RESEARCH ARTICLE

ISSN: 2455-8095
doi: https://doi.org/10.21477/ijapsr.10.1.01

Design and Optimization of Controlled Release Bilayer Floating Tablets of Famotidine Using HPMC Polymers

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ABSTRACT

The present study focuses on the formulation and evaluation of bilayer floating tablets of famotidine, a histamine H□-receptor antagonist widely used to manage acid-related gastrointestinal disorders. Due to famotidine's short biological half-life and limited bioavailability, a gastro-retentive bilayer system was developed to enhance its residence time in the stomach and provide sustained drug release. The formulation comprised a controlled-release (CR) layer containing famotidine and matrix-forming polymers like HPMC K15M, K100M, and calcium CMC, and an effervescent layer composed of sodium bicarbonate and citric acid to facilitate gastric buoyancy. Preformulation studies, including FTIR and DSC, confirmed the compatibility of the drug with selected excipients. The micrometric properties of both the drug and tablet blend indicated good flow characteristics, suitable for direct compression. The tablets were evaluated for physical parameters such as hardness, friability, weight variation, buoyancy lag time, and drug content, all of which were within acceptable limits. In vitro, drug release studies over 24 hours revealed a sustained release profile across all formulations, with F1 and F2 showing >100% release and F3 showing the most controlled profile (90. 4%). Drug release kinetics best fitted the first-order model ($R^2 > 0.95$) for most formulations, and the Higuchi model ($R^2 = 0.875–0.922$) confirmed diffusion-based release. The Hixson–Crowell model was less suitable. These results confirm the potential of bilayer floating tablets for improved bioavailability and patient compliance.

Keywords: Famotidine, bilayer tablets, floating drug delivery, gastro-retentive, controlled release, kinetic modeling

1. INTRODUCTION

Famotidine is a histamine H_2-receptor antagonist used to treat and manage conditions such as peptic ulcers, gastroesophageal reflux disease (GERD), and Zollinger-Ellison syndrome.[1] It works by inhibiting gastric acid secretion in the stomach, effectively relieving acid-related disorders.[2] Famotidine has a relatively short biological half-life of 2.5 to 3.5 hours, requiring frequent dosing. It exhibits good stability in acidic pH but has limited bioavailability due to poor solubility and rapid clearance, making it a suitable candidate for controlled and gastro-retentive drug delivery systems to enhance therapeutic efficacy and patient compliance.[3,4]

A gastroretentive bi-layer controlled drug delivery system is designed to prolong the gastric residence time of a drug and provide a sustained release profile. It consists of two layers: an immediate-release layer for rapid onset of action and a controlled-release layer to maintain consistent drug levels over an extended period.[5] This system is particularly beneficial for drugs like famotidine that are absorbed primarily in the stomach or upper small intestine. The floating or swelling nature of the system prevents premature transit, thereby enhancing bioavailability, reducing dosing frequency, and improving therapeutic outcomes in the management of acid-related gastrointestinal disorders.[6]

2. MATERIALS AND METHODS

The formulation utilized famotidine as the active drug, with HPMC K15M/K100M/K4M as release-controlling polymers and Avicel PH101/PH102 as directly compressible fillers. Calcium CMC, starch 1500, and povidone K-30 were used as binders, while sodium bicarbonate and citric acid created effervescence for gastric retention. Talc and magnesium stearate were included as glidant and lubricant, respectively, supporting tablet formation by direct compression.

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Received: 09-10-2024 **Accepted:** 18-12-2024 **Available Online:** 01-01-2025

2.1. Preformulation studies

2.1.1. Organoleptic evaluation

The organoleptic properties of famotidine, including color, odor, and taste, were evaluated using standard descriptive terminology. The drug appeared as an off-white powder, was odorless, and exhibited a slightly bitter taste.

2.1.2. Solubility studies

The solubility of famotidine was assessed in various solvents—distilled water, 0.1 N HCl, glacial acetic acid, anhydrous ethanol, and ethyl acetate—by adding an excess amount of drug to 100 mL of each solvent in a volumetric flask. These samples were agitated in a water bath shaker at 37 ± 0.5°C for 2 hours. The resulting dispersions were filtered using Whatman filter paper No. 1 and analyzed spectrophotometrically for drug content using standard calibration curves.[7-9]

2.1.3. Preparation of the calibration curve

To prepare the calibration curve for famotidine, 5.26 mL of the stock solution was accurately measured and transferred into a 10 mL volumetric flask. The volume was then made up to the mark using 0.1N hydrochloric acid as the diluent. This dilution resulted in a final famotidine concentration of 5.26 µg/mL. The prepared solution was mixed thoroughly to ensure uniformity. The absorbance of the resulting solution was measured at a wavelength of 255 nm using a UV-visible spectrophotometer. All measurements were carried out in triplicate to ensure the accuracy and reproducibility of the results.[10]

2.1.4. Infrared (IR) spectroscopy

The compatibility of famotidine with various excipients was assessed using Fourier Transform Infrared (FT-IR) spectroscopy. The IR spectra of pure drug and drug-excipient mixtures were recorded in the range of 4000–450 cm^{-1} using the KBr disc method. Famotidine (2 mg) was triturated with 300 mg of potassium bromide and compressed into 15 mm diameter pellets. The spectra were analyzed for characteristic peaks to identify any significant shifts or disappearances, indicating potential chemical interactions.[11]

2.1.5. Differential scanning calorimetry

Thermal analysis of famotidine was carried out using a Mettler Toledo DSC 823e system. Approximately 4 mg of the drug was sealed in an aluminum pan and scanned from 40°C to 325°C at a heating rate of 10°C/min under a nitrogen purge (20 mL/min). The onset temperature, peak temperature, and enthalpy of fusion were recorded. The thermograms were evaluated for thermal behavior and possible interactions with excipients.[12]

2.1.6. Micrometric properties

The bulk and tapped densities of famotidine were determined by gently transferring 25 g of the sample into a 100 mL graduated cylinder and measuring the volume before and after tapping using a USP Tap Density Tester. Carr's Compressibility Index and Hausner's Ratio were calculated to assess the flowability, using standard formulas. The angle of repose was measured by allowing 10 g of the powder to flow through a fixed funnel and measuring the height and radius of the formed pile. These micrometric parameters helped evaluate the powder's flow characteristics and suitability for direct compression.[13,14]

2.1.7. Particle size distribution, moisture content

The particle size distribution of famotidine was evaluated using a Malvern Particle Size Analyzer (Mastersizer-2000) employing the dry dispersion method. A consistent and uniform distribution curve was obtained, from which the geometric mean diameter was calculated. The moisture content of famotidine was assessed by weighing 1.5 g of the sample in a pre-dried aluminum foil and analyzing it using a Halogen Moisture Analyzer (METTLER TOLEDO HR73), confirming the drug's low hygroscopicity.[15]

2.2. Formulation of famotidine bi-layer floating tablets

Bi-layer floating tablets containing 40 mg of famotidine were prepared using a total tablet weight of 300 mg, consisting of a CR layer and an effervescent layer to achieve gastric retention and sustained release (Table 1 & 2).

Table 1: Bilayered tablets formulation (Prototype-1) of famotidine-controlled release layer

Ingredient (mg)	*F1*	*F2*	*F3*	*F4*	*F5*	*F6*
Famotidine	40	40	40	40	40	40
Avicel PH 101	56	35	86	80	60	66
HPMC K100M	–	–	65	70	40	50
Calcium CMC	30	35	–	–	50	35
HPMC K15M	65	80	–	–	–	–
Magnesium Stearate	2	2	2	2	2	2
Talc	2	2	2	2	2	2
Povidone K-30	5	6	5	6	6	5

Table 2: Effervescent layer

Ingredient (mg)	*F1*	*F2*	*F3*	*F4*	*F5*	*F6*
Avicel PH 102	50	50	50	50	50	50
Starch 1500	10	10	10	10	10	10
Sodium Bicarbonate	30	30	30	30	30	30
HPMC K4M	10	10	10	10	10	10
Citric Acid	–	10	–	–	–	–

2.2.1. Preparation method

All ingredients were accurately weighed and divided into two portions: the CR layer and the effervescent layer. CR layer ingredients (excluding magnesium stearate and talc) were granulated using povidone K-30, then dried in a hot air oven at 60°C for 30 minutes. The dried granules were passed through a 20# sieve, blended with magnesium stearate and talc, and compressed into tablets using an 8.73 mm punch. For the effervescent layer, all ingredients were mixed uniformly and compressed over the pre-compressed CR layer to form a bilayered floating tablet capable of gastric retention and sustained drug release.[16-18]

2.3. Evaluation of tablet blends and formulated tablets

The tablet blends were evaluated for their flow characteristics using parameters such as angle of repose, Carr's compressibility index, and Hausner's ratio, indicating suitability for direct compression.[16-18]

The prepared tablets were assessed for physical and mechanical properties, including hardness, friability, weight variation, thickness, and content uniformity. Hardness was measured using an Electrolab Digital Hardness Tester, while friability was tested using a Roche friabilator set to 100 revolutions at 25 rpm. Weight variation and thickness were evaluated according to USP XXIII specifications using a Vernier caliper.[19]

For content uniformity, five tablets were powdered, and an amount equivalent to 10 mg of famotidine was analyzed spectrophotometrically at 255 nm using 0.1 N HCl.[20]

In vitro, drug release studies were performed using a USP Type II dissolution apparatus in 900 mL of 0.1 N HCl at 37 ± 2°C and 50 rpm for 24 hours. Samples were withdrawn at predefined intervals, filtered, and analyzed at 255 nm to determine the amount of drug released.[21] The drug release profiles were further subjected to kinetic modeling using PCP Disso V2.08 software, applying models such as zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas to identify the release mechanism.[22]

3. RESULTS AND DISCUSSION

3.1. Preformulation studies

3.1.1. Organoleptic evaluation

Famotidine used in the study was observed as an off-white, odorless powder with a slightly unpleasant taste. These organoleptic characteristics were noted using standard descriptive methods.

Table 3: Solubility of famotidine in various media

Media	Solubility
Water	Very slightly soluble
0.1 N HCl	Completely soluble
Glacial Acetic Acid	Freely soluble
Anhydrous Ethanol	Very slightly soluble
Ethyl Acetate	Practically insoluble

Table 4: Absorbance values for standard calibration curve in 0.1 N HCl

Serial No.	Concentration (µg/mL)	Absorbance
1	5	0.184
2	10	0.341
3	16	0.562
4	20	0.725
5	26	0.887

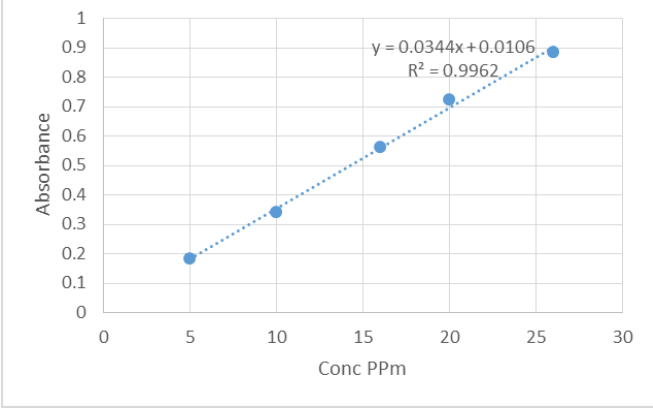

Figure 1: Calibration curve of famotidine

3.1.2. Solubility studies

Solubility evaluation was performed in various solvents to understand famotidine's behavior in different media. The results are presented in Table 3:

3.1.3. UV spectroscopy

A solution of 10 µg/mL famotidine in 0.1 N HCl was scanned in the range of 200–400 nm using a UV spectrophotometer. The maximum absorbance (λmax) was observed at 266 nm, which was used for further analytical quantification (Table 4 & Fig 1).

3.1.4. FTIR

The FTIR spectrum of pure famotidine exhibited characteristic peaks that confirmed the presence of its functional groups: a strong O–H/N–H stretching vibration around 3500–3200 cm^{-1}, C–H stretching near 3100 cm^{-1}, C=O stretching around 1680–1650 cm^{-1}, and S=O stretching observed near 1150–1200 cm^{-1}. These peaks are indicative of amine, sulfonamide, and other functional moieties present in the drug structure. When the FTIR spectrum

of the physical mixture of famotidine with the selected excipients (HPMC K15M, HPMC K100M, HPMC K4M, Avicel PH101/102, Calcium CMC, Povidone K-30, and others) was compared, no significant shifts, disappearance, or formation of new peaks were observed. This confirmed that there was no chemical interaction between famotidine and the excipients, indicating compatibility and stability of the drug in the bilayer formulation (Figures 2 & 3).

3.1.5. DSC Analysis

The DSC thermogram of pure famotidine showed a sharp endothermic peak at around 164–166°C, corresponding to its melting point, confirming its crystalline nature and thermal stability. In the physical mixture, the DSC thermogram retained the famotidine's endothermic peak, though with a slight reduction in intensity, which is typical due to the presence of polymers and excipients. No additional or unexpected peaks were detected, confirming the absence of any significant interaction between famotidine and the excipients. The thermal behavior suggests that the drug remains stable in the formulation and supports its suitability for bilayer tablet development using direct compression (Figure 4 & Figure 5).

3.1.6. Micrometric evaluation

The angle of repose for famotidine was found to be 48.76°, indicating poor flowability. The high compressibility index (~56%) and Hausner's ratio (>2.29) further support this conclusion, suggesting that the pure drug has a high tendency for particle cohesion and poor flow. These values indicate the necessity for adding flow-enhancing agents or using granulation techniques to improve blend uniformity and tablet ability during formulation (Table 5)

3.1.7. Particle size determination in Malvern analyzer

The Particle size (geometric mean diameter) of famotidine was found to be 1.7 pm (10%),6.954 pm (50%), and 20.245 pm (90%). Particle size distribution curves are shown in fig1

3.1.8. Moisture content

Famotidine has a moisture content of 0.28% which shows the drug which is selected for the formulation is more suitable because it is not hygroscopic.

3.1.9. Evaluation of the tablet blend

The angle of repose values (27.16°–35.87°) indicate fair to good flow properties for all floating tablet blends. Carr's

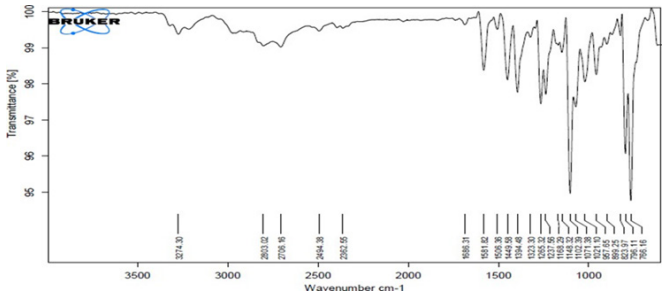

Figure 2: FTIR of pure drug

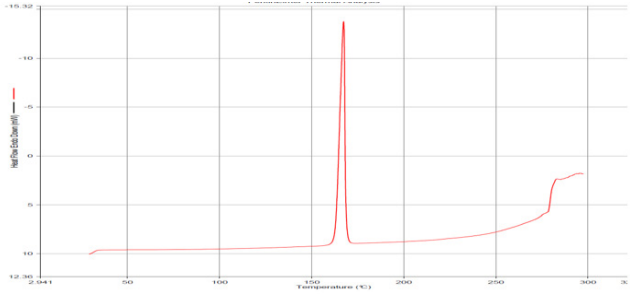

Figure 4: DSC chromatogram of pure drug

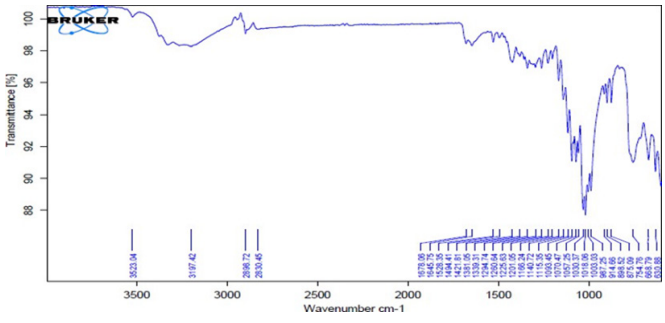

Figure 3: FTIR of FTIR of pure drug and physical mixture

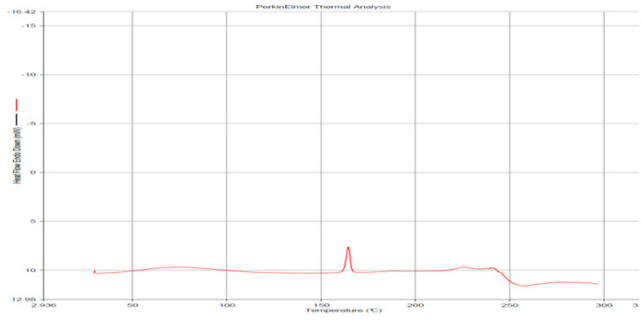

Figure 5: FTIR of pure drug and physical mixture

Table 5: Powder flow properties of pure drug (Famotidine)

Sl No.	*The angle of Repose (°)*	*Bulk Density (g/mL)*	*Tapped Density (g/mL)*	*Compressibility Index (%)*	*Hausner's Ratio*
1	49.09	0.209	0.476	56.25	2.277
2	48.13	0.208	0.478	56.37	2.298
3	49.06	0.209	0.480	56.39	2.296
Average	48.76	0.208	0.478	56.34	2.290

Table 6: Micrometric properties of the tablet blend for floating tablets

Sl. No	Parameter	F1	F2	F3	F4	F5	F6
1	Angle of Repose (°)	27.16°	30.16°	32.27°	35.87°	34.33°	34.23°
2	Bulk Density (g/mL)	0.386	0.405	0.412	0.556	0.605	0.678
	Tapped Density (g/mL)	0.432	0.420	0.488	0.570	0.634	0.776
3	Carr's Index (%)	11.12	12.34	12.59	14.66	13.89	14.57

index values ranged between 11.12% and 14.66%, which fall within acceptable limits, confirming adequate compressibility. The slight increase in bulk and tapped densities from F1 to F6 suggests variation in excipient composition, but all blends demonstrated suitable flow and packing characteristics for direct compression (Table 6).

3.2. Formulation of bilayer floating tablets

Polymers and excipients were carefully selected based on their functional roles in achieving controlled drug release and gastric retention in bilayer floating tablets. Calcium carboxymethyl cellulose (Calcium CMC) was included at concentrations of 5–15% not only for its binding properties but also for its ability to contribute to the floating mechanism. Microcrystalline cellulose (MCC), used in concentrations of 20–90%, was selected for its multifunctionality as a binder, diluent, disintegrant, and excellent compressibility and flowability, making it ideal for direct compression. Among the available grades, Avicel PH101 and PH102 were used due to their reported advantages in reducing crushing strength and disintegration time.

Povidone K-30, a water-soluble polymer, was incorporated in concentrations of 0.5–5% as a binder and diluent to assist granulation and tablet cohesion. Starch 1500 served a dual purpose as both a binder and a diluent. To enable the floating mechanism, sodium bicarbonate (25–50%) and citric acid anhydrous (0.3–2%) were used in the effervescent layer. Upon contact with gastric fluids, they react to release carbon dioxide, enabling the tablet to float and prolong gastric residence time.

The flow property of the pure drug was found to be moderate (Hausner's ratio ≈ 1.3), and to further improve the blend's flow, talc (1.0–10%) was used as a glidant and diluent, while magnesium stearate (0.5%) served as a lubricant, facilitating tablet ejection during compression.

3.3. Evaluation of famotidine tablets

Formulated tablets were evaluated for hardness, friability, weight variation, thickness, content uniformity, and dissolution (Table 7).

3.3.1. *Average Weight (mg)*

All formulations showed uniform tablet weights of around 300 mg, indicating consistent die fill and good control during the compression process.

3.3.2. *Thickness (mm)*

Tablet thickness ranged between 3.11 to 3.32 mm, which reflects uniform compression and acceptable tablet dimensions suitable for oral administration.

3.3.3. *Hardness (kg/cm²)*

Hardness values ranged from 4.8 to 5.9 kg/cm², indicating that the tablets possessed sufficient mechanical strength to withstand handling and packaging.

3.3.4. *Friability (%)*

All tablets exhibited friability within acceptable limits (<1%), with F1 showing no weight loss after 100 rotations, indicating excellent abrasion resistance.

3.3.5. *In Vitro Buoyancy (Floating Lag Time)*

The floating lag time ranged from 45 seconds to 1 minute 20 seconds, showing that all tablets initiated buoyancy promptly, which is essential for gastro-retentive action.

3.3.6. *% Drug Content*

Drug content for all formulations was in the range of 95.6% to 98.8%, confirming the uniform distribution

Table 7: Physical characteristics of bilayered famotidine floating tablets

F.Code	Avg. Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	In Vitro Buoyancy	% Drug Content
F1	300.2	3.12	5.6	0% after 100 rev	45 sec	95.6
F2	299.6	3.23	5.9	0.2% after 200 rev	55 sec	97.9
F3	301.8	3.18	5.5	–	1 min 10 sec	98.8
F4	300.7	3.32	5.2	–	52 sec	98.3
F5	302.1	3.11	4.8	–	1 min 5 sec	97.9
F6	299.8	3.25	5.0	–	1 min 20 sec	98.6

of famotidine within the tablets and compliance with Pharmacopeial standards.

3.3.7. *In vitro drug release of bi-layer floating tablets*

All formulations exhibited a sustained drug release profile over 24 hours. Initial drug release at 30 minutes ranged between 15.2% (F6) and 19.0% (F1), indicating minimal burst effect. By 12 hours, over 70% drug release was achieved across all batches. F1 and F2 showed the highest cumulative release (>102%), while F3 had a more controlled release profile (90.4% at 24 hr). These results suggest the effective design of bilayer tablets for prolonged gastric retention and consistent Famotidine release (Table 8 & Figure 6).

3.3.8. *Release kinetics of drug*

The first-order model showed the best fit for most formulations, with R^2 values > 0.95 for F1, F3–F6, indicating concentration-dependent release. F3 and F4 showed the highest correlation ($R^2 = 0.983$), confirming suitability for controlled release. The Higuchi model also fit well (R^2 = 0.875–0.922), suggesting a significant diffusion-based release mechanism. In contrast, the Hixson–Crowell model had low R^2 values (0.162–0.296) across all formulations, indicating that erosion or surface area changes were not the primary mechanism. Overall, the drug release was best explained by a combination of diffusion and concentration-dependent kinetics (Table 9).

Table 8: Dissolution data of bilayer floating tablets of famotidine

Time (hr)	*F1*	*F2*	*F3*	*F4*	*F5*	*F6*
0.5	19.0	17.5	18.5	18.0	18.3	15.2
1	21.5	21.0	22.6	22.0	23.2	22.3
2	31.8	30.3	32.9	32.1	31.7	32.4
4	46.1	43.1	46.2	45.0	46.4	47.9
6	57.3	53.2	56.7	56.0	57.9	58.3
8	66.2	61.1	63.5	64.3	67.2	66.5
10	74.0	66.9	69.6	70.9	72.3	73.2
12	80.7	72.8	73.8	78.3	79.1	80.0
16	90.3	84.9	81.7	86.5	84.6	85.6
20	98.0	97.6	86.3	94.0	91.1	92.4
24	103.7	102.9	90.4	96.7	96.8	97.3

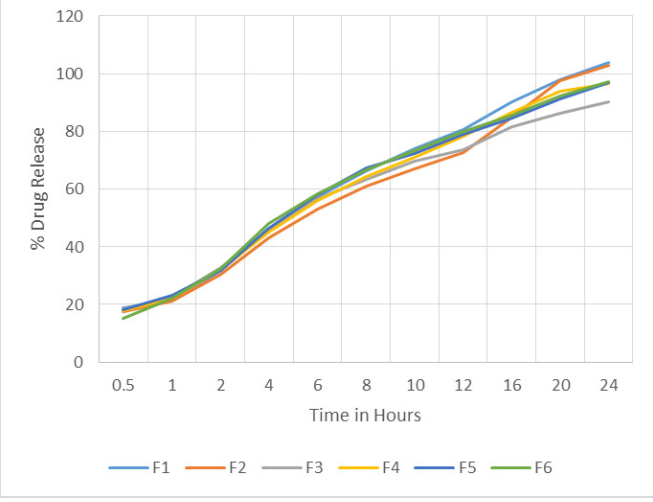

Figure 6: In vitro drug release of bi-layer floating tablet of famotidine

Table 9: Release kinetics of drug from bilayered floating tablets of famotidine

Model	*Parameter*	*F1*	*F2*	*F3*	*F4*	*F5*	*F6*
First Order	k	0.153	0.158	0.111	0.109	0.109	0.113
	R^2	0.970	0.869	0.983	0.983	0.967	0.956
Higuchi Model	k	24.14	23.71	22.79	22.56	22.25	22.29
	R^2	0.875	0.889	0.883	0.903	0.915	0.922
Hixson–Crowell	k	0.303	0.301	0.247	0.248	0.247	0.252
	R^2	0.162	0.195	0.167	0.258	0.218	0.296

4. CONCLUSION

The current study successfully developed and evaluated bilayer floating tablets of famotidine to address its limited gastric retention and bioavailability. The bilayer system, consisting of a controlled-release matrix and an effervescent floating layer, ensured prolonged gastric residence and sustained drug release over 24 hours. Preformulation studies confirmed the compatibility and stability of the drug with selected excipients through FTIR and DSC analyses. Micrometric evaluations established good flowability, allowing for efficient tablet compression by direct compression technique. All formulations demonstrated desirable physical properties with acceptable hardness, low friability, and consistent weight and thickness. The in vitro buoyancy lag times ranged from 45 seconds to 1 minute 20 seconds, ensuring quick floating onset. Drug content uniformity across all formulations was within Pharmacopeial limits. Dissolution profiles showed that formulations F1 and F2 achieved complete release, while F3 exhibited the most controlled release pattern, suitable for sustained therapeutic action. Kinetic analysis revealed that first-order and Higuchi models best described the release behavior, indicating concentration-dependent and diffusion-controlled mechanisms, respectively. The study concludes that bilayer floating tablets of famotidine can significantly improve therapeutic outcomes by enhancing gastric retention and minimizing dosing frequency. This delivery system holds promise for further in vivo studies and clinical applications.

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How to cite this article: Avvari S, Krovvidi J, Chikkala M, Sai Nadh AVSR, Sree GH, Jahnavi P. Design and Optimization of Controlled Release Bilayer Floating Tablets of Famotidine Using HPMC Polymers. Int J Appl Pharm Sci Res. (2025);10(1): 1-7. doi: https://doi.org/10.21477/ijapsr.10.1.01

Source of Support: Nil.

Conflict of Support: None declared.