

Development of Famotidine Swelling Matrix Tablets: In Vitro Evaluation and Release Kinetics Study

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ABSTRACT

The present study focuses on the formulation and evaluation of gastro-retentive swelling matrix tablets of Famotidine, a histamine H₂-receptor antagonist with a short half-life and limited bioavailability. The aim was to develop a controlled-release dosage form to enhance gastric retention and sustain drug release over 24 hours. Various hydrophilic polymers including HPMC K15M, HPMC K100M, Calcium CMC, Xanthan gum, and Avicel PH 101 were used to formulate six matrix tablet batches (F1–F6) using the direct compression method. Preformulation studies confirmed the drug's compatibility with selected excipients through FTIR and DSC analysis. Micrometric properties such as angle of repose, compressibility index, and Hausner's ratio indicated good flow characteristics of the blend. All tablets were evaluated for physical parameters including weight variation, thickness, hardness, friability, and content uniformity. In vitro, drug release studies conducted in 0.1 N HCl showed sustained release behavior across all formulations. F1 exhibited the fastest release (103.7% at 24 hrs), while F3 had the most controlled profile (90.4% at 24 hrs). Kinetic modeling of the release data indicated that the Higuchi model best described the release mechanism ($R^2 = 0.969$ – 0.998), suggesting diffusion-controlled drug release. The study concluded that the swelling matrix system effectively sustained the release of famotidine and holds promise for once-daily gastro-retentive dosage forms.

Keywords: Famotidine, Gastro-retentive tablets, Swelling matrix, Controlled release, HPMC, Kinetic modeling, FTIR, DSC, Higuchi model

1. INTRODUCTION

Famotidine is a histamine H₂-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}

Gastro-retentive swelling matrix systems are designed to prolong the gastric residence time of drugs by forming a swellable, expandable matrix upon contact with gastric fluids. These systems absorb water and swell significantly, increasing in size to prevent passage through the pyloric sphincter.⁵ This approach is particularly beneficial for drugs like famotidine that are primarily absorbed in the stomach or upper small intestine. The prolonged gastric

retention not only improves the bioavailability of such drugs but also reduces dosing frequency and enhances therapeutic outcomes by maintaining a consistent plasma drug concentration over an extended period.⁶

2. MATERIALS AND METHODS

2.1. Chemicals and reagents

All materials and excipients used in the study, including famotidine, HPMC K15M, HPMC K100M, Avicel PH 101, Calcium CMC, Xanthan gum, Povidone K-30, Talc, and Magnesium Stearate, were procured from S.D. Fine-Chem Limited, Mumbai. Analytical grade solvents and reagents used for dissolution and spectroscopic studies were obtained from Merck India Pvt. Ltd. All chemicals used were of pharmaceutical or analytical grade and were used as received without further purification.

2.2. Preformulation studies

2.2.1. Organoleptic evaluation

The organoleptic properties of famotidine, including color, odor, and taste, were evaluated using standard

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descriptive terminology. The drug appeared as an off-white powder, was odorless, and exhibited a slightly bitter taste.

2.2.2. 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 $37 \pm 0.5^\circ\text{C}$ 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

2.2.3. UV Spectroscopy

A stock solution of famotidine (1000 $\mu\text{g/mL}$) was prepared in 0.1 N HCl, and a working solution (10 $\mu\text{g/mL}$) was obtained by serial dilution. The absorption maxima (λ_{max}) was determined by scanning from 200 to 400 nm using a Perkin Elmer Lambda-40 UV/VIS spectrophotometer, with λ_{max} observed at 255 nm.^{8,9}

2.2.4. 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 $\mu\text{g/mL}$. 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

2.2.5. 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

2.2.6. 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

2.2.7. 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}

2.2.8. 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

2.3. Formulation procedure

All the ingredients were accurately weighed. Granulated the MCC and HPMC with povidone k-30 solution and kept for drying for 30 min in a hot air oven. The powder was sieved through 20# mesh after drying and the blend was mixed with magnesium stearate, xanthan gum, and talc and triturated for 1 minute. The final blend was compressed into tablets using an 8.73mm punch. Swelling matrix tablets containing 40 mg of famotidine were prepared with a total tablet weight of 250 mg (Table 1).

Table 1: Formulation of swelling matrix tablets of famotidine

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Famotidine	40	40	40	40	40	40
Avicel PH 101	64	79	60	80	70	77
HPMC K100M	—	—	60	67	—	—
Calcium CMC	35	30	39	37	34	22
HPMC K15M	80	70	—	—	80	80
Xanthan Gum	20	20	20	15	15	20
Magnesium Stearate	3	3	3	3	3	3
Talc	3	3	3	3	3	3
Povidone K-30	5	5	5	5	5	5

2.4. 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 $37 \pm 2^\circ\text{C}$ 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 DISCUSSIONS

3.1. Preformulation studies

3.1.1. Organoleptic

Famotidine was observed as an off-white, odorless powder with a slightly unpleasant taste.

3.1.2. Solubility evaluation

Its solubility was assessed in various solvents, and the results are presented below, highlighting its high solubility in acidic media, which supports its suitability for gastric-targeted formulations (Table 2).

3.1.3. UV spectroscopy

A solution of 10 $\mu\text{g/mL}$ famotidine in 0.1 N HCl was scanned in the range of 200–400 nm using a UV spec-

Table 2: Solubility of famotidine in different media

Medium	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 3: Absorbance Values for Standard Calibration Curve in 0.1 N HCl

Serial No.	Concentration ($\mu\text{g/mL}$)	Absorbance
1	5	0.184
2	10	0.341
3	16	0.562
4	20	0.725
5	26	0.887

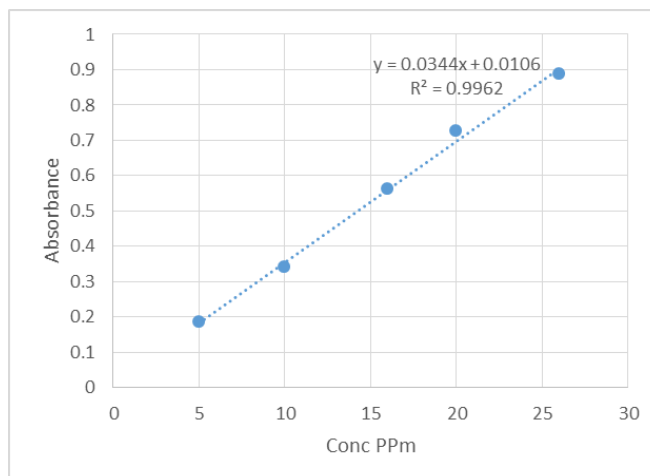


Fig 1: Calibration curve of famotidine

trophotometer. The maximum absorbance (λ_{max}) was observed at 266 nm, which was used for further analytical quantification (Table 3 & Fig 1).

3.1.4. FTIR Interpretation

The FTIR spectrum of pure famotidine displayed distinct characteristic peaks at 3505.68 cm^{-1} (O–H stretching), 3103.5 cm^{-1} (C–H stretching), 2936.8 cm^{-1} (CH_3/CH_2 stretching), and 1638.4 cm^{-1} (C=C stretching), along with multiple bending vibrations between $1400\text{--}600\text{ cm}^{-1}$, confirming the presence of functional groups associated with the drug. In the physical mixtures with excipients such as HPMC K15M, calcium CMC, Avicel PH 101, and xanthan gum, these characteristic peaks remained unchanged without the appearance of new peaks or significant shifts. This suggests the absence of chemical interactions, indicating that famotidine is compatible with the selected excipients (Figure 2 & 3).

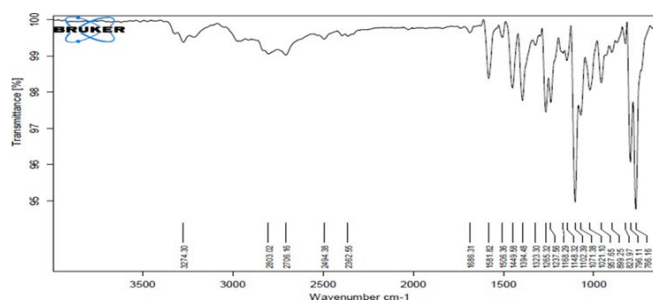


Fig 2.: FTIR of Pure Drug

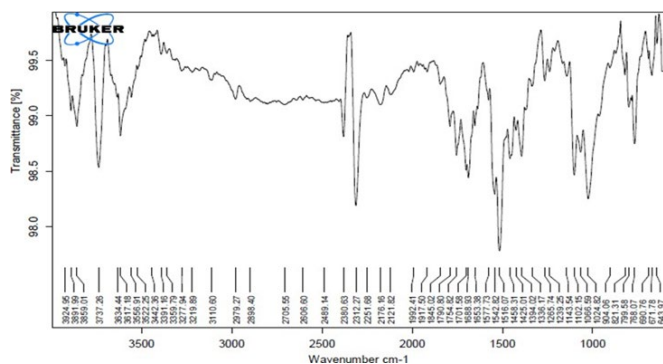


Fig.3: FTIR of Pure drug and Physical Mixture

3.1.5. DSC interpretation

The DSC thermogram of pure famotidine showed a sharp endothermic peak at 165.77 °C, which corresponds to its melting point and confirms its crystalline and pure nature. The thermograms of the physical mixtures of famotidine with various excipients retained the same endothermic peak with slight variations in intensity and onset, without the appearance of any additional peaks. These findings indicate no significant interaction between the drug and excipients, thus confirming their thermal compatibility for use in the swelling matrix tablet formulation (Figures 4& 5).

3.1.6. Micrometric evaluation

The micrometric evaluation of pure famotidine revealed a high angle of repose (~48.76°) and compressibility index (>56%), indicating poor flowability. The Hausner's ratio (>2.29) further supports this conclusion. These values suggest that famotidine has low bulk density and requires flow enhancers or granulation for direct compression (Table 3).

3.1.7. Particle size determination

The Particle size (geometric mean diameter) of famotidine was found to be 1.7 µm (10%), 6.954 µm (50%), and 20.245 µm (90%). Particle size distribution curves are shown in Figure 6.

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.

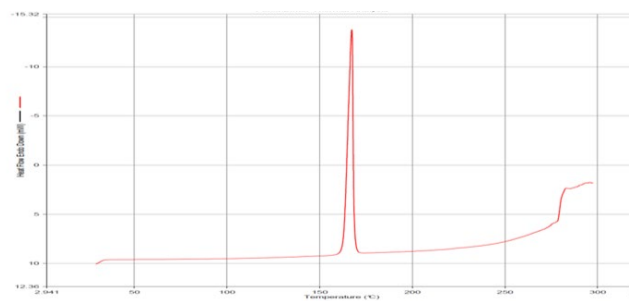


Fig 4: DSC Chromatogram of Pure drug

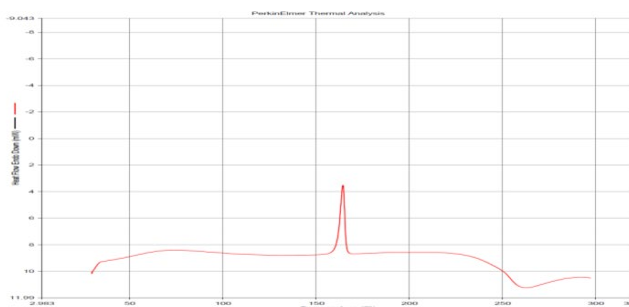


Fig 5: DSC chromatogram of drug and Physical Mixture

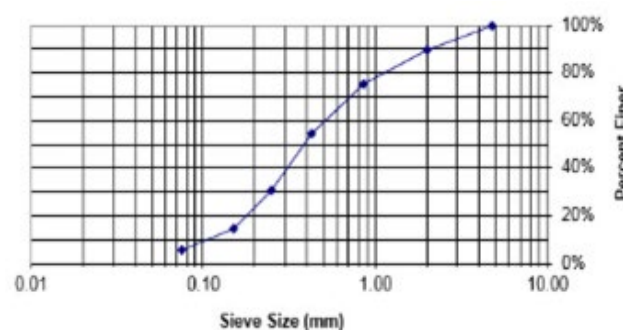


Fig 6: Size Determination of famotidine

3.2. Evaluation of the tablet blend

The micrometric properties of all formulations (S1–S6) indicated angle of repose values below 35°, suggesting acceptable to good flow properties. Carr's index values ranged from 11.89% to 16.50%, and Hausner's ratios (not shown) likely affirm this, confirming that all tablet blends had adequate flowability for direct compression (Table 4).

3.3. Formulation of swelling matrix tablets

Excipients were selected based on their ability to modulate drug release in controlled-release swelling matrix

Table 3: Powder flow properties of pure famotidine

S. 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	56.367	2.298
3	49.06	0.209	0.480	56.394	2.296
Average	48.76	0.208	0.478	56.337	2.290

Table 4: Micrometric Properties of the Tablet Blend for Swelling Matrix Tablets

Parameter	S1	S2	S3	S4	S5	S6
Angle of Repose (°)	25.16°	31.11°	34.23°	34.57°	32.74°	33.63°
Bulk Density (g/mL)	0.376	0.399	0.405	0.450	0.600	0.687
Tapped Density (g/mL)	0.412	0.411	0.498	0.496	0.624	0.699
Carr's Index (%)	15.15	12.74	11.89	15.69	13.98	16.50

Table 5: Physical characteristics of famotidine swelling matrix tablets

Formulation	Average Weight (mg)	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)	% Drug Content
F1	250.3	3.13	5.5	0% (100 rev), 0.1% (200 rev)	97.65
F2	251.6	3.12	5.4	–	95.59
F3	249.18	3.15	5.2	–	96.86
F4	250.7	3.12	5.3	–	97.30
F5	252.5	3.17	5.1	–	97.20
F6	249.18	3.11	5.3	–	97.60

tablets. Calcium Carboxymethyl cellulose (Calcium CMC), used at concentrations between 5–15%, swells significantly upon contact with water, aiding in sustained drug release. Microcrystalline cellulose (MCC, 20–90%), specifically Avicel PH101, was chosen due to its multifunctional role as a binder, diluent, disintegrants, and its excellent compressibility and flow characteristics, making it ideal for direct compression. Among MCC grades, PH101 was selected for its reported benefits in reducing tablet hardness and improving disintegration time. Xanthan gum, a natural polymer, was included for its gel-forming ability and usefulness in controlled-release formulations.

Polyvinylpyrrolidone (Povidone K-30) was incorporated at 0.5–5% concentration, serving as a binder in solid dosage forms. Starch 1500 was also used for its dual role as a binder and diluent. The powder blend demonstrated moderate flow properties (Hausner's ratio ≈ 1.3). To enhance flow, talc (1.0–10.0%) was employed as a glidants, while magnesium stearate (0.5%) was added as a lubricant to ensure smooth tablet ejection and prevent sticking during compression.

3.4. Evaluation of famotidine tablets

Formulated tablets were evaluated for hardness, friability, weight variation, thickness, content uniformity, and dissolution (Table 5).

3.4.1. Average weight

All formulations had consistent tablet weights ranging from 249.18 mg (F3, F6) to 252.5 mg (F5), indicating good weight uniformity during compression.

3.4.2. Thickness

Tablet thickness was uniform across all batches, ranging from 3.11 mm (F6) to 3.17 mm (F5), ensuring consistent tablet dimensions.

3.4.3. Hardness

The hardness of tablets varied between 5.1–5.5 kg/cm², with F1 showing the highest (5.5), indicating sufficient mechanical strength to withstand handling.

3.4.4. Friability

Only F1 was tested, showing 0% friability after 100 revolutions and 0.1% after 200 revolutions, which is well below the acceptable limit of 1%, confirming excellent durability.

3.4.5. % Drug content

All formulations showed drug content between 95.59% (F2) and 97.65% (F1), demonstrating a uniform distribution of famotidine within the matrix.

3.5. In vitro drug release of swelling matrix tablets

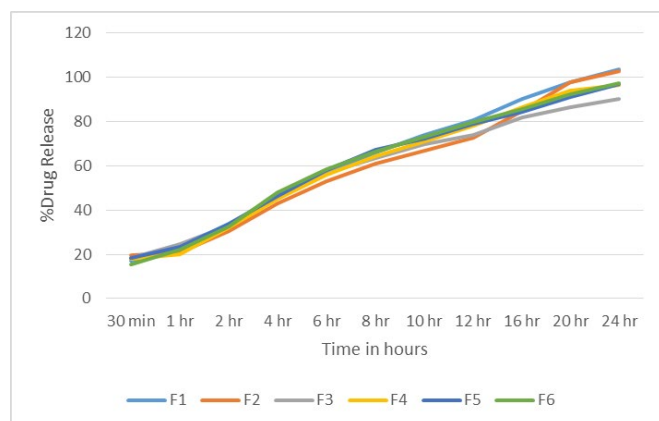
Table 5 presents the dissolution profiles of six formulations (F1–F6) of famotidine swelling matrix tablets over 24 hours, demonstrating sustained drug release. Initial drug release at 30 minutes ranged from 15.2% (F6) to 19.0%

Table 6: Dissolution data of swelling matrix famotidine tablets

Time	F1	F2	F3	F4	F5	F6
30 min	17.0	19.5	18.5	18.0	18.3	15.2
1 hr	21.5	21.0	24.6	20.0	23.2	22.3
2 hr	31.8	30.3	32.9	32.1	33.7	32.4
4 hr	46.1	43.1	46.2	45.0	46.4	47.9
6 hr	57.3	53.2	56.7	56.0	57.9	58.3
8 hr	66.2	61.1	63.5	64.3	67.2	66.5
10 hr	74.0	66.9	69.6	70.9	72.3	73.2
12 hr	80.7	72.8	73.8	78.3	79.1	80.0
16 hr	90.3	84.9	81.7	86.5	84.6	85.6
20 hr	98.0	97.6	86.3	94.0	91.1	92.4
24 hr	103.7	102.9	90.4	96.7	96.8	97.3

Table 7: Release Kinetics of Swelling Matrix Tablets (F1–F6)

Formulation	First Order k	First Order R^2	Higuchi k	Higuchi R^2	Hixson–Crowell k	Hixson–Crowell R^2
F1	0.177	0.838	22.42	0.993	0.384	0.671
F2	0.167	0.771	21.34	0.998	0.368	0.739
F3	0.102	0.975	20.52	0.969	0.225	0.509
F4	0.132	0.904	21.49	0.987	0.288	0.625
F5	0.124	0.904	21.53	0.978	0.275	0.571
F6	0.132	0.902	21.70	0.980	0.287	0.592

**Fig.7:** In vitro drug release of famotidine swelling matrix tablet

(F1), with all formulations showing controlled release without a burst effect. By 8 hours, drug release reached approximately 60–67%, and by 12 hours, it ranged from 72.8% (F2) to 80.7% (F1), indicating steady and prolonged release. At 24 hours, the cumulative release varied from 90.4% (F3) to 103.7% (F1), confirming complete or near-complete drug release. Overall, the data suggests effective swelling matrix behavior, with F1 showing the fastest release and F3 the most controlled, making the system suitable for once-daily dosing (Table 6 & Fig. 7)

3.6. Release kinetics data of the famotidine

The combined release kinetics data of the famotidine swelling matrix tablets (F1–F6) revealed that all formulations showed the best fit with the Higuchi model, with high R^2 values ranging from 0.969 to 0.998, indicating a predominantly diffusion-controlled drug release mechanism. The First-order model also showed a good correlation for some formulations, particularly F3 ($R^2 = 0.975$), suggesting a partial concentration-dependent release. In contrast, the Hixson–Crowell model exhibited lower R^2 values (0.509–0.739), implying that surface area and erosion effects played a minimal role in the drug release process (Table 7).

4. CONCLUSION

The study successfully formulated and evaluated gastroretentive swelling matrix tablets of famotidine using a direct compression method. Incorporating hydrophilic

polymers like HPMC K15M, HPMC K100M, and Xanthan gum played a significant role in achieving controlled swelling and sustained drug release. Micromeritic evaluations of both pure drug and tablet blends confirmed that the flow properties were acceptable for direct compression. Physicochemical characterization using FTIR and DSC confirmed no significant interaction between the drug and excipients, indicating good compatibility.

The in vitro drug release profiles demonstrated prolonged and steady release of famotidine over 24 hours, minimizing the need for frequent dosing. Among all formulations, F1 released the drug more rapidly, while F3 showed the most controlled release, making it a strong candidate for further development. Kinetic modeling data indicated that the Higuchi model provided the best fit, confirming diffusion as the predominant mechanism of drug release from the matrix.

Overall, the developed gastro-retentive swelling matrix tablets of famotidine could enhance patient compliance and therapeutic efficacy by maintaining consistent plasma drug levels, especially in conditions like GERD and peptic ulcer disease. Future in vivo studies can further validate the potential of these formulations for clinical application.

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