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FLOATING DRUG DELIVERY SYSTEMS: A COMPREHENSIVE REVIEW ON FORMULATION, CHARACTERIZATION, AND THERAPEUTIC APPLICATIONS

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ABSTRACT

Floating drug delivery systems (FDDS), also referred to as gastro retentive drug delivery systems (GRDDS), are oral dosage forms designed to prolong gastric residence time, improving the absorption and bioavailability of drugs with narrow absorption windows or local gastric activity. FDDS employ mechanisms such as effervescence, swelling, low-density matrices, and bioadhesion to remain buoyant in gastric fluids. This review comprehensively discusses mechanisms of floating, formulation strategies, polymers and excipients, characterization parameters, and therapeutic applications. Techniques including effervescent and non-effervescent systems, raft-forming systems, floating microspheres, and bio adhesive floating systems are elaborated. Key evaluation parameters such as buoyancy lag time, total floating time, in vitro release, swelling index, density, and stability studies are described. Therapeutic applications of FDDS in anti-ulcer, antihypertensive, antidiabetic, and cardiovascular therapy are highlighted. Challenges such as high-density drugs, variability in gastric emptying, formulation complexity, and scale-up are discussed. Recent advances, including floating nanoparticles, microcapsules, and 3D-printed gastro retentive systems, promise personalized and efficient drug delivery. FDDS remain a

promising platform for enhanced oral bioavailability, controlled release, and patient compliance.

KEYWORDS: Floating drug delivery, Gastro retentive system, Controlled release, Effervescent system, Bio adhesive polymers, Therapeutic applications, Gastric retention.

INTRODUCTION

Oral drug delivery is the most common and convenient route, but conventional systems often suffer from short gastric residence time, poor bioavailability, and incomplete absorption, particularly for drugs absorbed predominantly in the stomach or upper small intestine.[1]

Floating drug delivery systems (FDDS) were developed to overcome these challenges by prolonging gastric retention, thereby improving drug solubility, bioavailability, and therapeutic effect. FDDS float on gastric fluids due to lower density than gastric contents ($\leq$1.004 g/cm^3).[1,2]

FDDS are especially beneficial for

- Drugs with narrow absorption windows: e.g., Riboflavin, Furosemide.
- Drugs unstable in the intestine or colon: e.g., Ranitidine, Amoxicillin.
- Drugs with local activity in the stomach: e.g., Antacids and anti-H. pylori antibiotics.[3]

Mechanisms of Floating

1. Effervescent Systems: Gas-generating agents produce CO_2 in the stomach, causing the dosage form to float.[3]

2. Non-Effervescent Systems: Swellable polymers increase tablet volume and reduce density, keeping it buoyant.

3. Raft-Forming Systems: Polymers form viscous, floating gel matrices in the stomach.

4. Bioadhesive Floating Systems: Combine buoyancy with adhesion to gastric mucosa for dual retention.

FDDS not only enhance absorption but also allow controlled or sustained release, reduce dosing frequency, and improve patient compliance. Recent innovations include floating microspheres, nanoparticles, and 3D-printed gastroretentive dosage forms, enabling personalized and targeted therapy.[4]

ADVANTAGES OF FDDS

- Prolonged Gastric Retention: Maintains dosage form in the stomach for several hours, ensuring drug availability for absorption.
- Improved Bioavailability: Ensures better absorption of drugs with narrow absorption windows.
- Controlled and Sustained Drug Release: Maintains therapeutic plasma concentrations.
- Reduced Dose Frequency: Improves patient compliance.
- Localized Drug Action: Useful for drugs acting locally in the stomach.
- Reduced Side Effects: By avoiding systemic peaks, FDDS minimizes off-target toxicity.
- Versatile Formulation: Can deliver hydrophilic and poorly soluble drugs, small molecules, peptides, and macromolecules.
- Compatibility with Combination Therapy: Can be formulated with multiple drugs for synergistic effect.[5,6]

LIMITATIONS OF FDDS

- Variability in Gastric Emptying: Food intake, posture, and motility can influence system retention.
- High-Density Drugs: May sink and fail to float.
- Formulation Complexity: Requires optimization of polymer, gas-forming agent, and excipient levels.[7]
- Limited Dose Capacity: Large doses may compromise floating ability.
- Potential Gastric Irritation: Effervescent systems can generate CO_2, causing local discomfort.
- Scale-Up Challenges: Reproducibility and mechanical strength can be problematic for industrial manufacturing.[8]
- Short Shelf-Life for Some Formulations: Especially effervescent tablets exposed to moisture.

CLASSIFICATION OF FDDS

Floating drug delivery systems (FDDS) are designed to prolong the gastric residence time of drugs, enhancing their bioavailability and therapeutic effectiveness. These systems can be classified based on the mechanism of floatation, formulation design, and type of polymers used.[8,9]

1. Effervescent Floating Systems: Effervescent floating systems contain carbon dioxide-generating agents, such as sodium bicarbonate and citric acid, which produce gas when they come in contact with gastric fluids. The released gas becomes entrapped in a swollen polymer matrix, decreasing the density of the dosage form and allowing it to float on the gastric contents. Hydrophilic polymers such as HPMC or PEO are commonly used to form the swelling matrix, while plasticizers like PEG or glycerol provide mechanical stability. These systems are advantageous because they float rapidly and provide sustained drug release, making them particularly suitable for drugs with a narrow absorption window. However, they may cause gastric irritation due to gas formation and are sensitive to moisture, which can trigger premature gas release. Examples include effervescent floating tablets of ranitidine hydrochloride and metformin hydrochloride.[10,11]

2. Non-Effervescent Floating Systems: Non-effervescent systems rely on swellable polymers to reduce the density of the dosage form, allowing it to float without gas generation. Polymers such as HPMC, PEO, and sodium alginate absorb gastric fluid and swell, creating a low-density matrix that provides controlled drug release. Unlike effervescent systems, non-effervescent FDDS do not cause gas-related irritation and are more stable for moisture-sensitive drugs. However, the onset of floatation is slower, and factors like gastric pH and motility may affect the floating performance. Common examples include floating tablets of atenolol hydrochloride and furosemide.[12]

3. Raft-Forming Floating Systems: Raft-forming systems utilize gel-forming polymers such as sodium alginate or gellan gum to produce a viscous floating gel or “raft” upon contact with gastric fluids. The gel traps carbon dioxide and maintains buoyancy while providing a controlled release of the drug. These systems are particularly useful for local treatment of the stomach and for protecting acid-labile drugs, as they reduce reflux and provide prolonged gastric retention. The floating and gelation efficiency of these systems depends on the ionic content and pH of the stomach. Examples include antacid formulations like Gaviscon® and amoxicillin-containing anti-H. pylori therapies.[13]

4. Bioadhesive Floating Systems: Bioadhesive floating systems combine buoyancy with mucosal adhesion to achieve dual retention in the stomach. Bioadhesive polymers such as chitosan, Carbopol, or sodium alginate adhere to the gastric mucosa, while swellable polymers provide floating capability. This dual mechanism prolongs drug residence time, enhances drug absorption, and improves bioavailability. Factors such as mucus turnover and

food intake may affect the bioadhesive property. Bioadhesive floating tablets of famotidine and metformin are examples of this approach.[14]

5. Floating Microspheres and Nanoparticles

Floating microspheres and nanoparticles are low-density hollow carriers that float in gastric fluid while slowly releasing the drug. Drugs are encapsulated in a polymeric shell, allowing for controlled release and improved absorption. Polymers such as ethyl cellulose, Eudragit, and HPMC are commonly used, and particle size plays a key role in floating behavior and drug release kinetics. These systems are suitable for hydrophilic and hydrophobic drugs, including peptides and proteins. Examples include floating microspheres of ibuprofen and floating nanoparticles of famotidine.[15,16]

6. 3D-Printed Floating Systems: 3D printing technology has enabled the development of personalized floating drug delivery systems with precise control over geometry, density, and drug release profiles. Hollow and low-density 3D-printed tablets float in gastric fluid, while the polymer matrix controls drug release. Polymers such as HPMC, PVA, and PLA are commonly used, often in combination with plasticizers like PEG or glycerol. These systems allow for customized dosing and release profiles, making them particularly suitable for personalized medicine. Examples include 3D-printed floating tablets of paracetamol and cardiovascular drugs.[17,18]

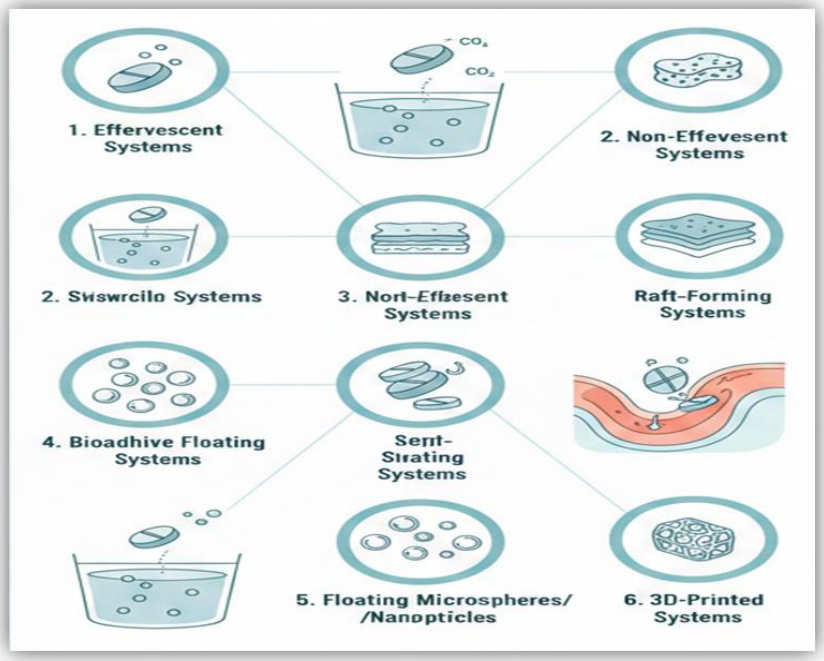

Fig I: Classification of FDDS.

FORMULATION STRATEGIES OF FLOATING DRUG DELIVERY SYSTEMS

The formulation of floating drug delivery systems (FDDS) requires careful selection of excipients and optimization of preparation methods to achieve prolonged gastric residence, controlled drug release, and effective floating behavior. The key components and preparation techniques play a critical role in determining the system's buoyancy, drug release profile, stability, and patient compliance.[19,20,39]

Components of FDDS

- **Polymers:** Hydrophilic and swellable polymers such as hydroxypropyl methylcellulose (HPMC), Carbopol, sodium alginate, and polyethylene oxide (PEO) are commonly employed in FDDS formulations. These polymers regulate the swelling behavior of the dosage form, which is essential for reducing density and enabling floating. They also contribute to controlled and sustained drug release by forming a gel barrier that modulates drug diffusion into the gastric fluids. The selection of polymer type and concentration is critical, as it affects the matrix integrity, floating lag time, and drug release kinetics.[21]

- **Gas-Forming Agents:** Effervescent FDDS utilize gas-generating compounds such as sodium bicarbonate, potassium bicarbonate, citric acid, and tartaric acid. Upon contact with gastric fluids, these agents react to produce carbon dioxide, which is trapped in the polymeric matrix, lowering the overall density of the dosage form. The amount and ratio of gas-forming agents determine the floating lag time, buoyancy duration, and robustness of the system.[22]

- **Bioadhesive Polymers**: In systems combining floating with mucosal adhesion, polymers such as chitosan, Carbopol, and sodium alginate are used for their mucoadhesive properties. These polymers interact with the mucin layer of the gastric lining, prolonging gastric residence time and improving the absorption of drugs with a narrow absorption window. The bioadhesive property can be influenced by polymer type, molecular weight, and concentration.[38]

- **Plasticizers:** Plasticizers, including polyethylene glycol (PEG) and glycerol, are incorporated to enhance the mechanical strength and flexibility of the floating dosage form. Plasticizers prevent brittleness and cracking of tablets or microspheres during storage, handling, and swelling in gastric fluids.[23]

➢ **Fillers and Diluents:** Excipients such as **l**actose, microcrystalline cellulose (MCC), and dicalcium phosphate are added to improve compressibility, flow properties, and content uniformity of the dosage form. They also influence the overall density of the system, which is critical for buoyancy.[24]

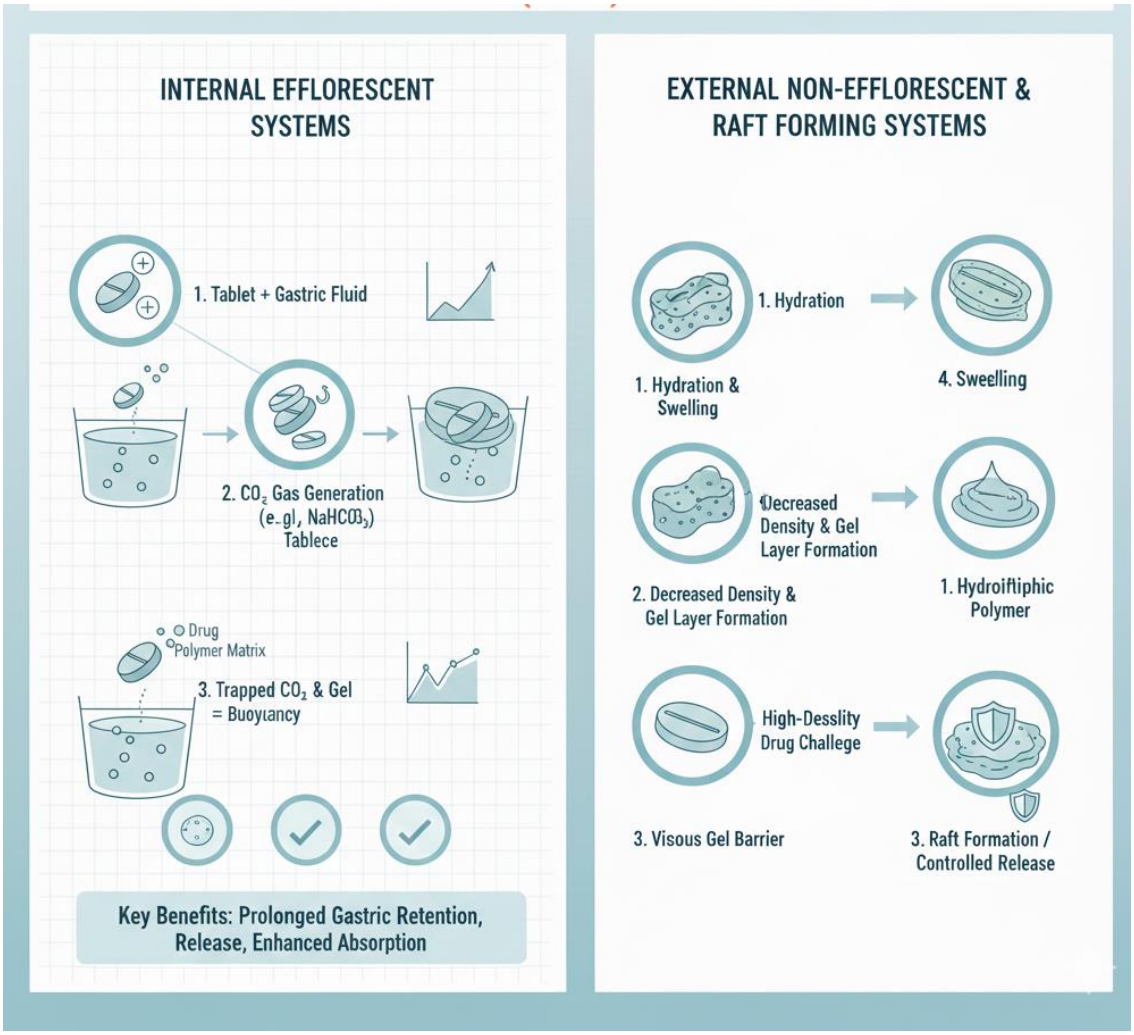

Fig II: Mechanism of Latin Delivery system.

METHODS OF PREPARATION

1. Direct Compression: Direct compression is a simple and cost-effective method for preparing floating tablets. The drug and excipients are blended and compressed directly into tablets. This method is suitable for heat- and moisture-stable drugs and allows for the rapid development of formulations with reproducible density and buoyancy.[37]

2. Wet Granulation: Wet granulation improves compressibility, flowability, and content uniformity. The drug and excipients are mixed with a suitable binder solution, granulated,

dried, and compressed into tablets. This method is preferred for drugs that are poorly compressible or require controlled release.[25,40]

3. Solvent Evaporation: This technique is widely used for the preparation of floating microspheres and nanoparticles. The drug is dissolved or dispersed in a polymer solution, and the solvent is evaporated under controlled conditions to produce hollow or low-density microspheres. Solvent evaporation allows precise control over particle size, porosity, and drug loading.[26]

4. Spray Drying: Spray drying produces low-density microspheres or granules with a hollow structure, enabling rapid and prolonged floating in gastric fluids. A polymer-drug solution is atomized into a heated chamber, where solvent evaporation forms solid microspheres. Spray drying is particularly advantageous for thermolabile drugs due to its rapid drying process.

5. 3D Printing: 3D printing technology offers a highly versatile and customizable approach to FDDS design. It allows the creation of tablets with precisely controlled geometry, internal hollow structures, and floating properties, as well as programmable drug release profiles. This technique is especially valuable for personalized medicine, enabling tailored dosing for individual patients.[27]

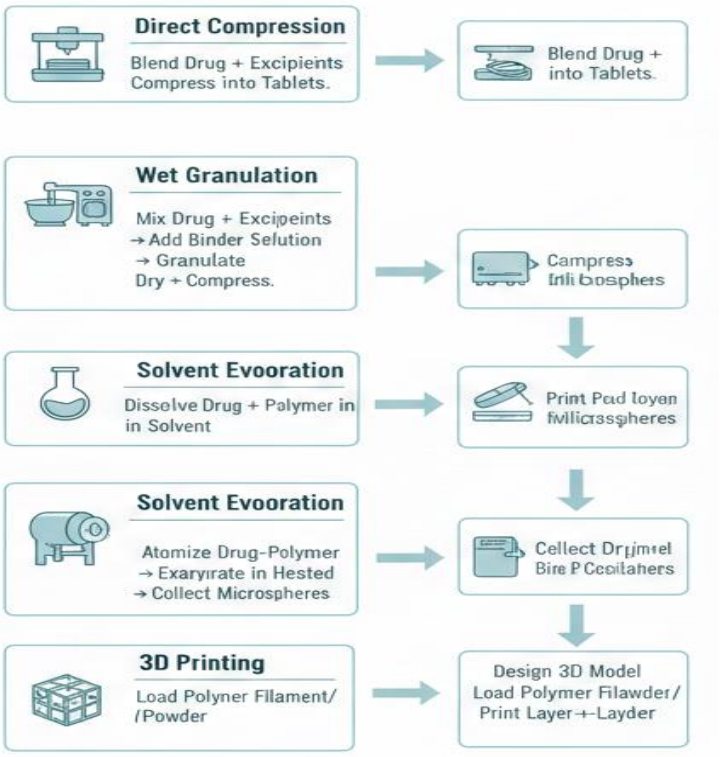

Fig II : Preparation Methods of FDDS.

FACTORS AFFECTING FORMULATION

Several formulation and process variables influence the performance of floating drug delivery systems.

- **Polymer Type and Concentration:** Determines the swelling behavior, gel strength, floating duration, and drug release profile. High polymer content generally increases floating time but may slow drug release.[28]

- **Amount of Gas-Forming Agents:** Affects the floating lag time, buoyancy, and duration of flotation. Insufficient gas generation may lead to incomplete floating.

- **Tablet Density and Hardness:** Low-density systems are essential for floatation, while adequate hardness ensures mechanical integrity during handling and gastric residence.

- **Drug Solubility and Stability:** Water-soluble drugs may diffuse rapidly, requiring polymer optimization for sustained release, while acid-sensitive drugs require protective matrices.[36]

- **Processing Method:** Choice of direct compression, wet granulation, spray drying, or 3D printing affects particle size, porosity, and buoyancy.[29,30]

CHARACTERIZATION OF FDDS

Table I: Characterization of FDDS.

PARAMETER	PURPOSE	TECHNIQUES
Buoyancy Lag Time	Time to float on gastric fluid	USP dissolution apparatus
Total Floating Time	Duration the system remains buoyant	Visual observation/in vitro
Swelling Index	Extent of polymer expansion	Gravimetric measurement
In Vitro Drug Release	Drug release kinetics	USP II paddle method
Floating Strength	Resistance to gastric motility	Mechanical testing
Density	Determines buoyancy	Pycnometer
Morphology	Surface and internal structure	SEM
Stability Studies	Shelf-life, drug integrity	ICH-guided accelerated testing

THERAPEUTIC APPLICATIONS OF FDDS:

- **Anti-Ulcer/Antacid:** Drugs like Ranitidine, Famotidine, Omeprazole are formulated in floating systems for sustained gastric retention and prolonged therapeutic effect.
- **Antibiotics:** Amoxicillin and other antibiotics are delivered via FDDS for targeted eradication of H. pylori in the stomach.

- **Antihypertensive Drugs:** Metoprolol, Verapamil benefit from controlled plasma levels and reduced dosing frequency.
- **Antidiabetic Drugs:** Glibenclamide, Repaglinide in floating formulations show enhanced bioavailability and better glycemic control**.**
- **Cardiovascular Drugs:** Furosemide, Atenolol have improved absorption in the stomach and upper GI tract via FDDS.
- **NSAIDs and Analgesics:** Ibuprofen, Diclofenac delivered in floating systems reduce dosing frequency and minimize gastrointestinal irritation.
- **Combination Therapy:** FDDS can carry multiple drugs for synergistic, sequential, or site-specific release**,** enhancing therapeutic efficacy.
- **Gastrointestinal Targeting:** Drugs requiring local action in the stomach or upper small intestine, such as misoprostol**,** can be delivered efficiently.
- **Antifungal Drugs:** Floating systems improve gastric retention for drugs like fluconazole, enhancing absorption.
- **Vitamins and Nutraceuticals:** Vitamins like B12 and calcium benefit from prolonged gastric residence for better absorption.[31]

CONCLUSION

Floating drug delivery systems (FDDS) are highly versatile, innovative oral dosage forms that enhance the bioavailability and therapeutic efficacy of drugs with narrow absorption windows or local gastric action. By prolonging gastric residence time, they facilitate controlled or sustained drug release, reduce dosing frequency, and improve patient compliance.[32]

Various approaches, including effervescent, non-effervescent, raft-forming, bioadhesive, microspheres, and 3D-printed systems, have been developed to optimize buoyancy, stability, and drug release kinetics. Despite challenges like variability in gastric emptying, high-density drugs, formulation complexity, and scale-up issues, ongoing research in nanotechnology, 3D printing, and stimuli-responsive polymers promises next-generation FDDS.[33]

Overall, FDDS represent a promising platform for oral controlled drug delivery, improving therapeutic outcomes and offering clinical potential in gastric, cardiovascular, diabetic, and chronic disease management.[34]

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