Journal of Biomedical and Pharmaceutical Research
Available Online at www.jbpr.in
CODEN: - JBPRAU (Source: - American Chemical Society)
NLM (National Library of Medicine): ID: (101671502)
Index Copernicus Value 2023: 85.86
Volume 14, Issue 6; 2025, 72-74

ISSN (Online): 2279-0594
ISSN (Print): 2589-8752

Review Article

Formulation and Evaluation of Gastro – Retentive Floating Tablets of Ranitidine Hcl Using HPMC and Sodium Bicarbonate

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Article Info: Received: 18-09-2025 / Revised: 27-10-2025 / Accepted: 28-11-2025
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DOI: https://doi.org/10.32553/jbpr.v14i6.1387
Conflict of interest statement: No conflict of interest

Abstract:
Oral drug delivery remains the most preferred route of administration due to its convenience and cost-effectiveness; however, it faces significant challenges such as variable gastric emptying times and narrow absorption windows. Ranitidine Hydrochloride (HCl), a widely used H2-receptor antagonist for treating peptic ulcers, GERD, and Zollinger-Ellison syndrome, exhibits low bioavailability (approx. 50%) due to its preferential absorption in the upper gastrointestinal tract and short biological half-life. To overcome these limitations, Gastro-Retentive Drug Delivery Systems (GRDDS), specifically effervescent floating tablets, have emerged as a promising solution. This review synthesizes current research on formulating floating matrices using hydrophilic polymers like Hydroxypropyl Methylcellulose (HPMC) and gas-generating agents like Sodium Bicarbonate. By enhancing gastric residence time, these systems ensure sustained drug release, improve therapeutic efficacy, and reduce dosing frequency, thereby optimizing patient compliance in acid-related disorders.
Keywords: Gastro-Retentive Drug Delivery System (GRDDS); Floating Tablets; Ranitidine Hydrochloride; HPMC; Sodium Bicarbonate; Effervescent System; Gastric Residence Time.

Introduction

The Challenge of Oral Drug Delivery

The oral route is favored for its convenience, but the complex physiology of the gastrointestinal (GI) tract presents hurdles for many active pharmaceutical ingredients (APIs).

A critical factor is Gastric Emptying Time (GET), which is highly variable and influenced by factors such as food intake, age, and disease state. This variability significantly impacts the bioavailability of drugs with a "narrow absorption window" (NAW). Drugs that are primarily absorbed in the stomach or upper small intestine, like Ranitidine, can pass through this region too quickly in conventional dosage forms, leading to incomplete absorption and sub-therapeutic plasma levels. [1]

Gastro-Retentive Drug Delivery Systems (GRDDS)

To address these pharmacokinetic issues, GRDDS have been developed to prolong the

retention of the dosage form within the stomach. By resisting gastric emptying, these systems provide a continuous release of the drug at its optimal absorption site. Various mechanisms have been employed to achieve this, including:

- Bioadhesive Systems: These adhere to the gastric mucosa to resist emptying.
- High-Density Systems: These sink to the bottom of the stomach (antrum) to avoid peristaltic waves.
- Expandable Systems: These swell to a size larger than the pyloric sphincter, preventing passage.
- Floating Drug Delivery Systems (FDDS): Among these strategies, FDDS have gained prominence due to their simplicity and safety. They possess a bulk density lower than that of gastric fluids (<1.004 g/cm³), allowing them to float on the stomach contents while releasing the drug over an extended period. [2]

Ranitidine Hydrochloride: A Candidate for Gastro-Retention

Ranitidine HCl is a potent histamine H2-receptor antagonist used to inhibit gastric acid secretion. Despite its clinical utility, it suffers from a short half-life (2–3 hours) and poor absorption in the lower GI tract.

This necessitates frequent dosing (e.g., 150 mg twice daily), which can compromise patient adherence and lead to fluctuating plasma concentrations. [3] A gastro-retentive formulation that sustains drug release for 12–24 hours would not only maintain stable plasma concentrations but also allow for a convenient once-daily dosing regimen, significantly improvinghe management of chronic conditions like GERD and Zollinger-Ellison syndrome. [4]

Formulation Strategies

The Effervescent Floating Mechanism

The most effective strategy for creating a floating tablet involves an effervescent mechanism. This approach utilizes a gas-generating agent, typically Sodium Bicarbonate, which reacts with the acidic gastric environment (HCl) to produce carbon dioxide (CO_2) gas.

The liberated CO_2 is trapped within the hydrocolloid matrix of the tablet. This entrapment reduces the specific gravity of the tablet to less than 1.0, imparting immediate buoyancy. [5]

The Role of Polymers

The success of this system relies on a synergistic interaction between the gas generator and a matrix-forming polymer. Hydroxypropyl Methylcellulose (HPMC) is the polymer of choice due to its non-toxic nature and excellent gel-forming properties.

Upon contact with gastric fluid, HPMC hydrates to form a viscous, gelatinous barrier on the tablet surface. This gel layer performs two critical functions: [6]

- Gas Entrapment: It traps the generated CO_2 bubbles, ensuring the tablet floats.
- Release Control: It retards the diffusion of the drug, ensuring a sustained release profile. By adjusting the viscosity grade (e.g., K4M, K15M, K100M) and concentration of HPMC, formulators can precisely tune the release kinetics to match the desired therapeutic profile. [7]

Critical Evaluation Parameters

To ensure clinical efficacy, developed formulations must undergo rigorous physicochemical evaluation.

Pre-Formulation and Compatibility Standard protocols include FT-IR spectroscopy to verify that no adverse chemical interactions occur between Ranitidine HCl and excipients like Sodium Bicarbonate or HPMC.

Additionally, micromeritic properties such as the Angle of Repose and Carr's Index are assessed to ensure the powder blend has sufficient flowability for uniform tablet compression. Poor flow can lead to weight variation and inconsistent drug content. [8]

Buoyancy and Dissolution Testing

The two most critical performance metrics for FDDS are:

- Floating Lag Time (FLT): The time required for the tablet to rise to the surface. An ideal formulation should float within minutes (< 15 mins) to prevent premature emptying.
- Total Floating Time (TFT): The duration the tablet remains buoyant. This should exceed 12 hours to cover the entire dosing interval. [9]

  In-vitro drug release is evaluated using USP Paddle apparatus in simulated gastric fluid (0.1N HCl). The release data is typically fitted to kinetic models (Zero-Order, Higuchi, and Korsmeyer-Peppas) to elucidate the release mechanism (diffusion vs. erosion). [10]

Stability

Long-term stability studies, conducted as per ICH Q1A (R2) guidelines, monitor parameters such as hardness, drug content, and dissolution profile upon storage at accelerated conditions (40°C/75% RH).

These studies confirm that the floating capability and sustained release characteristics are maintained throughout the product's shelf life and that the drug does not degrade into toxic byproducts. [11]

Conclusion

The development of gastro-retentive floating tablets represents a logical and effective evolution in the delivery of Ranitidine Hydrochloride.

By overcoming the physiological barriers of gastric emptying, these systems maximize the drug's absorption window, leading to improved bioavailability and therapeutic consistency.

The synergistic use of HPMC and Sodium Bicarbonate provides a robust, cost-effective platform for achieving both buoyancy and controlled release.

As evidenced by recent advancements in bilayer tablets and 3D printing, the field continues to evolve, promising even more personalized and efficient treatments for acid-related gastrointestinal disorders in the future.

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