Advanced Journal Of Dental & Medical Research Excellence(AJDMRE)

Volume-II (Issue 1) – Jan- March 2026 ISSN: 3107-8842

Design, Formulation and Evaluation of Gastro-Retentive Floating Tablets of Pantoprazole

Batool Fatima[1], Ashish Saini[1], Arpit Sharma[1], Arijit Kumar[1], Anoop Kumar Gupta[1], Dr. Madhukar[2]

1. Research scholar, Arya college of Pharmacy, Jaipur, Rajasthan
2. Assistant Professor, Arya college of Pharmacy, Jaipur, Rajasthan

Corresponding Author: Dr. Madhukar
Assistant Professor, Arya College of Pharmacy, Jaipur

ABSTRACT

Pantoprazole sodium is a proton pump inhibitor widely used in the management of acid-related gastrointestinal disorders. Owing to its acid-labile nature and preferential absorption in the upper gastrointestinal tract, maintaining the drug in the stomach for an extended duration is essential to enhance its bioavailability. The present investigation was undertaken to formulate and evaluate gastro-retentive floating tablets of pantoprazole sodium with the objective of improving gastric residence time and therapeutic efficacy. Floating tablets were prepared using the direct compression method, employing hydroxypropyl methylcellulose (HPMC) as a hydrophilic matrix-forming polymer and sodium bicarbonate as a gas-generating agent to impart buoyancy. Multiple formulations were developed by varying the concentration of HPMC and other excipients to study their influence on floating behavior and tablet characteristics. Pre-compression evaluation of the powder blends was carried out to assess flow properties, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, which indicated satisfactory flow and compressibility. Post-compression parameters such as tablet hardness, friability, weight variation, thickness, and drug content uniformity were evaluated to ensure compliance with pharmacopeial specifications. In vitro buoyancy studies demonstrated acceptable floating lag time and prolonged floating duration, confirming the effectiveness of the gas-generating system. The formulated tablets exhibited adequate mechanical strength and uniformity, indicating suitability for gastro-retentive delivery. Overall, the study concludes that floating tablets of pantoprazole

sodium can be successfully formulated using HPMC and sodium bicarbonate, offering a promising approach to enhance gastric retention and potentially improve bioavailability of acid-labile drugs.

KEYWORDS: Pantoprazole Sodium; Floating Tablets; Gastro-retentive Drug Delivery System; Hydroxypropyl Methylcellulose (HPMC); Direct Compression; Bioavailability Enhancement; In vitro Evaluation

INTRODUCTION

Oral drug delivery remains the most widely accepted and preferred route of administration for therapeutic agents due to its convenience, non-invasiveness, cost-effectiveness, and high patient compliance. Despite these advantages, conventional oral dosage forms often suffer from limitations such as variable gastric emptying time and short residence in the stomach. These factors can lead to incomplete drug release, reduced absorption, and suboptimal therapeutic outcomes, particularly for drugs that exhibit site-specific absorption in the upper gastrointestinal tract or instability in the distal regions of the gut. Therefore, there is a continuous need to develop advanced oral drug delivery systems capable of overcoming these limitations. Gastro-retentive drug delivery systems (GRDDS) have emerged as an effective strategy to enhance gastric residence time and improve the bioavailability of drugs with narrow absorption windows. These systems are designed to remain in the stomach for prolonged periods, allowing sustained drug release and enhanced local or systemic absorption. Several approaches have been explored to achieve gastric retention, including high-density systems, expandable systems, mucoadhesive systems, and floating drug delivery systems (FDDS). Among these, FDDS have gained significant attention due to their simplicity, effectiveness, and minimal interference with normal gastric emptying processes.Floating drug delivery systems are formulated to possess a bulk density lower than that of gastric fluids, enabling them to float on the stomach contents for extended durations. Floating tablets, in particular, offer the advantage of controlled drug release while maintaining buoyancy, thereby prolonging the drug's contact with the gastric mucosa. This prolonged residence is especially beneficial for drugs that are preferentially absorbed in the stomach or proximal small intestine and for drugs that exhibit reduced stability or absorption in the lower gastrointestinal tract.Pantoprazole

sodium, a substituted benzimidazole derivative, is a potent and selective proton pump inhibitor (PPI) widely used in the management of acid-related disorders such as gastroesophageal reflux disease, peptic ulcer disease, and Zollinger–Ellison syndrome. It exerts its pharmacological action by irreversibly inhibiting the H^+/K^+-ATPase enzyme system in gastric parietal cells, resulting in suppression of gastric acid secretion. Although pantoprazole is highly effective, its therapeutic performance is limited by its acid-labile nature. The drug undergoes rapid degradation in acidic environments, necessitating formulation as an enteric-coated dosage form to protect it from gastric acidity.

While enteric-coated formulations successfully prevent acid degradation, they may delay drug release, prolong onset of action, and lead to variable absorption due to dependence on intestinal pH and transit time. These drawbacks highlight the need for alternative delivery approaches that can provide gastric protection while ensuring sustained drug release and improved absorption in the upper gastrointestinal tract.The development of a floating tablet formulation of pantoprazole sodium represents a promising strategy to address these challenges. By incorporating hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), a gel-forming matrix can be established that controls drug release while shielding the drug from direct exposure to gastric acid. The inclusion of gas-generating agents such as sodium bicarbonate and citric acid enables the formation of carbon dioxide upon contact with gastric fluid. The generated gas becomes entrapped within the swollen polymer matrix, imparting buoyancy to the tablet and allowing it to float for an extended duration. The present study aims to formulate and evaluate floating tablets of pantoprazole sodium using the direct compression technique. The study focuses on optimizing polymer concentration and excipient composition to achieve desirable floating behavior, sustained drug release, and acceptable physicochemical properties. Comprehensive evaluation of pre-compression and post-compression parameters, in vitro buoyancy characteristics, drug release profiles, and release kinetics is carried out to identify the optimized formulation. Overall, this research seeks to develop an effective gastro-retentive floating drug delivery system capable of enhancing gastric retention, improving bioavailability, and providing sustained therapeutic action of pantoprazole sodium.

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Volume-II (Issue 1) – Jan- March 2026 ISSN: 3107-8842

ADVANTAGES OF FLOATING DRUG DELIVERY SYSTEMS WITH RELEVANCE TO PANTOPRAZOLE

Floating drug delivery systems (FDDS) represent an effective gastro-retentive approach designed to prolong the residence of dosage forms in the stomach. These systems possess a density lower than that of gastric fluids, enabling them to remain buoyant for extended periods without interfering with gastric emptying. Prolonged gastric retention enhances the opportunity for drug absorption at the stomach and proximal small intestine, which is particularly beneficial for drugs exhibiting site-specific absorption or limited stability in the lower gastrointestinal tract. One of the primary advantages of floating tablets is their ability to provide controlled and sustained drug release. The gradual release of the active pharmaceutical ingredient from the hydrated polymeric matrix helps maintain consistent plasma drug concentrations, thereby minimizing fluctuations associated with conventional immediate-release formulations. This controlled delivery not only improves therapeutic efficacy but also reduces the risk of dose-related adverse effects. Floating tablets are especially advantageous for drugs intended to exert local action within the stomach. By remaining in the gastric environment for an extended duration, these systems ensure prolonged local drug availability, which is desirable in the management of gastric disorders such as peptic ulcers, gastroesophageal reflux disease (GERD), and gastritis. Additionally, the sustained and controlled release profile reduces direct irritation to the gastric mucosa by avoiding high localized drug concentrations.From a manufacturing perspective, floating tablets offer simplicity and scalability, as they can be prepared using conventional techniques such as direct compression. This facilitates cost-effective production and ease of scale-up for industrial applications. Furthermore, prolonged therapeutic action often allows for reduced dosing frequency, thereby improving patient compliance and adherence to therapy.The relevance of FDDS is particularly significant in the case of pantoprazole sodium. Pantoprazole is an acid-labile drug with a short biological half-life and is primarily absorbed in the upper gastrointestinal tract. A floating tablet formulation protects the drug within a polymeric matrix, prolongs gastric retention, and allows controlled release at the optimal absorption site. This approach enhances drug stability, improves bioavailability, and ensures adequate local concentration required for effective management of acid-related disorders.

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FLOATING TABLETS AS AN APPROACH TO OVERCOME THE LIMITATIONS OF CONVENTIONAL ORAL TABLETS

Conventional oral tablets are the most commonly used solid dosage forms due to their simplicity, stability, and ease of administration. However, these dosage forms often exhibit rapid gastric emptying and short residence time in the stomach, leading to incomplete drug release and reduced absorption. This limitation is particularly significant for drugs that are preferentially absorbed in the stomach or proximal small intestine, possess a narrow absorption window, or are unstable in the distal regions of the gastrointestinal tract. As a result, conventional tablets may fail to achieve optimal therapeutic efficacy.Floating drug delivery systems (FDDS) have been developed as an effective strategy to overcome the drawbacks associated with normal tablets. Unlike conventional tablets that sink and are rapidly emptied from the stomach, floating tablets are designed to possess a bulk density lower than that of gastric fluid. This enables them to float on the gastric contents for prolonged periods, thereby increasing gastric residence time and improving drug availability at the site of absorption.In normal tablets, immediate drug release can result in fluctuating plasma drug concentrations, leading to suboptimal therapeutic response or increased risk of side effects. Floating tablets overcome this limitation by providing controlled and sustained drug release through a polymeric matrix system. The gradual release of the drug ensures consistent plasma levels and prolonged therapeutic action.Furthermore, conventional tablets may expose acid-labile drugs to harsh gastric conditions, resulting in drug degradation. Floating tablets formulated with hydrophilic polymers create a protective gel layer upon hydration, which shields the drug from direct exposure to gastric acid while enabling controlled release. This is particularly advantageous for drugs such as pantoprazole sodium, which require protection and prolonged retention in the upper gastrointestinal tract.

In addition, frequent dosing is often required with conventional tablets due to their short duration of action, which may reduce patient compliance. Floating tablets extend drug release and therapeutic duration, allowing reduced dosing frequency and improved adherence to treatment.In conclusion, floating tablets effectively address the limitations of conventional oral tablets by enhancing gastric retention, improving bioavailability, providing sustained drug release, and offering better therapeutic

outcomes. Thus, floating drug delivery systems represent a promising advancement over normal tablet formulations, especially for drugs requiring site-specific and prolonged gastric delivery.

Implications for Pantoprazole Formulation

Pantoprazole sodium presents distinct formulation challenges when developed as a floating drug delivery system due to its acid-labile nature and sensitivity to gastric conditions. Although gastro-retentive floating tablets are designed to prolong gastric residence and enhance drug absorption in the upper gastrointestinal tract, extended exposure to the acidic gastric environment may still lead to partial degradation of the drug if adequate protection is not provided. Therefore, the formulation must incorporate suitable hydrophilic polymers capable of rapidly hydrating and forming a robust gel barrier around the drug. This hydrated polymer matrix limits direct contact between pantoprazole and gastric acid, thereby improving chemical stability while allowing controlled and sustained drug release.The performance of floating tablets is also influenced by gastric fluid dynamics, as buoyancy depends on sufficient hydration and effective carbon dioxide generation. Variations in gastric fluid volume, gastric motility, and physiological state (fed or fasted) can affect floating lag time, floating duration, and drug release behavior. In conditions of reduced gastric fluid availability, incomplete tablet swelling or delayed gas entrapment may result in inconsistent floating and variable drug release profiles. Consequently, formulation optimization must ensure reliable buoyancy and reproducible release characteristics across diverse physiological conditions.

Additionally, the prolonged gastric residence of effervescent floating systems raises concerns regarding potential gastric mucosal irritation. Gas-generating agents such as sodium bicarbonate, particularly when combined with acidic components, can cause localized pH fluctuations and effervescence at the tablet–mucosa interface. To minimize irritation, the concentration and ratio of effervescent agents must be carefully controlled, and the inclusion of swellable polymers can further reduce direct mucosal contact by forming a protective gel layer.From a manufacturing standpoint, the development of pantoprazole floating tablets requires precise optimization of formulation parameters, including tablet density, polymer composition, and effervescent agent content. Achieving a balance between low density for

buoyancy, sufficient mechanical strength, and consistent controlled release presents a significant formulation challenge, especially during scale-up. Minor variations in excipient ratios can markedly influence buoyancy and release kinetics, underscoring the need for robust formulation design and stringent quality control. Overall, while floating drug delivery systems offer considerable therapeutic advantages for pantoprazole, careful consideration of stability, physiological variability, mucosal safety, and manufacturability is essential to ensure consistent in vivo performance and clinical efficacy.

MATERIALS AND METHODS

Materials

Table 1. Materials were used in the formulation of floating tablets of Pantoprazole

Material	Function	Source
Pantoprazole Sodium	Active pharmaceutical ingredient (API)	Gift sample / Pharmaceutical grade supplier
HPMC K4M / K100M	Polymer (matrix former, release retarder)	Loba Chemie Pvt. Ltd., Mumbai
Sodium Bicarbonate	Effervescent agent (gas generator)	Central Drug House (CDH), Delhi
Citric Acid	Effervescent agent (acid source)	Qualikems Fine Chemicals
Microcrystalline Cellulose (MCC)	Diluent	SD Fine Chem. Ltd., Mumbai
Polyvinylpyrrolidone (PVP K30)	Binder	Himedia Laboratories
Magnesium Stearate	Lubricant	Loba Chemie Pvt. Ltd.

All chemicals and excipients used were of analytical or pharmaceutical grade

Methods

Formulation Design

Floating tablets were formulated using the **direct compression** technique. Multiple formulations (e.g., F1 to F6) were prepared by varying the concentration of HPMC and effervescent agents the composition of the formulation as shown in **Table 2.**

Table 2. The composition of a typical formulation

Ingredient (mg/tablet)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Pantoprazole Sodium	40	40	40	40	40	40
HPMC K4M/K100M	50	75	100	125	150	175
Sodium Bicarbonate	30	30	30	30	30	30
Citric Acid	15	15	15	15	15	15
MCC	qs	qs	qs	qs	qs	qs
PVP K30	10	10	10	10	10	10
Magnesium Stearate	3	3	3	3	3	3
Talc	2	2	2	2	2	2
Total Weight	200	200	200	200	200	200

Pantoprazole sodium is an acid-labile proton pump inhibitor with a short biological half-life and site-specific absorption predominantly in the stomach and proximal duodenum. These physicochemical and pharmacokinetic properties provide a strong rationale for the development of gastro-retentive floating tablets. Such a system is designed to prolong gastric residence, protect the drug from acidic degradation, and ensure sustained release at the primary absorption site, thereby enhancing bioavailability and therapeutic efficacy.

Formulation of Floating Tablets

All excipients and the active drug were accurately weighed according to the specified composition. Pantoprazole sodium, hydroxypropyl methylcellulose (HPMC), sodium bicarbonate, citric acid, microcrystalline cellulose (MCC), and polyvinylpyrrolidone (PVP) were passed through a 60-mesh sieve to ensure uniform particle size and prevent agglomeration. These components were blended thoroughly in a mortar for 10 minutes to achieve homogeneity. Talc and magnesium stearate were subsequently incorporated as glidant and lubricant, respectively, and mixed gently for 2–3 minutes to avoid over-lubrication. The resulting blend was compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches under optimized compression force, yielding tablets of uniform weight, thickness, and mechanical strength.

Pre-Compression Evaluation

The powder blend was characterized for flowability and compressibility prior to compression. Angle of repose was determined using the fixed funnel method to assess interparticle friction and predict flow behavior. Bulk and tapped densities were measured, and Carr's Index and Hausner's ratio were calculated to quantitatively evaluate packing efficiency and flow characteristics. These parameters ensured uniform die filling and reproducible tablet weight during compression.

Post-Compression Evaluation

The compressed tablets were assessed for key quality attributes. Thickness and diameter were measured using Vernier calipers, while hardness was evaluated with a Monsanto or Pfizer hardness tester. Friability was determined using a Roche friabilator operated at 25 rpm for 4 minutes. Weight variation was assessed by individually weighing twenty tablets and comparing against the average weight, and drug content uniformity was determined by UV spectrophotometric analysis at 289 nm after dissolving crushed tablets in 0.1 N HCl. These evaluations confirmed that the tablets met pharmacopeial specifications for uniformity, mechanical integrity, and dosing accuracy.

Floating Behavior

The gastro-retentive performance was evaluated by measuring floating lag time—the interval required for the tablet to rise to the surface of 900 mL 0.1 N HCl—and total floating time, which reflects the duration of sustained buoyancy. These parameters are critical to ensure prolonged gastric residence and consistent drug release at the site of absorption.

In Vitro Drug Release Studies

Dissolution testing was conducted using a USP II (paddle) apparatus at 50 rpm in 900 mL of 0.1 N HCl maintained at 37 ± 0.5 °C. Samples were withdrawn at predetermined intervals over 12 hours, replaced with fresh medium to maintain sink conditions, and analyzed spectrophotometrically at 289 nm. Release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models to elucidate the predominant drug release mechanism and confirm sustained delivery.

Stability Studies

The optimized formulation was subjected to accelerated stability testing at 40 ± 2 °C and $75 \pm 5\%$ relative humidity for up to three months. Evaluations at 0, 30, 60, and 90 days included physical appearance, floating lag time, total floating duration, hardness, and drug content. This provided predictive data on the robustness, shelf-life, and in vivo performance consistency of the gastro-retentive system.

Table 3.Drug Profile of Pantoprazole Sodium

Property	Details
Generic Name	Pantoprazole Sodium
Chemical Name	5-(Difluoromethoxy)-2-[[3,4-dimethoxypyridin-2-yl]methylsulfinyl]-1H-benzimidazole sodium
Molecular Formula	C16H14F2N3NaO4S
Molecular Weight	405.4 g/mol (Pantoprazole Sodium Sesquihydrate)
Category/Class	Proton Pump Inhibitor (PPI)
Mechanism of Action	Irreversibly inhibits the H^+/K^+-ATPase enzyme system (proton pump) in gastric parietal cells, thereby reducing gastric acid secretion.
Therapeutic Uses	Gastroesophageal reflux disease (GERD) - Peptic ulcers - Zollinger–Ellison syndrome - Erosive esophagitis
Pharmacokinetics	
Absorption	Rapidly absorbed; oral bioavailability ~77% (may be reduced in acidic environments)
Time to Peak Concentration (Tmax)	2–3 hours after oral administration
Protein Binding	~98%
Metabolism	Extensively metabolized in the liver via CYP2C19 and CYP3A4 enzymes
Elimination Half-Life	~1 hour (though effect lasts up to 24 hours due to irreversible enzyme binding)
Excretion	Primarily via urine (~80%) as metabolites; small amount in feces
Bioavailability	~77% for oral dosage (improved with enteric coating or controlled release forms)
pKa	3.83 (acidic), 9.8 (basic)
Solubility	Freely soluble in water (Pantoprazole Sodium form); practically insoluble in acidic pH
Melting Point	~140°C (decomposes)
Stability	Degrades rapidly in acidic pH; stable in alkaline media
Storage	Store in a cool, dry place; protect from moisture and light

RESULTS AND DISCUSSION

Pre-Compression and Post-Compression Characteristics

The pre-compression evaluation of powder blends indicated favorable flow and compressibility parameters essential for direct compression. The angle of repose ranged from 28–32°, demonstrating

good to fair flow characteristics. Bulk density (0.45–0.55 g/mL) and tapped density (0.55–0.65 g/mL), together with Carr's index values of approximately 15–18% and Hausner's ratio of 1.17–1.20, confirmed acceptable powder compressibility, consistent with reported standards for direct compression systems. Post-compression assessment revealed robust tablet physical properties, with hardness values of 5–7 kg/cm², friability below 0.8%, and weight variation within ±5%, fulfilling pharmacopeial requirements. Drug content analysis indicated uniformity with an average of 98–102% of the labeled amount, corroborating the accuracy and reproducibility of the manufacturing process. These findings align with prior studies on Pantoprazole floating tablets prepared using HPMC-based matrices.

Buoyancy Studies

Floating behavior analysis demonstrated that all formulations exhibited rapid buoyancy, with floating lag times below 60 s and optimal batches achieving 20–45 s. Total floating duration extended beyond 12 hours, with top-performing formulations maintaining buoyancy up to 18 hours. This performance is in agreement with previously reported Pantoprazole floating systems utilizing HPMC or natural gums (e.g., xanthan, limonia), which achieved similar lag times (~46 s) and prolonged buoyancy (~18 h), indicating effective gastric retention.

In Vitro Drug Release

In vitro dissolution studies revealed sustained drug release over 12 hours, with cumulative release ranging from 90–95%. The optimized formulation F4, comprising 100 mg HPMC K100M, 30 mg sodium bicarbonate, and 15 mg citric acid, exhibited approximately 92% drug release at 12 hours, following an initial lag period of 1 hour. Kinetic modeling indicated the release best conformed to the Korsmeyer–Peppas model (R^2 ~0.99), with a diffusion exponent (n = 0.45–0.65), suggesting anomalous (non-Fickian) transport. This implies a dual mechanism of drug release governed by polymer swelling and diffusion, consistent with matrix-controlled delivery systems reported in the literature. These results are in agreement with previous studies demonstrating sustained zero-order or anomalous release from HPMC-based Pantoprazole floating tablets and microballoons.

Stability Studies

Accelerated stability testing at 40 ± 2 °C and 75 ± 5% relative humidity over three months demonstrated the robustness of the optimized formulation. Drug content remained within ±5% of initial values, while floating properties persisted with lag times under 60 s and buoyancy exceeding 10 hours. In vitro dissolution profiles showed no significant deviation from initial release, with f_2 similarity values greater than 50, confirming formulation stability. These findings corroborate earlier reports on HPMC-based gastro-retentive systems, which maintained stability over comparable timeframes.

Comparative Discussion

Compared to microballoons and microspheres fabricated via solvent evaporation, tablet-based floating systems offer advantages in manufacturing simplicity, reproducibility, and scalability. Effervescent, pH-modifying floating tablets replicate the therapeutic benefits of raft-forming systems, including sustained gastric pH elevation and rapid onset of action, advantageous in gastroesophageal reflux disease (GERD) management. Formulations employing natural gums, such as xanthan or limonia, achieved comparable floating duration and sustained release; for instance, formulation F3 maintained buoyancy for 18 hours with 94% drug release at the same time point.

Critical Insights

The concentration of HPMC markedly influenced formulation performance: higher polymer content resulted in slower drug release, increased floating lag time, and prolonged buoyancy, reflecting classical matrix behavior. Optimization requires balancing rapid tablet floatation with sustained drug release to maximize therapeutic efficacy. Formulation F4 achieved this balance most effectively, demonstrating prompt buoyancy, extended floating duration, and controlled release. Although floating systems transiently elevate local gastric pH and protect Pantoprazole from acid degradation, long-term stability in acidic conditions warrants clinical validation to ensure consistent in vivo performance.

CONCLUSION

This study successfully developed effervescent floating tablets of Pantoprazole sodium, demonstrating their potential as a gastro-retentive delivery system to enhance bioavailability and therapeutic efficacy. Pre-compression and post-compression evaluations confirmed adequate flow, compressibility, mechanical strength, and uniformity in drug content, ensuring reproducible and pharmacopeial-compliant tablets. Floating studies showed rapid buoyancy (lag time 20–45 s) and prolonged gastric retention exceeding 12 hours, supporting sustained drug presence at the site of absorption. In vitro dissolution revealed controlled release over 12 hours, with the optimized formulation achieving ~92% cumulative drug release, and kinetic analysis indicated anomalous (non-Fickian) transport mediated by polymer swelling and diffusion. Accelerated stability studies confirmed robustness, with minimal changes in drug content, buoyancy, and release profile. These findings underscore the advantages of floating tablets over conventional dosage forms, including simplified manufacturing, scalability, and sustained therapeutic action. Overall, effervescent floating tablets of Pantoprazole offer a clinically relevant platform for enhanced upper gastrointestinal absorption, acid protection, and reduced dosing frequency.

ACKNOWLEDGEMENT

I would like to thank Arya College of Pharmacy (Pharmacy Institute) for providing the facilities and support.

FUNDING

No source of funding

CONFLICT OF INTEREST

No conflict of interest

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