incorporate alkalizing excipients such as sodium carbonate, magnesium oxide, calcium carbonate, or trisodium phosphate. These agents create a localized alkaline zone (pH > 7) inside the formulation, helping maintain the chemical stability of PPIs during prolonged gastric residence. Beyond stabilizing the drug, alkalizers can also assist with drug dissolution and participate in gas generation when carbonates are used, thereby supporting buoyancy. Their use is well established for gastroretentive dosage forms aimed at protecting acid-labile compounds [2].

2. Embedding enteric-coated pellets within floating matrices

A widely applied strategy for PPIs is the incorporation of enteric-coated pellets or mini-tablets (e.g., omeprazole MUPS) into polymeric floating matrices. The floating matrix ensures gastric retention, while the enteric coating prevents direct exposure of the PPI to gastric acid.
This configuration reduces the risk of premature coat rupture and slows fluid penetration, helping

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maintain pellet integrity throughout gastric retention. Moreover, floating omeprazole pellets produced by extrusion-spheronization have demonstrated both good buoyancy and robust acid protection, confirming that multiparticulate systems can simultaneously achieve floatation and chemical stability [21].

3. Optimization of gas-forming agents and polymers

The buoyant performance of floating PPI systems depends strongly on the interaction between gas-formers, polymer properties, and processing parameters. Gas-formers such as sodium bicarbonate release CO? in acidic conditions, creating internal pores that reduce density.
The viscosity, hydration behavior, and swelling capacity of polymers (such as various HPMC grades or carbomers) determine how effectively this gas is retained. Additionally, compression force influences porosity and liquid uptake, which can either enable quick buoyancy or delay it if the matrix becomes too dense. Proper optimization ensures short floating lag time, extended total floating duration, and sufficient mechanical strength to withstand gastric agitation [2,4].

4. Raft-forming systems

Raft-forming platforms, typically based on alginate combined with bicarbonates and calcium salts, generate a lightweight gel “raft” that floats on gastric contents. These systems have the capacity to sustain gastric residence while simultaneously offering some degree of acid neutralization. Embedding enteric-coated PPI pellets or small units into raft-forming gels is a promising approach because the raft provides buoyancy, while the enteric layer protects the acid-labile drug [19].

5. 3D-printed floating architectures

Advances in 3D printing allow the creation of structures such as hollow shells, partially coated designs, and low-density infills that promote floatation while isolating sensitive PPIs from gastric acid. These constructs can be engineered to incorporate alkalizers, compartmentalized cores, or delayed-permeability barriers to maintain PPI stability. Current innovations in 3D-printed gastroretentive systems show strong potential for tailoring buoyancy and protection in PPI delivery [5-10].

6. Super-porous hydrogels (SPHs) surrounding enteric-coated PPI units

SPHs rapidly swell in gastric fluid, forming lightweight, porous networks capable of instant floatation and strong gastric retention. Embedding enteric-coated PPI mini-tablets or pellets inside SPHs can combine the mechanical benefits of SPHs with the chemical protection of enteric coatings.Recent developments in SPH technology show excellent strength, high porosity, and good compatibility with controlled-release platforms [11,12].

7. Hollow multiparticulate systems

Multiparticulates with intrinsic hollow cores provide immediate buoyancy due to their low density. These systems can be engineered to include outer enteric coatings or layered protective films, making them particularly suitable for PPIs. Their modular nature allows fine-tuning of both buoyancy and release behavior, as demonstrated in work on hollow-structured floating multiparticulates [13].

8. Polymer engineering for moisture and acid protection

PPIs are susceptible not only to acid but also to humidity. Using polymers with hydrophobic properties, moisture-barrier coatings, or polymer combinations that slow water ingress can preserve drug integrity throughout gastric residence. Principles from modern pharmaceutics underscore the importance of polymer selection for stabilizing labile compounds in gastroretentive systems [20].

9. Incorporation of pH-responsive materials

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Floating systems can also integrate pH-responsive polymers or hydrogels that remain intact in gastric fluid but change structure at higher pH. This ensures that the PPI remains protected during gastric retention and is released only when the dosage form reaches a more alkaline environment.

3D-printed pH-sensitive gastric devices further support this application [9].

10. Zein-based protective carriers

Zein, a hydrophobic storage protein, forms matrices that limit water permeation, making it suitable for stabilizing acid-labile molecules. Incorporating zein nanoparticles or zein-polymer hybrids into floating formulations may help preserve PPI stability while modifying release behaviors.
Recent advancements show zein's potential in oral delivery systems for labile drugs [18].

Recent advancements in FDDS for PPIs

Advances in additive manufacturing and melt-processing technologies have enhanced the precision and performance of floating drug-delivery systems. State-of-the-art 3D-printing techniques and hot-melt extrusion enable controlled architecture, predictable buoyancy, and improved protection of moisture- and acid-labile PPIs [5-10]. Complementary material-based innovations-such as super-porous hydrogels and floating-bioadhesive multiparticulates-provide rapid swelling, low density, and extended gastric residence [11-13]. Additionally, hybrid partially coated and osmotic floating designs offer refined modulation of drug-release kinetics. These advancements collectively support the development of more stable and efficacious FDDS for PPI delivery.Partially coated systems and osmotic floating devices.Advanced designs incorporating asymmetric membranes and low-density chambers modulate drug release [8].

Quality evaluation of floating tablets

1) Physical tests

Hardness, friability, weight variation, thickness/diameter per IP 2024 and USP-NF 2024-2025 [14,15,22].

2) Buoyancy behavior

Measured through floating lag time and total floating duration in 0.1 N HCl, common in FDDS studies [2,4].

3) Dissolution studies

Two-stage dissolution:

- pH 1.2 (simulated gastric fluid)
- pH 6.8 (phosphate buffer)

following IP, USP <711>, and FDA guidelines [14,15,23].

4) Assay and content uniformity

Performed using validated UV/HPLC methods per ICH Q2(R2) [17].

5) Stability studies

Conducted following ICH Q1A(R2) at:

- Accelerated: 40°C / 75% RH

- Long-term: 25°C / 60% RH [16].

6) In vivo gastric retention

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Evaluated using Gamma-scintigraphy or radiopaque markers. [24]

Relevance to omeprazole floating tablets

Omeprazole's extreme acid sensitivity, moisture lability, and duodenal absorption window make it an ideal candidate for FDDS. Floating matrix tablets:

- provide localized pH control
- prolong gastric retention
- facilitate controlled release near the duodenum
- improve stability using alkalizers
- minimize variability seen with conventional enteric-coated formulations [2]

These attributes strongly support omeprazole FDDS development.

DISCUSSION

The materials summarized in Table 1 show that buoyancy and drug protection in PPI formulations depend on how polymers manage hydration, swelling, and gas retention. HPMC and PEO provide predictable gel formation, while carbopol and alginate contribute rapid matrix expansion and viscosity. These properties directly influence floating lag time and the maintenance of an alkaline microenvironment-both essential for stabilizing acid-labile PPIs during extended gastric residence. Comparing floating approaches highlights that no single design solves all PPI-related challenges. Effervescent matrices are efficient at initiating floatation and supporting internal pH regulation, but they rely heavily on polymer networks that can retain generated gas. Non-effervescent and super-porous systems offer more consistent buoyancy but require additional protective elements, such as enteric-coated pellets or hydrophobic barriers, to safeguard the drug. Multiparticulates, raft systems, and 3D-printed constructs represent a shift toward modular designs, where buoyancy, acid protection, and release control are assigned to separate structural components rather than one matrix. Evaluation outcomes reinforce this interdependence. Buoyancy tests reveal whether the polymer-gas former combination creates sufficient porosity, while dissolution profiles indicate whether the protective strategies remain intact under gastric conditions. Stability data consistently show that moisture ingress-before and during administration-remains a critical threat for PPIs, meaning that even well-floating systems must incorporate materials that limit water penetration. Overall, the findings suggest that effective floating PPI systems succeed when they combine robust buoyancy, local pH modulation, and multilayer drug protection. Formulations designed around these principles-whether simple effervescent tablets or advanced printed architectures-are best positioned to deliver stable, predictable release of PPIs such as omeprazole.

CONCLUSION

FDDS provide a practical and scientifically validated approach for addressing the major formulation challenges associated with proton pump inhibitors. Their capacity to extend gastric residence, stabilize acid-labile drugs through microenvironmental pH control, and deliver PPIs near their optimal absorption site makes them particularly advantageous over conventional systems. Advances in materials science, processing technologies, and regulatory guidance further strengthen their potential for developing reliable and high-quality formulations. Overall, FDDS represent an effective platform for improving the performance of PPI therapies, with floating omeprazole tablets serving as a leading example of their clinical and technological relevance.

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ABBREVIATIONS

PPI - Proton Pump Inhibitors
FDDS - Floating Drug Delivery System
GRDDS - Gastro Retentive Drug Delivery System
HPMC - Hydroxypropyl Methylcellulose
PEO - Polyethylene Oxide

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CONFLICT OF INTERESTS

The author has declared no conflict of interest.

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