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Research Article

Formulation and Evaluation of Floating Tablets of Ranitidine Hydrochloride

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ABSTRACT

Ranitidine hydrochloride is a histamine H_2-receptor antagonist widely used in the treatment of gastric ulcers, gastroesophageal reflux disease (GERD), and Zollinger–Ellison syndrome. However, its short biological half-life and absorption primarily in the upper gastrointestinal tract limit its therapeutic efficiency. The present study aims to formulate and evaluate gastroretentive floating tablets of ranitidine hydrochloride to prolong gastric residence time and enhance bioavailability. Floating tablets were prepared using hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC), along with gas-generating agents like sodium bicarbonate. Various formulation batches were evaluated for pre-compression parameters, post-compression characteristics, buoyancy behavior, and in vitro drug release. Results demonstrated that optimized formulations exhibited acceptable hardness, friability, drug content, and prolonged floating duration with controlled drug release over 12 hours. The study concludes that floating drug delivery systems can effectively improve the pharmacokinetic profile of ranitidine hydrochloride.

INTRODUCTION

1. Overview of Oral Drug Delivery Systems

Oral drug delivery is the most widely used route of drug administration due to its convenience, cost-effectiveness, and high patient compliance. Tablets, capsules, and liquid formulations are commonly preferred because they are easy to administer and do not require specialized medical supervision. However, despite these advantages, conventional oral dosage forms often face significant limitations in maintaining consistent therapeutic drug levels in the body.

One of the major challenges is the variability in gastric emptying time, which can lead to unpredictable drug absorption. Many drugs are absorbed primarily in the upper part of the gastrointestinal tract (GIT), particularly the stomach and the proximal small intestine. When

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such drugs pass quickly through the stomach, their absorption becomes incomplete, leading to reduced bioavailability and therapeutic effectiveness (Aulton & Taylor, 2018).

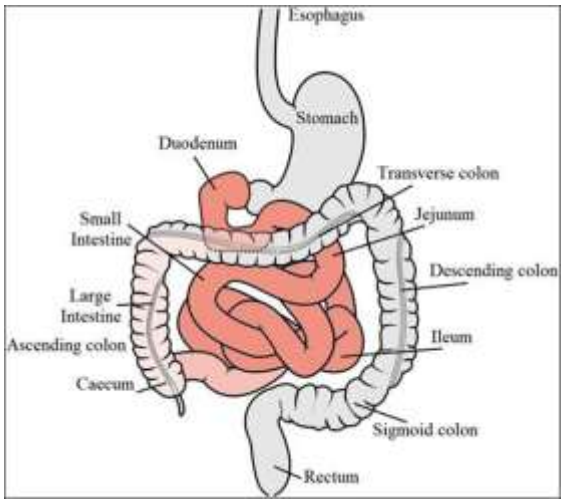

Figure 1: Anatomy of the Gastrointestinal Tract Showing Drug Absorption Sites

2. Limitations of Conventional Dosage Forms

Conventional oral dosage forms are designed to release the drug immediately after administration. While this may be beneficial for rapid onset of action, it often results in fluctuations in plasma drug concentration. These fluctuations can cause sub-therapeutic levels or toxic effects, especially for drugs with a narrow therapeutic index.

Rapid gastric emptying further complicates the issue by reducing the residence time of the drug in the stomach. This is particularly problematic for drugs that:

- Are poorly soluble in intestinal pH
- Are unstable in alkaline environments
- Have a narrow absorption window

As a result, frequent dosing becomes necessary to maintain therapeutic levels, which can reduce patient compliance and increase the risk of side effects (Lachman et al., 2013).

3. Concept of Gastroretentive Drug Delivery Systems (GRDDS)

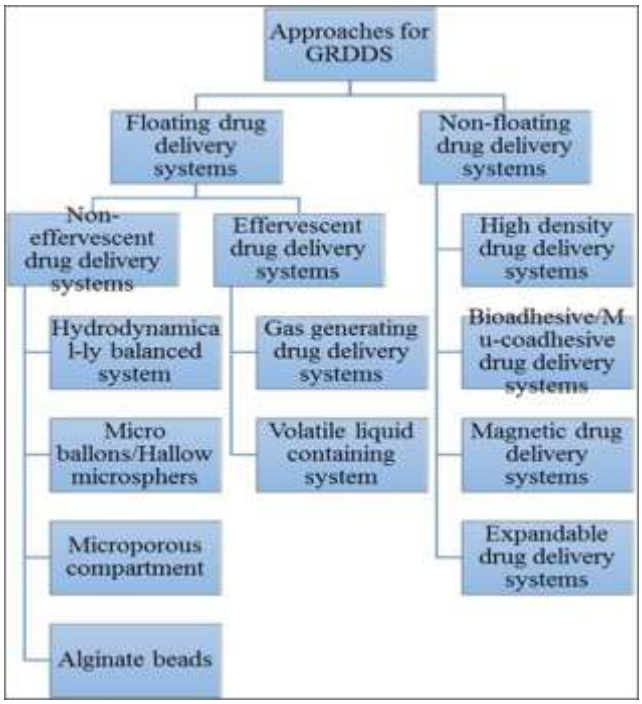

Figure 2: Classification of Gastroretentive Drug Delivery Systems

To overcome the limitations of conventional dosage forms, gastroretentive drug delivery systems (GRDDS) have been developed. These systems are designed to prolong the retention time of dosage forms in the stomach, thereby enhancing drug absorption and improving bioavailability.

GRDDS can be classified into several types, including:

- Floating systems
- Swelling systems
- Mucoadhesive systems
- High-density systems

Among these, floating drug delivery systems have gained significant attention due to their simplicity and effectiveness. By remaining in the stomach for extended periods, these systems allow sustained

drug release and improved therapeutic outcomes (Streubel et al., 2006).

4. Floating Drug Delivery Systems: Mechanism and Advantages

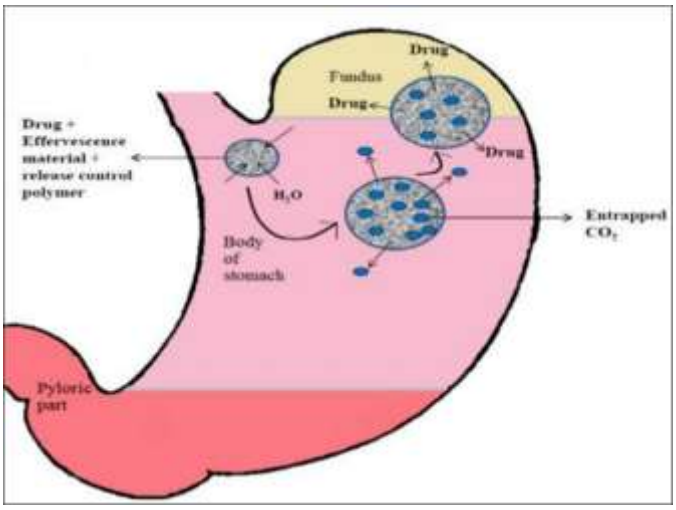

Figure 3: Mechanism of Floating Drug Delivery System

Floating drug delivery systems are designed to have a density lower than that of gastric fluids, allowing them to float on the surface of stomach contents. These systems typically contain gas-generating agents such as sodium bicarbonate, which react with gastric acid to produce carbon dioxide. The generated gas gets entrapped in the polymer matrix, reducing the density of the dosage form and enabling it to float.

The advantages of floating systems include:

- Prolonged gastric residence time
- Sustained and controlled drug release
- Reduced dosing frequency
- Improved patient compliance

Additionally, floating systems can enhance the bioavailability of drugs that are absorbed in the upper GIT. By maintaining the drug in the stomach for a longer duration, these systems ensure continuous drug release at the absorption site (Deshpande et al., 1997).

5. Suitability of Ranitidine Hydrochloride for Floating Systems

Ranitidine hydrochloride is a histamine H_2-receptor antagonist commonly used in the treatment of peptic ulcers, gastroesophageal reflux disease (GERD), and other acid-related disorders. It is considered an ideal candidate for gastroretentive drug delivery systems due to its pharmacokinetic properties.

Key Characteristics of Ranitidine Hydrochloride

- **Short biological half-life (2–3 hours):** Requires frequent dosing
- **Site-specific absorption:** Primarily absorbed in the upper GIT
- **Moderate bioavailability (~50%):** Limited due to first-pass metabolism

Because of these characteristics, conventional formulations of ranitidine may not provide optimal therapeutic outcomes. Floating drug delivery systems can address these limitations by

prolonging gastric retention and ensuring sustained drug release (Jain et al., 2010).

6. Role of Polymers in Floating Tablets

Hydrophilic polymers play a crucial role in the formulation of floating tablets. Polymers such as Hydroxypropyl Methylcellulose (HPMC) are widely used due to their ability to form a gel-like structure upon contact with gastric fluids.

This gel barrier serves multiple functions:

- Controls the rate of drug release
- Maintains tablet integrity
- Entraps generated gas to facilitate floating

The viscosity grade and concentration of the polymer significantly influence the drug release profile. Higher polymer concentrations generally result in slower drug release due to increased gel strength and diffusion resistance (Colombo et al., 2000).

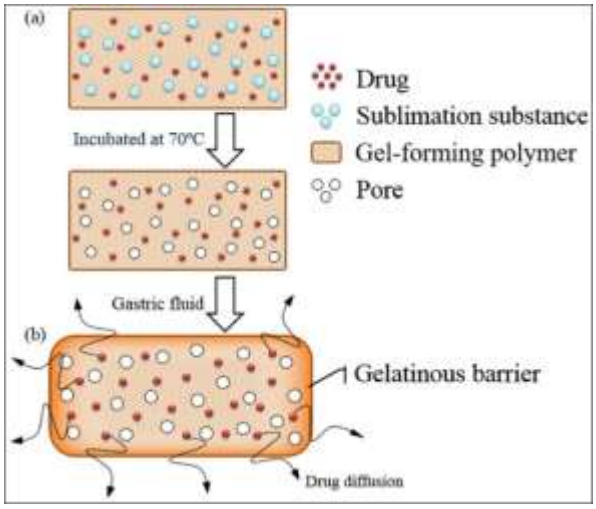

Figure 4: Swelling and Gel Formation of HPMC Matrix Tablet

7. Mechanism of Buoyancy and Drug Release

The buoyancy of floating tablets is achieved through an effervescent mechanism. When the tablet comes into contact with gastric fluid, the gas-generating agent reacts to produce carbon dioxide. This gas becomes trapped within the hydrated polymer matrix, decreasing the overall density of the tablet.

Drug release from floating tablets occurs through a combination of:

- Diffusion through the gel layer
- Erosion of the polymer matrix

The release kinetics often follow Higuchi or Korsmeyer–Peppas models, indicating a controlled and predictable release pattern. This ensures that the drug is released gradually over an extended period, maintaining consistent plasma drug levels (Siepmann & Peppas, 2011).

8. Therapeutic Benefits of Floating Ranitidine Tablets

Floating tablets of ranitidine hydrochloride offer several therapeutic advantages over conventional formulations:

- Enhanced bioavailability due to prolonged gastric retention
- Reduced dosing frequency, improving patient compliance
- Sustained drug release, minimizing plasma fluctuations
- Improved efficacy in acid-related disorders

Clinical and in vitro studies have demonstrated that floating formulations can significantly improve drug release profiles and gastric retention time, leading to better therapeutic outcomes (Gharti et al., 2012).

2. LITERATURE REVIEW

Several researchers have extensively investigated floating drug delivery systems (FDDS) of ranitidine hydrochloride to improve its gastric retention, bioavailability, and controlled drug release.

Jain et al. (2010) developed floating tablets of ranitidine hydrochloride using a 3^2 factorial design to systematically evaluate the influence of formulation variables such as polymer ratio (HPMC and xanthan gum) and excipient concentration. Their study demonstrated that polymer ratio plays a crucial role in controlling drug release kinetics, floating lag time, and tablet hardness. An increase in polymer concentration resulted in enhanced swelling behavior and modified release patterns, while the addition of aerosil improved tablet hardness without significantly affecting buoyancy. The optimized formulation followed non-Fickian diffusion, indicating a combined mechanism of drug diffusion and polymer relaxation.

Gharti et al. (2012) formulated floating tablets using hydroxypropyl methylcellulose (HPMC) and polyethylene oxide (PEO) as hydrophilic polymers along with sodium bicarbonate as a gas-generating agent. Their findings revealed that polymer concentration significantly influences drug release and matrix integrity, with higher concentrations delaying drug release due to increased gel strength. The study also highlighted that floating lag time decreases with increasing sodium bicarbonate concentration, while total floating duration remained more than 24 hours for all formulations. This work confirmed that effervescent systems effectively maintain prolonged gastric retention and controlled drug delivery.

Verma et al. (2015) prepared floating tablets using different grades of HPMC (K4M and K100M) in combination with sodium bicarbonate and citric acid as effervescent agents. Their study demonstrated that higher viscosity polymers (HPMC K100M) produced slower drug release profiles compared to lower viscosity grades, due to stronger gel barrier formation. Additionally, the incorporation of gas-generating agents significantly improved buoyancy and reduced floating lag time. The formulations exhibited sustained drug release and maintained matrix integrity, confirming the suitability of HPMC-based systems for gastroretentive applications.

Further advancements were reported by Nigusse et al. (2021), who developed combined floating, bioadhesive, and swellable matrix tablets of ranitidine hydrochloride. Their study emphasized that gastroretentive systems not only prolong gastric residence time but also reduce plasma drug fluctuations, enhance absorption in the upper gastrointestinal tract, and improve overall therapeutic efficacy. The combination of multiple retention mechanisms (floating and bioadhesion) further improved formulation performance compared to single-mechanism systems .

Kumar et al. (2008) investigated a floating osmotic drug delivery system of ranitidine and reported that drug release is primarily influenced by the concentration of hydrophilic polymers and membrane characteristics, while floating lag time is dependent on the amount of gas-generating agents. Their optimized formulation exhibited floating lag time below 2 minutes and sustained release up to 12 hours, demonstrating the importance of formulation design in achieving desired therapeutic outcomes.

More recent studies have reinforced the importance of hydrophilic polymers and effervescent systems. Sharma et al. (2025) highlighted that the use of HPMC in combination with sodium bicarbonate significantly enhances gastric residence time, ensures sustained drug

release, and improves bioavailability of ranitidine hydrochloride, which inherently suffers from low bioavailability (~50%) and a short half-life. These findings confirm that floating drug delivery systems are a promising strategy for optimizing drug therapy in acid-related disorders.

3. AIM, OBJECTIVES, AND PLAN OF WORK

3.1 Aim

To formulate and evaluate gastroretentive floating tablets of Ranitidine Hydrochloride to enhance gastric residence time and achieve sustained drug release.

3.2 Objectives

- To develop floating tablets using suitable polymers (e.g., HPMC)
- To optimize gas-generating agents for buoyancy
- To evaluate pre- and post-compression parameters
- To study floating behavior (lag time and duration)
- To perform in vitro drug release studies
- To optimize formulation based on release profile

Plan of Work

3.3 Plan of Work

- Literature review and characterization of Ranitidine Hydrochloride
- Compatibility study using FTIR
- Formulation of floating tablets by direct compression
- Evaluation of powder blend (pre-compression parameters)
- Evaluation of tablets (hardness, friability, drug content)
- Buoyancy and in-vitro dissolution studies
- Drug release kinetics and optimization of formulation

4. MATERIALS AND METHODS

4.1 Materials

All chemicals and reagents used in the study were of analytical grade.

Sr. No.	Material	Category	Manufacturer (Dummy)
1	Ranitidine Hydrochloride	Active Pharmaceutical Ingredient	MedChem Laboratories Pvt. Ltd., Mumbai, India
2	HPMC K100M	Polymer	Colorcon Asia Pvt. Ltd., Goa, India
3	Sodium Bicarbonate	Gas-generating agent	Loba Chemie Pvt. Ltd., Mumbai, India
4	Citric Acid	Effervescent agent	S.D. Fine Chemicals Ltd., Mumbai, India
5	Microcrystalline Cellulose (MCC)	Diluent	FMC Biopolymer, Gujarat, India
6	Magnesium Stearate	Lubricant	Himedia Laboratories, Mumbai, India
7	Talc	Glidant	Nice Chemicals Pvt. Ltd., Kerala, India

4.2 Instruments

Sr. No.	Instrument	Make & Model (Dummy)
1	Digital Weighing Balance	Shimadzu, Model AY-220
2	Tablet Compression Machine	Cadmach Machinery, Model CMD-8
3	UV-Visible Spectrophotometer	LabIndia, Model UV-3092
4	Dissolution Test Apparatus (USP Type II)	Electrolab, Model TDT-08L
5	Friability Test Apparatus	Roche Friabilator, Model EF-2
6	Hardness Tester	Monsanto Hardness Tester, Model MH-5
7	Vernier Caliper	Mitutoyo, Model CD-6" CSX
8	FTIR Spectrophotometer	Bruker, Model Alpha II

4.3 Methods

4.3.1 Preformulation Studies

a. Identification of Drug

- The drug Ranitidine Hydrochloride was identified by melting point determination and FTIR analysis.

b. Drug–Excipient Compatibility Study

- FTIR spectroscopy was used to study compatibility between drug and excipients.
- Physical mixtures were prepared and scanned in the range of 4000–400 cm^{-1}.

4.3.2 Preparation of Floating Tablets

Floating tablets were prepared by direct compression method.

Procedure:

1. All ingredients were accurately weighed using a digital balance.
2. The drug and excipients were passed through sieve No. 40.
3. The drug was mixed with polymer (HPMC K100M) and MCC uniformly.
4. Sodium bicarbonate and citric acid were added and mixed thoroughly.
5. Magnesium stearate and talc were added as lubricants and mixed gently.
6. The final blend was compressed into tablets using a tablet compression machine.

4.3.3 Evaluation of Powder Blend (Pre-compression)

a. Angle of Repose

- Measured by funnel method to assess flow properties.

b. Bulk Density and Tapped Density

- Determined using a measuring cylinder method.

c. Carr's Index and Hausner Ratio

- Calculated using standard formulas to evaluate compressibility.

4.3.4 Evaluation of Tablets (Post-compression)

a. Weight Variation

- 20 tablets were weighed individually and compared with average weight.

b. Hardness

- Measured using Monsanto hardness tester.

c. Friability

- Determined using Roche friabilator at 25 rpm for 4 minutes.

d. Thickness

- Measured using Vernier caliper.

e. Drug Content

- Tablets were crushed, dissolved in 0.1 N HCl, and analyzed using UV spectrophotometer at 314 nm.

4.3.5 Buoyancy Studies

Procedure:

- Tablets were placed in 100 mL of 0.1 N HCl (pH 1.2) at 37 ± 0.5°C.
- Floating lag time and total floating duration were recorded.

4.3.6 In-vitro Dissolution Study

Procedure:

1. Dissolution study was performed using USP Type II apparatus.
2. 900 mL of 0.1 N HCl was used as dissolution medium.
3. Temperature maintained at 37 ± 0.5°C and speed at 50 rpm.
4. Samples were withdrawn at predetermined intervals (1, 2, 4, 8, 12 hours).
5. Samples were analyzed using UV spectrophotometer at 314 nm.

4.3.7 Drug Release Kinetics

- Drug release data were fitted into:
  - Zero-order model
  - First-order model
  - Higuchi model

5. RESULTS

5.1 Preformulation Studies

The drug Ranitidine Hydrochloride was confirmed by melting point (134–138°C), which was found within the reported range.

FTIR spectra of pure drug and drug–excipient mixture showed no significant shift in characteristic peaks, indicating compatibility between drug and excipients.

5.2 Evaluation of Powder Blend (Pre-compression)

Parameter	Result
Angle of Repose	26.5° ± 0.8
Bulk Density	0.45 g/cm³
Tapped Density	0.52 g/cm³
Carr's Index	13.46%
Hausner Ratio	1.15

Result:

The powder blend showed good flow properties and compressibility, suitable for direct compression.

5.3 Evaluation of Tablets (Post-compression)

Parameter	Result
Weight Variation	398 ± 3 mg
Hardness	6.0 ± 0.5 kg/cm²

Friability	0.62%
Thickness	4.2 ± 0.2 mm
Drug Content	98.8 ± 1.2%

Result:
All parameters were within acceptable pharmacopeial limits, indicating uniformity and mechanical strength of tablets.

5.4 Buoyancy Studies

Parameter	Result
Floating Lag Time	42 ± 5 sec
Total Floating Time	>12 hours

Result:
Tablets showed rapid buoyancy and prolonged floating behavior, confirming effective gas generation and matrix integrity.

5.5 In-vitro Drug Release Study

Time (hrs)	% Drug Release
1	18.5%
2	30.2%
4	48.6%
8	74.3%
12	96.5%

Result:

The formulation exhibited sustained drug release up to 12 hours, indicating effective control by polymer matrix.

5.6 Drug Release Kinetics

- Best fit observed for Higuchi model (R^2 = 0.992)
- Korsmeyer–Peppas model indicated non-Fickian diffusion (n = 0.68)

Result:

Drug release followed a combined mechanism of diffusion and polymer erosion.

6. CONCLUSION

The present study successfully developed gastroretentive floating tablets of Ranitidine Hydrochloride using the direct compression method. The formulated tablets exhibited satisfactory pre-compression and post-compression characteristics, indicating good flow properties, uniformity, and mechanical strength.

The incorporation of hydrophilic polymer (HPMC K100M) and gas-generating agents (sodium bicarbonate and citric acid) resulted in rapid floating behavior with prolonged buoyancy (>12 hours). The optimized formulation showed a controlled and sustained drug release profile up to 12 hours, which is beneficial for maintaining therapeutic drug levels.

Drug release kinetics followed the Higuchi model with non-Fickian diffusion, suggesting a combined mechanism of diffusion and polymer erosion. Overall, the developed floating tablets demonstrated improved gastric retention and sustained drug delivery.

Thus, floating drug delivery systems of Ranitidine Hydrochloride can be considered a promising approach to enhance bioavailability, reduce dosing frequency, and improve patient compliance in the management of acid-related disorders.

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