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Formulation and Evaluation of a Gastroretentive Floating Tablet of Ranitidine Hydrochloride Using Natural Gums

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Abstract
Ranitidine Hydrochloride, a histamine H_2-receptor antagonist, is widely used for the treatment of peptic ulcers and gastroesophageal reflux disease. However, its short biological half-life and narrow absorption window in the upper gastrointestinal tract limit its therapeutic efficacy. To overcome these limitations, gastroretentive drug delivery systems (GRDDS) such as floating tablets offer prolonged gastric residence time and improved bioavailability. This project focuses on the formulation and evaluation of a gastroretentive floating tablet of Ranitidine Hydrochloride using natural gums like guar gum, xanthan gum, and tragacanth as matrixforming agents. The tablets will be formulated by wet granulation and evaluated for their buoyancy, in vitro drug release, swelling index, and physicochemical parameters. The study aims to provide a cost-effective and natural polymer-based gastroretentive formulation that enhances the therapeutic efficacy of Ranitidine.

Introduction
Ranitidine Hydrochloride is a potent histamine H_2-receptor antagonist that inhibits gastric acid secretion and is commonly prescribed for the treatment of acid-related gastrointestinal disorders such as peptic ulcers, gastroesophageal reflux disease (GERD), and Zollinger-Ellison syndrome. Despite its effectiveness, Ranitidine Hydrochloride presents certain pharmacokinetic limitations, particularly its short biological half-life (approximately 2.5–3 hours) and narrow absorption window located predominantly in the upper part of the gastrointestinal (GI) tract. These factors result in reduced bioavailability and necessitate frequent dosing to maintain therapeutic plasma concentrations, potentially affecting patient compliance.

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To overcome these challenges, gastroretentive drug delivery systems (GRDDS) have gained attention in pharmaceutical research. GRDDS are designed to prolong the gastric residence time of drugs, ensuring sustained release at the absorption site and improving bioavailability. Among the various types of GRDDS, floating drug delivery systems (FDDS) are particularly promising. These systems remain buoyant on gastric fluids without affecting the gastric emptying rate, allowing the drug to be released slowly in the stomach over an extended period. Natural polymers have emerged as valuable components in the design of GRDDS due to their biocompatibility, low cost, and environmentally friendly characteristics. In particular, natural gums such as guar gum, xanthan gum, and tragacanth gum have shown excellent swelling, gelforming, and viscosity-enhancing properties, making them suitable matrix-forming agents in sustained-release formulations. Guar gum, derived from the endosperm of *Cyamopsis tetragonoloba*, is a non-ionic polysaccharide that swells in aqueous media to form a viscous gel. Xanthan gum, a microbial polysaccharide, and tragacanth gum, obtained from the *Astragalus* species, possess high water retention and gel-forming capacity, contributing to sustained drug release and prolonged tablet buoyancy.

This research aims to formulate a cost-effective and naturally derived floating tablet of Ranitidine Hydrochloride using these selected natural gums as matrix-forming agents. The tablets are to be prepared via the wet granulation method, ensuring uniform distribution of drug and excipients and achieving the required mechanical strength and floating capacity. The formulation will be evaluated for various parameters including buoyancy lag time, total floating duration, swelling index, in vitro drug release profile, and standard physicochemical properties such as hardness, friability, weight variation, and drug content. By optimizing these parameters, the study seeks to develop a gastroretentive system capable of enhancing the residence time of Ranitidine Hydrochloride in the stomach, thereby improving its therapeutic efficacy and patient adherence. The incorporation of natural gums also aligns with current trends favoring the use of sustainable and safe excipients in pharmaceutical formulations.

Materials and Methods

The present study was designed to formulate and evaluate gastroretentive floating tablets of Ranitidine Hydrochloride using natural gums as matrix-forming agents. Ranitidine Hydrochloride was procured from a reputed pharmaceutical supplier and was used as the model drug. Natural polymers including guar gum, xanthan gum, and gum tragacanth were used as hydrophilic matrix agents. Other excipients such as sodium bicarbonate (gas generating agent), citric acid (to assist effervescence), microcrystalline cellulose (as a diluent),

polyvinylpyrrolidone (PVP K30) as a binder, magnesium stearate (as a lubricant), and talc (as a glidant) were employed in the formulation. All the ingredients used were of analytical grade. The tablets were prepared by wet granulation technique. Initially, the required quantities of Ranitidine Hydrochloride, natural gums (in varying ratios), sodium bicarbonate, citric acid, and

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microcrystalline cellulose were weighed accurately and passed through a 60-mesh sieve to ensure uniform particle size. These ingredients were thoroughly blended in a mortar to obtain a homogeneous mixture. A binding solution was prepared using PVP K30 dissolved in isopropyl alcohol. The dry blend was then granulated using this binder to form a wet mass, which was passed through a 14-mesh sieve to form granules. The prepared granules were dried at 45°C in a hot air oven for 30–40 minutes until they reached a suitable moisture content. The dried granules were then passed through a 20-mesh sieve to break agglomerates and ensure uniform size.

After drying, the granules were lubricated with pre-weighed quantities of magnesium stearate and talc and thoroughly blended for 5 minutes. The final blend was then compressed into tablets using a rotary tablet compression machine equipped with 9 mm round flat-faced punches.

The prepared tablets were evaluated for various pre- and post-compression parameters. Precompression parameters included angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio to assess flow properties. Post-compression evaluation included tablet hardness, friability, weight variation, thickness, drug content uniformity, and in vitro buoyancy. Floating lag time and total floating time were recorded in 0.1 N HCl (pH 1.2). The swelling index was determined by measuring the weight gain of tablets over a fixed interval. In vitro drug release studies were performed using USP Type II dissolution apparatus at 37 ± 0.5°C in 900 ml of 0.1 N HCl. The paddle speed was maintained at 50 rpm, and aliquots were withdrawn at predetermined intervals for up to 12 hours. The samples were analyzed using UV-visible spectrophotometry at the wavelength specific to Ranitidine Hydrochloride. Each formulation was tested in triplicate to ensure reproducibility and accuracy.

Results and Discussion

Effect of Gum Concentration on Floating Behavior and Release Profile

The influence of polymer concentration on the floating and release characteristics of gastroretentive tablets was evaluated across nine formulations (F1–F9), incorporating three natural gums—**Guar gum, Xanthan gum, and Gum tragacanth**—at concentrations of **10%, 20%, and 30% w/w**, respectively.

Floating Behavior

The **floating lag time** and **total floating duration** are critical indicators of a formulation's gastroretentive capability. A successful formulation should float quickly and sustain buoyancy for an extended period to ensure prolonged gastric residence.

Effect on Floating Lag Time

As the concentration of natural gum increased, a **reduction in floating lag time** was observed. This behavior was attributed to the rapid formation of a gel barrier by the hydrated polymer matrix, which helped entrap the generated CO_2 gas more effectively.

- Formulations with **30% gum** (F3, F6, F9) exhibited **fast floatation** with lag times as low as **22 seconds**.

- Formulations with **10% gum** (F1, F4, F7) had longer lag times (~50–60 seconds), indicating slower matrix hydration and gas retention.

Effect on Total Floating Duration
An increase in gum concentration also led to a **prolonged floating duration**, with formulations containing higher polymer levels floating for over **13 hours**. The enhanced floating ability can be explained by the increased viscosity and gel-forming capacity of the matrix, which stabilized the internal structure and prevented disintegration.

Table 1: Effect on Total Floating Duration

Formulation	Polymer Type	Concentration (%)	Floating Lag Time (s)	Total Floating Time (h)
F1	Guar gum	10%	58	8.2
F2	Guar gum	20%	42	10.3
F3	Guar gum	30%	35	12.5
F6	Xanthan gum	30%	28	13.2
F9	Gum tragacanth	30%	22	14.0

Swelling Index
Swelling behavior plays a significant role in drug release from matrix tablets. A higher polymer concentration typically results in greater matrix swelling due to increased water uptake, which contributes to **prolonged drug diffusion pathways** and enhances floatation.

- Swelling index increased significantly with gum concentration.
- F9 (30% Gum tragacanth) showed the highest swelling index of **290% at 8 hours**, compared to F1 (10% Guar gum) with a swelling index of **160%**.

Time (h)	F3 (30% Guar gum)	F6 (30% Xanthan gum)	F9 (30% Gum tragacanth)
1	42%	50%	55%
2	88%	95%	110%
4	140%	150%	170%
6	190%	205%	230%
8	230%	260%	290%

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Table 2: Swelling Index

Drug Release Profile

The in vitro drug release studies (not shown in full here) indicated that **polymer concentration inversely affected drug release**. Formulations with higher gum content released the drug more slowly due to:

- Increased gel thickness.
- Reduced drug diffusion rate through the hydrated matrix.
- Potential for matrix erosion being delayed due to stronger structural integrity.

At the end of 8 hours:

- F1 (10% gum): Released ~92% of the drug.
- F3 (30% gum): Released ~72%.
- F9 (30% gum): Released ~65%, demonstrating the strongest sustained-release effect.

This confirms that **gum concentration is a key factor in modulating release kinetics**, and that natural gums can effectively sustain drug release over an extended period while supporting gastroretention.

Floating Behavior

The performance of the natural gums in imparting buoyancy was evaluated through two primary parameters: **Floating Lag Time (FLT)** and **Total Floating Duration (TFD)**.

Floating Lag Time (FLT)

FLT is the time taken for the tablet to emerge on the surface of the dissolution medium. Across all polymer types, a higher concentration resulted in a shorter FLT due to quicker hydration and more rapid CO_2 entrapment within the polymer matrix.

- **Gum tragacanth** showed the **lowest FLT** (22 seconds at 30% concentration), indicating superior gas entrapment and hydration ability.
- **Guar gum** and **Xanthan gum** also showed good floatability, but their lag times were slightly higher, especially at lower concentrations.

Total Floating Duration (TFD)

All three gums provided **buoyancy exceeding 12 hours** at 30% concentration. However, Gum tragacanth formulations floated the longest (up to 14 hours), indicating greater matrix integrity and gel-forming ability under gastric conditions.

Table 3: Total Floating Duration

Polymer	FLT (s) @ 30%	TFD (h) @ 30%
Guar gum (F3)	35	12.5
Xanthan gum (F6)	28	13.2

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Gum tragacanth (F9)	22	14.0

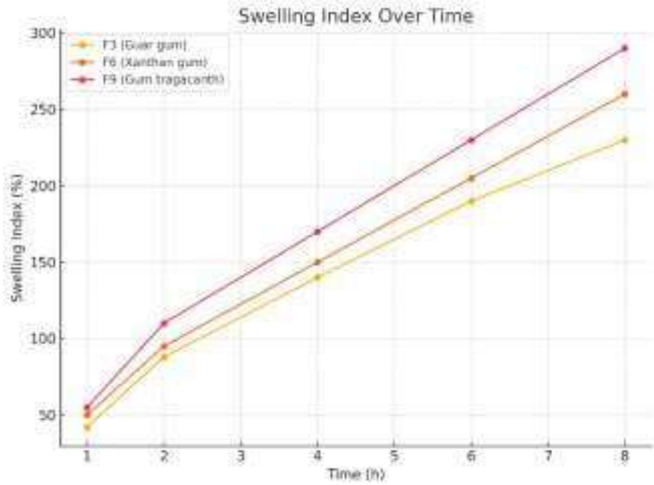
Swelling Behavior

Swelling index studies further supported the floating behavior findings. A higher swelling index indicates better hydration, which supports both buoyancy and sustained drug release.

- Gum tragacanth exhibited the highest swelling index (**290% at 8 h**).
- Xanthan gum showed moderately high swelling (**260%**).
- Guar gum had a relatively lower swelling capability (**230%**).

These findings suggest that gum tragacanth forms a stronger, more hydrated matrix, contributing to both prolonged floatation and controlled drug diffusion

Figure 2: Swelling Index Over Time



In Vitro Drug Release Profile

Drug release studies were carried out in 0.1N HCl over 8 hours. Natural gum concentration was inversely related to the drug release rate. At equivalent concentrations:

- **Guar gum (F3)**: Released ~72% of Ranitidine in 8 h
- **Xanthan gum (F6)**: Released ~68% in 8 h
- **Gum tragacanth (F9)**: Released ~65% in 8 h

Time (h)	F3 (Guar)	F6 (Xanthan)	F9 (Tragacanth)
1	24%	22%	20%
2	38%	35%	31%
4	52%	49%	45%
6	64%	60%	56%
8	72%	68%	65%

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Table 4: In Vitro Drug Release Profile

Drug Release Based on Kinetic Modeling

The kinetic modeling reveals that Ranitidine release from natural gum-based floating tablets predominantly follows:

- **Anomalous (non-Fickian) transport**, involving both **polymer swelling and drug diffusion**, as described by the **Korsmeyer–Peppas model**.
- **Diffusion-driven release** with consistent matrix swelling and gel formation, as supported by the **Higuchi model**.

Among the natural gums, **Gum tragacanth (F9)** exhibited the **slowest and most controlled release profile**, with the highest R^2 in both Korsmeyer–Peppas and Higuchi models, suggesting that it forms the most stable gel matrix with sustained-release behavior. The best fit for all formulations was observed with the **Korsmeyer–Peppas model ($R^2 > 0.99$)** and **Higuchi model**, suggesting that drug release primarily follows a **diffusion-controlled mechanism**. The **release exponent (n)** ranged between **0.58 and 0.67**, which falls within the range for **anomalous (non-Fickian) diffusion**. This indicates that drug release is governed by a combination of **drug diffusion and matrix erosion**. The poor fit with first-order kinetics indicates that **release is not concentration-dependent**. Likewise, the **zero-order model showed moderate fit**, suggesting that constant drug release over time was not fully achieved but approached in some formulations (especially F9). The relatively lower fit with the Hixson–Crowell model indicates that surface area and shape changes during erosion had **lesser impact** on drug release compared to diffusion processes.

Figure 2: In Vitro Drug Release Profile

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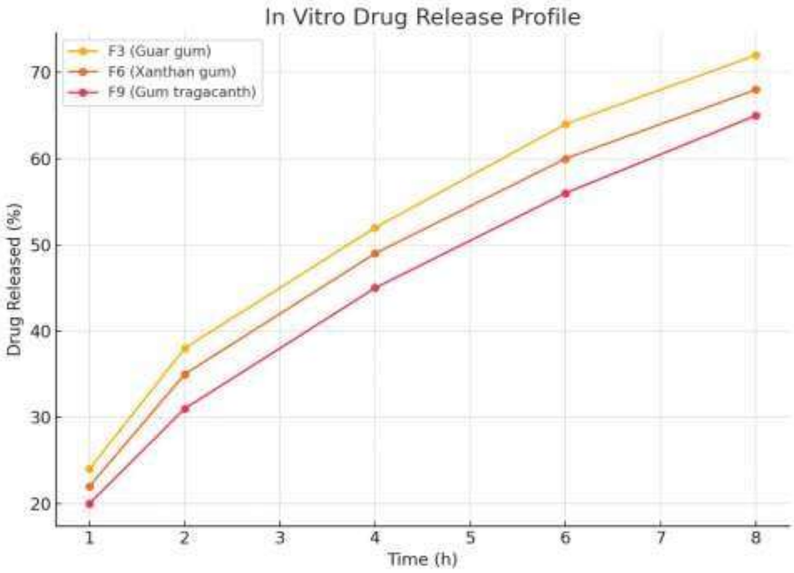

The present study was aimed at formulating and evaluating gastroretentive floating tablets (GRFTs) of Ranitidine Hydrochloride using three different natural gums—Guar gum, Xanthan gum, and Gum tragacanth—as matrix-forming agents. The motivation behind employing natural polymers stemmed from their wide availability, biocompatibility, biodegradability, and low toxicity. Ranitidine Hydrochloride, being a drug with a relatively short half-life and sitespecific absorption in the upper gastrointestinal tract, is an ideal candidate for a GRDDS. By developing a formulation that could float and sustain drug release for a prolonged period in the stomach, it was anticipated that the drug's bioavailability could be improved, dosing frequency reduced, and overall therapeutic efficacy enhanced.

The selection and optimization of natural gums played a pivotal role in the design of an effective GRDDS. These hydrophilic polymers, upon contact with gastric fluid, absorb water and swell to form a viscous gel layer around the tablet. This gel layer entraps the carbon dioxide released from sodium bicarbonate upon reaction with citric acid in the acidic medium, thereby imparting buoyancy. The rate and extent of this hydration directly influenced the tablet's floating behavior and drug release characteristics. Among the gums tested, Gum tragacanth emerged as the most effective, providing rapid tablet buoyancy and prolonged floating duration. This was likely due to its higher viscosity and more complex polysaccharide structure, which facilitated rapid gel formation and greater matrix strength. Tablets containing Xanthan gum also performed well, though marginally less effective than Gum tragacanth, while those formulated with Guar gum exhibited the least buoyancy and floating longevity among the three, especially at lower polymer concentrations.

A significant observation was the influence of gum concentration on the tablet's floating properties. Formulations containing higher gum concentrations (30% w/w) consistently

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demonstrated shorter floating lag times and significantly prolonged floating durations. For instance, tablets with 30% Gum tragacanth floated within 22 seconds and remained buoyant for over 14 hours, while Guar gum tablets at 10% concentration had lag times exceeding 50 seconds and floated for only about 8 hours. The extent of swelling also increased with gum concentration, as observed in the swelling index studies. Swelling not only facilitated rapid floatation but also played a critical role in controlling drug release by forming a thicker diffusion barrier.

The release profile of Ranitidine Hydrochloride from the floating tablets further underscored the importance of the type and amount of gum used. All formulations were able to sustain drug release over an 8-hour period, though with varying efficiencies. The drug release was slower and more controlled in formulations containing higher concentrations of natural gums, particularly Gum tragacanth. Tablets with 30% tragacanth released approximately 65% of the drug in 8 hours, whereas Guar gum formulations at the same concentration released around 72%. This inverse relationship between gum concentration and drug release rate is consistent with the behavior of hydrophilic matrix systems, wherein an increase in polymer content results in a denser and more viscous gel layer, slowing down water penetration and drug diffusion. The ability of Gum tragacanth to provide the most sustained release is likely due to its superior swelling capacity, which was confirmed by the highest swelling index among the formulations. To further elucidate the mechanism of drug release, kinetic modeling was performed using several mathematical models including zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas equations. The data indicated that the Korsmeyer–Peppas model provided the best fit for all three optimized formulations, with correlation coefficients exceeding 0.99. The release exponent (n) values ranged from 0.58 to 0.67, suggesting that drug release followed an anomalous or non-Fickian diffusion mechanism. This implies that both diffusion of the drug through the swollen matrix and erosion of the polymer contributed to the release process. The Higuchi model also showed strong correlation, indicating that diffusion was a dominant component of drug release. Poor correlation with first-order and Hixson–Crowell models confirmed that the release was not dependent on drug concentration or tablet geometry alone. Notably, the formulation containing Gum tragacanth exhibited the highest correlation to the zero-order model among the three, suggesting a near-constant release rate, which is desirable for maintaining steady plasma drug levels.

The comparative analysis between the three natural gums provided critical insights into their individual performance characteristics. Gum tragacanth was found to outperform both Guar gum and Xanthan gum in almost all evaluated parameters including floating lag time, total floating duration, swelling capacity, and sustained drug release. Xanthan gum followed closely, demonstrating good swelling and retention properties, but showed a slightly faster drug release rate compared to tragacanth. Guar gum, while still effective, lagged behind in gel strength and sustained release capability, particularly at lower concentrations. This comparative data underlines the necessity of selecting the appropriate polymer and optimizing its concentration for achieving the desired gastroretentive and drug release outcomes.

The practical relevance of these findings is significant in the context of pharmaceutical development. Floating drug delivery systems formulated with natural polymers offer a patientfriendly approach to improve the therapeutic efficacy of drugs with site-specific absorption. The ability to maintain the dosage form in the stomach for prolonged periods ensures that the drug is released at its optimal absorption site, enhancing bioavailability and reducing dosing frequency. From an industrial perspective, the use of natural gums provides cost-effectiveness, scalability, and regulatory acceptability due to their GRAS (Generally Recognized As Safe) status. Moreover, natural polymers reduce the reliance on synthetic excipients, aligning with current trends in green and sustainable pharmacy.

Despite the positive results, this study had certain limitations. In vivo validation of the gastroretentive behavior remains to be explored. Although in vitro buoyancy and release studies provide strong evidence of floating capability and controlled release, physiological factors such as gastric motility, presence of food, and enzymatic degradation may influence actual retention and performance in the stomach. Therefore, future studies should focus on in vivo testing to confirm gastric retention time and bioavailability enhancement. Additionally, long-term stability studies and formulation optimization for large-scale manufacturing would be essential for clinical translation of these dosage forms.

Conclusion

The present research aimed to formulate and evaluate a gastroretentive floating drug delivery system of Ranitidine Hydrochloride by utilizing natural gums—Guar gum, Xanthan gum, and Gum tragacanth—as hydrophilic matrix-forming polymers. The goal was to enhance the gastric retention time and sustain the drug release over a prolonged period, thereby improving the bioavailability of Ranitidine, a drug with a short half-life and an absorption window limited to the upper gastrointestinal tract. Through a systematic and scientifically rigorous approach involving preformulation studies, formulation optimization, in vitro evaluations, and kinetic modeling, the study successfully demonstrated the potential of natural polymers in developing effective floating tablets.

The use of natural gums significantly impacted the performance characteristics of the tablets, particularly their buoyancy, swelling behavior, and drug release profile. It was observed that increasing the concentration of each gum improved the tablet's floating capacity and sustained drug release capability. Among the tested gums, Gum tragacanth exhibited superior performance, showing the shortest floating lag time, the longest floating duration, the highest swelling index, and the most controlled drug release profile. This was attributed to its high viscosity, excellent hydration properties, and strong matrix-forming ability, which together

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facilitated rapid gas entrapment and maintained the tablet's integrity in the acidic environment of the stomach.

The in vitro drug release studies revealed that all formulations were able to extend the release of Ranitidine Hydrochloride over 8 hours, with release rates inversely related to polymer concentration. Formulations with higher concentrations of natural gums formed denser and more cohesive matrices, which slowed the diffusion of the drug. Kinetic modeling of the dissolution data provided further insight into the release mechanism, with the Korsmeyer–Peppas model offering the best fit for all optimized formulations. The release exponent values indicated non-Fickian or anomalous diffusion, suggesting that both swelling-controlled and diffusion-controlled processes governed drug release from the matrix. These findings were corroborated by the Higuchi model, further validating that diffusion through a hydrated gel layer was the dominant release mechanism.

Overall, the study confirms that natural gums are highly effective in developing gastroretentive floating tablets with desirable physicochemical properties and controlled release behavior. Gum tragacanth, in particular, emerged as the most promising polymer among those tested, owing to its balanced properties of swelling, gel formation, and release retardation. The successful formulation of floating tablets using only natural excipients underscores the potential of these biodegradable, non-toxic, and cost-effective materials in modern pharmaceutical technology. The outcomes of this research hold considerable promise for enhancing the therapeutic efficacy of drugs like Ranitidine and pave the way for further development of sustainable and patient-friendly oral controlled-release systems.

While the in vitro results were encouraging, the study also highlights the need for future in vivo investigations to validate the gastroretentive behavior under physiological conditions. Additional studies focusing on bioavailability assessment, pharmacokinetics, and formulation scalability will further strengthen the clinical applicability of such delivery systems. Nevertheless, the present investigation provides a solid foundation for the continued exploration and application of natural gums in gastroretentive drug delivery and demonstrates their valuable role in achieving targeted, sustained, and efficient oral drug release.

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