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FLOATING TABLETS: A COMPREHENSIVE REVIEW

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ABSTRACT

Oral drug delivery remains the most preferred route of administration owing to its convenience, cost-effectiveness, and high patient compliance. However, conventional oral dosage forms often suffer from limitations such as variable gastric emptying, poor bioavailability of drugs absorbed in the upper gastrointestinal tract, and the inability to provide sustained therapeutic levels. To address these challenges, gastro-retentive drug delivery systems (GRDDS) have been developed to prolong gastric residence time, thereby improving drug absorption and therapeutic efficacy. Among the various GRDDS approaches, floating tablets have gained considerable attention due to their ability to remain buoyant on gastric fluids for extended periods without affecting gastric emptying. Floating tablets offer several advantages, including improved bioavailability of drugs with narrow absorption windows, enhanced solubility of drugs in acidic pH, and controlled drug release. This review provides a comprehensive overview of floating tablets, including the principles of gastro-retention, mechanisms of buoyancy, classification, formulation strategies, and evaluation parameters. Particular emphasis is placed on effervescent and non-effervescent floating systems, polymer selection, role of excipients, and technological approaches for formulation. The article also discusses the factors influencing the performance of floating tablets, in vitro and in vivo evaluation techniques, and the therapeutic applications of these systems in the management of gastric disorders, cardiovascular diseases, and infections caused by *Helicobacter pylori*. Furthermore, recent advances such as Quality by Design (QbD), nanotechnology, and 3D printing in floating drug delivery are highlighted.

The review concludes with future perspectives emphasizing the clinical potential of floating tablets as an effective gastro-retentive strategy for enhancing therapeutic outcomes.

KEYWORDS: Floating drug delivery system; Gastro-retentive tablets; Buoyancy; Effervescent systems; Controlled release; Gastric retention.

1. INTRODUCTION

Oral drug delivery is considered the most convenient and widely accepted route for the administration of therapeutic agents. Nearly 60% of marketed dosage forms are designed for oral delivery, attributed to their simplicity, non-invasiveness, high patient compliance, and cost-effectiveness compared to parenteral and transdermal systems. Despite its advantages, conventional oral dosage forms often suffer from unpredictable pharmacokinetic profiles due to variable gastrointestinal (GI) physiology. Factors such as gastric emptying rate, pH variability, presence or absence of food, and enzymatic activity influence the drug's residence time in the stomach, thereby affecting its dissolution, absorption, and bioavailability.[1-3]

A significant proportion of drugs exhibit absorption windows in the upper part of the small intestine or require an acidic environment for solubility. Drugs such as riboflavin, levodopa, furosemide, ciprofloxacin, and metformin display limited bioavailability when delivered through conventional dosage forms, primarily due to premature gastric emptying. For such molecules, the development of gastro-retentive drug delivery systems (GRDDS) has emerged as an innovative solution. GRDDS are designed to prolong the gastric residence time of the dosage form, thereby providing sustained drug release and improving absorption.[4-5]

Among the different strategies for gastro-retention—such as swelling systems, mucoadhesive systems, high-density systems, and floating systems—floating tablets have attracted significant attention. Floating tablets, also known as hydrodynamically balanced systems (HBS), are low-density formulations that remain buoyant in gastric fluids without affecting gastric emptying. They float on the surface of gastric contents, slowly releasing the drug at a controlled rate.[6-7]

The concept of floating drug delivery was first introduced in the late 1970s, and since then, extensive research has been devoted to developing various floating systems. Floating tablets are advantageous in the delivery of drugs that are poorly soluble in alkaline pH, drugs with a narrow absorption window in the upper GI tract, and drugs intended for local action in the

stomach. Moreover, they offer sustained plasma concentration, reduced dosing frequency, and improved patient adherence.[8]

This review aims to provide an in-depth analysis of floating tablets as a gastro-retentive strategy, with emphasis on their design, formulation, evaluation, and therapeutic applications, while also addressing recent advances and future perspectives in this rapidly evolving field.

2. Gastro-retentive Drug Delivery Systems (GRDDS)[9-13]

2.1 Definition and Objectives

GRDDS are oral dosage forms designed to remain in the stomach for prolonged periods, thereby enhancing gastric retention and improving bioavailability of drugs with specific absorption characteristics. The primary objective of GRDDS is to:

- Prolong gastric residence time.
- Provide controlled and sustained drug release.
- Improve bioavailability of drugs with narrow absorption windows.
- Enhance solubility of drugs in acidic conditions.
- Achieve site-specific delivery for local stomach action.

2.2 Classification of GRDDS[14]

GRDDS are broadly classified into the following categories

1. Floating Drug Delivery Systems (FDDS): Based on buoyancy, these systems float on gastric contents.
   - Effervescent systems (gas-generating).
   - Non-effervescent systems (swelling polymers, raft-forming).
2. Swelling and Expanding Systems: Tablets expand significantly in size after contact with gastric fluid, preventing passage through the pyloric sphincter.
3. Mucoadhesive Systems: Formulations adhere to the gastric mucosa using bioadhesive polymers.
4. High-Density Systems: Designed with density >2.5 g/cm^3 to remain in the stomach by gravity.
5. Magnetic Systems: Contain magnetic materials that are retained in the stomach using external magnetic fields.

2.3 Advantages of GRDDS

- Improved bioavailability of drugs with absorption windows in the upper intestine.
- Sustained and controlled release of drugs.
- Reduced fluctuations in plasma drug levels.
- Site-specific drug delivery for treatment of gastric disorders.
- Reduced dosing frequency and improved compliance.

2.4 Limitations of GRDDS

- Unsuitable for drugs unstable in gastric pH.
- Limited applicability in patients with gastric motility disorders.
- Risk of gastric irritation for certain drugs.
- Dependence on fed or fasted state for gastric retention.

3. Floating Drug Delivery Systems (FDDS)[15-17]

3.1 Principle of Buoyancy

Floating systems are designed to have a bulk density lower than gastric fluids (1.004 g/cm^3). Once ingested, they remain buoyant in the stomach without significantly affecting gastric emptying. While floating, the drug is gradually released, and the dosage form is eventually emptied after complete drug release.

3.2 Types of Floating Systems

1. Effervescent Floating Systems:
   - Incorporate gas-generating agents (e.g., sodium bicarbonate, citric acid, tartaric acid).
   - Upon contact with gastric fluid, CO_2 is liberated and trapped in the hydrocolloid matrix, reducing density and enabling floatation.
   - Examples: Floating tablets of ciprofloxacin, metformin.

2. **Non-Effervescent Floating Systems**
   - Rely on swelling polymers or gel-forming agents (e.g., HPMC, carbopol, xanthan gum).
   - Upon hydration, they form a viscous gel layer entrapping air, thus maintaining buoyancy.
   - More stable compared to effervescent systems.

3. **Raft-Forming Systems**
   - Form viscous, cohesive gels that float on gastric contents.
   - Used particularly for anti-reflux formulations (e.g., alginate-based systems).

4. **Single-Unit vs. Multiple-Unit Floating Systems**
   - Single-unit: Tablets or capsules; risk of dose dumping if system fails.
   - Multiple-unit: Floating microspheres, beads, granules; reduced risk of local irritation and better gastric distribution.

4. Formulation Aspects of Floating Tablets[18-21]

4.1 Drug Selection Criteria

Drugs suitable for floating tablets generally exhibit:

- Narrow absorption window in stomach/upper intestine.
- Poor solubility in alkaline pH.
- Local action in the stomach (e.g., antibiotics for *H. pylori*).
- Short half-life requiring sustained release.

Examples: Amoxicillin, metformin, ciprofloxacin, famotidine, domperidone.

4.2 Polymer Selection

- Hydrocolloids: HPMC, carbopol, sodium alginate, guar gum.
- Swelling agents: Xanthan gum, locust bean gum.
- Matrix formers: Polyethylene oxide.

4.3 Excipients Used

- Gas-generating agents: Sodium bicarbonate, citric acid, tartaric acid.
- Diluents: Lactose, MCC, dicalcium phosphate.
- Binders: PVP, starch paste.
- Lubricants: Magnesium stearate, talc.

4.4 Formulation Techniques

1. Direct Compression: Simple, economical, widely used for floating tablets.
2. Wet Granulation: Ensures uniform distribution of excipients and gas-generating agents.
3. Melt Granulation: Uses melted binders for granule formation.
4. Hot-Melt Extrusion and Spray Drying: Advanced techniques for modified release floating systems.

5. Evaluation of Floating Tablets[22-23]

5.1 Preformulation Studies

- Drug-excipient compatibility (FTIR, DSC).

- Flow properties: angle of repose, compressibility index.

5.2 In-Vitro Evaluation

- Hardness and Friability: Mechanical strength.
- Weight Variation and Content Uniformity.
- Swelling Index: Degree of polymer hydration.
- Floating Lag Time (FLT): Time for tablet to rise to surface.
- Total Floating Time (TFT): Duration of buoyancy (ideally >12 h).
- In-vitro Drug Release: Dissolution testing in simulated gastric fluid.

5.3 In-Vivo Evaluation

- Radiographic Studies (X-ray): Using barium sulfate as marker.
- Gamma Scintigraphy: Non-invasive monitoring of tablet location.
- Pharmacokinetic Studies: Bioavailability and drug release profiles.

5.4 Stability Studies

- Performed as per ICH guidelines (accelerated and long-term).

6. Factors Affecting Performance

- Physiological Factors: Gastric pH, motility, fed/fasted state, presence of enzymes.
- Formulation Factors: Tablet density (<1 g/cm³ required), polymer type and viscosity, concentration of gas-generating agents, compression force during manufacturing.

7. Applications of Floating Tablets

- Anti-ulcer Therapy: Famotidine, ranitidine, omeprazole.
- Antibiotics for H. pylori: Amoxicillin, clarithromycin, tetracycline.
- Antidiabetic Agents: Metformin, glipizide.
- Cardiovascular Drugs: Propranolol, verapamil.
- Local Action Drugs: Antacids, sucralfate.

8. Recent Advances and Future Perspectives

- Quality by Design (QbD): Systematic design of floating tablets for predictable performance.
- Nanotechnology-Based Floating Systems: Nanoemulsions, nanofibers.
- 3D Printing: Personalized floating dosage forms with tailored drug release.
- Smart Polymers: Stimuli-responsive systems for pH or enzyme-triggered release.

- Combination GRDDS: Multi-mechanistic systems combining floating, mucoadhesion, and swelling.

9. CONCLUSION

Floating tablets represent a promising gastro-retentive strategy for enhancing oral drug delivery of molecules with absorption windows in the stomach or upper intestine. By providing prolonged gastric residence time and controlled release, they overcome limitations of conventional dosage forms and improve therapeutic efficacy. Although challenges remain, including patient variability in gastric physiology and manufacturing complexities, recent technological advances such as QbD, nanotechnology, and 3D printing hold immense potential for the development of next-generation floating tablets. Continued research and clinical validation will further establish floating tablets as a robust platform for targeted and sustained drug delivery.

10. Conflict of Interest

The authors declare no conflict of interest.

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