



Formulation and Evaluation of Gastroretentive Mucoadhesive Tablets of Famotidine for Sustained Drug Delivery

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ABSTRACT

The present study aims to formulate and evaluate gastroretentive mucoadhesive tablets of Famotidine to enhance its bioavailability and extend gastric retention. Famotidine, a histamine H₂-receptor antagonist, has a short half-life and limited bioavailability, making it an ideal candidate for gastroretentive systems. Mucoadhesive tablets were developed using polymers such as HPMC K15M, HPMC K100M, Carbopol, and Xanthan gum, along with Avicel PH102 as filler, by direct compression method. Preformulation studies confirmed the drug's identity and compatibility with excipients through FTIR and DSC, revealing no significant interactions. Micrometric properties indicated poor flow for the pure drug, which was improved using lubricants and glidants. The tablets were evaluated for physical parameters, drug content, and in vitro drug release. All formulations met Pharmacopoeial standards, and F3 demonstrated the most controlled release, reaching 98.4% in 24 hours. Dissolution data fitted best with the Higuchi model ($R^2 = 0.980$) indicating diffusion-controlled release, while First Order kinetics also showed good correlation, confirming concentration-dependent behavior. The Hixson–Crowell model was the least fitting, suggesting minimal role of erosion. These findings demonstrate that the optimized formulation effectively prolongs gastric residence time and provides sustained release, thereby potentially reducing dosing frequency and improving patient compliance. The mucoadhesive tablet system developed in this study offers a promising approach for the controlled delivery of Famotidine.

Keywords: Famotidine, Gastroretentive drug delivery, Mucoadhesive tablets, Controlled release, HPMC, Carbopol, Diffusion, First-order kinetics, In vitro evaluation

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].

Gastroretentive mucoadhesive drug delivery systems are designed to adhere to the gastric mucosa and remain in the stomach for an extended period, allowing for sustained and localized drug release. These systems employ mucoadhesive polymers such as HPMC, Carbopol, or sodium alginate that form a gel-like structure upon contact with gastric fluids, enhancing the tablet's retention at the absorption site. For drugs like Famotidine, this approach not only increases bioavailability but also improves patient compliance by reducing dosing frequency. The controlled release from the mucoadhesive matrix ensures a steady drug level, minimizing fluctuations in plasma concentration and enhancing the therapeutic outcome.



2. Materials and Methodology

2.1 Materials

The formulation of Famotidine mucoadhesive tablets involved pharmaceutical-grade ingredients including Famotidine as the active drug, Avicel PH102 (Microcrystalline Cellulose) as a binder and diluent, and Carbopol, HPMC K15M, and HPMC K100M as mucoadhesive and controlled release polymers. Xanthan gum was included for its swelling and viscosity-modifying properties. Magnesium stearate and talc were used as lubricants and glidants to improve powder flow during direct compression. Additionally, povidone K-30 was employed as a binder for granulation.

2.2 Preformulation Studies

2.2.1 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 odourless, 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 Preparation of the calibration curve

From the stock solution, 5–26 mL were transferred to 10 mL volumetric flasks and were diluted with the 0.1N HCl, up to the mark to obtain famotidine concentration of 5–26 µg/mL respectively. Absorbance of each solution was measured at 255 nm in triplicate.

2.2.4 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 $4000\text{--}450\text{ cm}^{-1}$ 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 [10].

2.2.5 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 $10^\circ\text{C}/\text{min}$ 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 [11].

2.2.6 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 [12,13].

2.2.7 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 [14].



2.2.8 Formulation of Mucoadhesive Tablets of Famotidine

Mucoadhesive tablets containing 40 mg of Famotidine were formulated with a total tablet weight of 250 mg using various mucoadhesive and matrix-forming polymers to achieve prolonged gastric retention and controlled drug release (Table 1).

Table 1: Formulation of Mucoadhesive Tablets of Famotidine

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Famotidine	40	40	40	40	40	40
Avicel PH 102	104	90	80	100	105	102
HPMC K100M	–	60	–	50	–	–
Carbopol	30	34	34	30	34	30
HPMC K15M	50	–	70	–	49	52
Xanthan Gum	20	20	20	24	15	20
Magnesium Stearate	3	3	3	3	3	3
Talc	3	3	3	3	3	3

2.2.9 Formulation Procedure

All excipients were accurately weighed, and the Avicel PH 102 and HPMC polymers were granulated using a povidone K-30 solution as a binder. The wet mass was dried in a hot air oven at 60°C for 30 minutes and passed through a 20# mesh to ensure uniform particle size. The dried granules were then blended with magnesium stearate, xanthan gum, and talc, and triturated for 1 minute to ensure homogeneity. The final blend was compressed into mucoadhesive tablets using an 8.73 mm round punch via direct compression method.

2.2.10 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 [15-17].

The prepared tablets were assessed for physical and mechanical properties, including hardness, friability, weight variation, thickness, and content uniformity. Hardness was measured using an Electro lab 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.

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.

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.

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.

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.



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 2:

Table 2: 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

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

Table 3: 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

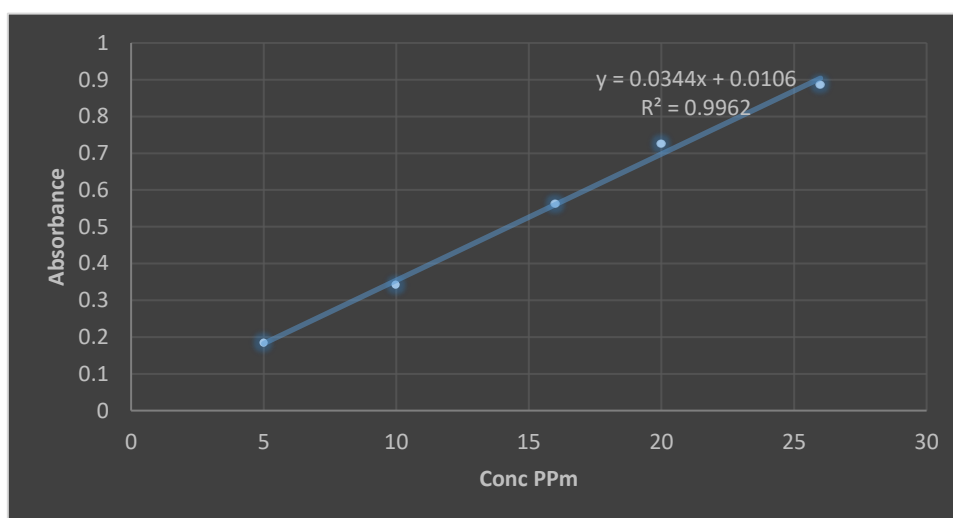


Fig 1: Calibration curve of Famotidine

3.1.3 FTIR Interpretation:

The FTIR spectrum of pure Famotidine displayed characteristic peaks corresponding to its functional groups, including N–H and O–H stretching vibrations around 3400–3200 cm^{-1} , C–H stretching near 3100 cm^{-1} , C=N and C=C stretching between 1600–1500 cm^{-1} , and S=O stretching near 1150–1300 cm^{-1} , confirming the integrity of the drug structure. In the FTIR spectrum of the physical mixture of Famotidine with formulation excipients such as HPMC K100M, HPMC K15M, Carbopol, Xanthan Gum, and Avicel PH102, all characteristic peaks of the drug were retained without any significant shifts, disappearance, or formation of new peaks.

This indicates no chemical interaction between Famotidine and the excipients, confirming their compatibility for formulation into mucoadhesive tablets (Figure 2 & 3).

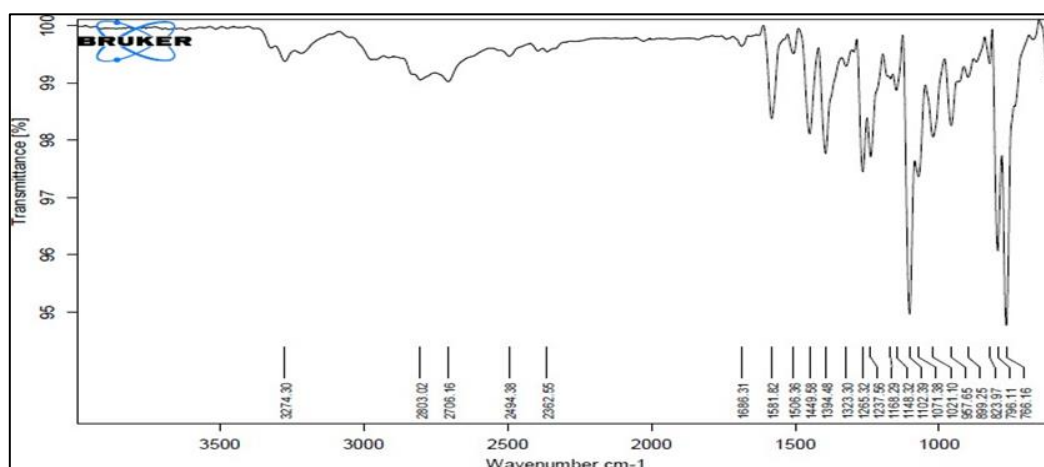


Fig 2.: FTIR of Pure Drug

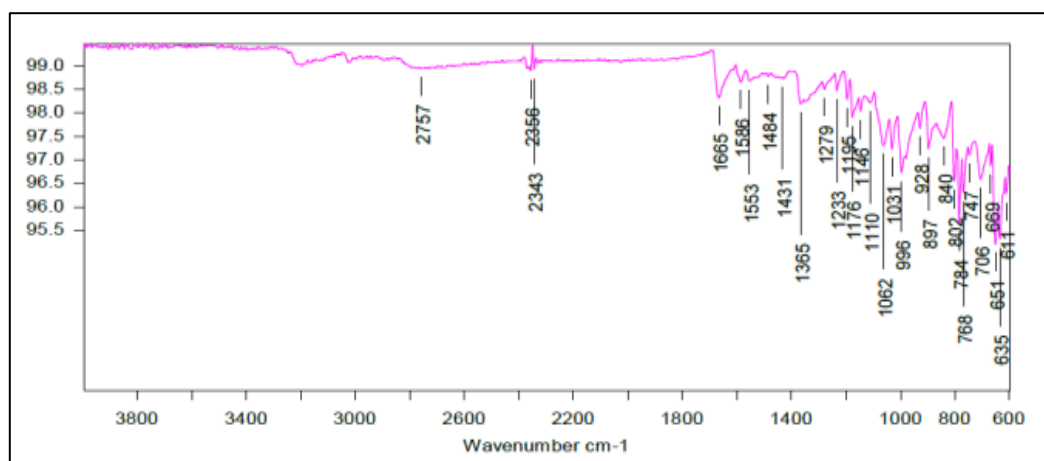


Fig 3: FTIR of FTIR of Pure drug and Physical Mixture

3.1.4 DSC

The DSC thermogram of pure Famotidine showed a sharp endothermic peak around 164–166°C, corresponding to its melting point, which confirms its crystalline nature and thermal stability. The DSC thermogram of the physical mixture exhibited the Famotidine melting peak with slight broadening and a minor decrease in intensity, which is typical due to the dilution effect of excipients. Importantly, there were no additional or unexpected thermal events, indicating the absence of drug-excipient interaction. This confirms that Famotidine remains thermally stable and compatible with the selected excipients used in the mucoadhesive tablet formulation. (Figure 4 & Figure 5).

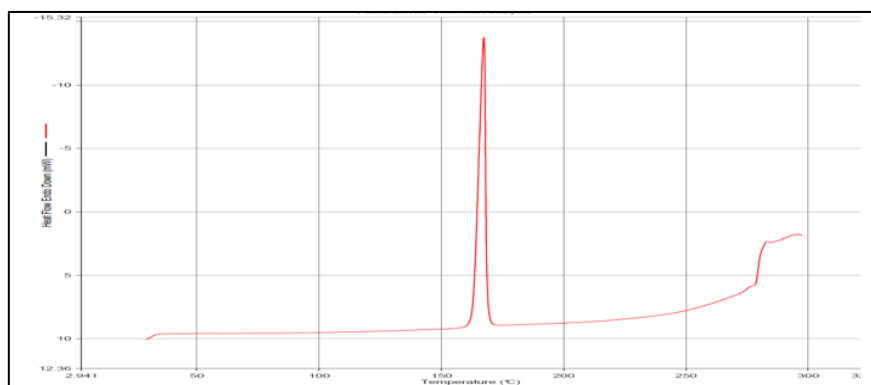


Fig 4: DSC Chromatogram of Pure drug

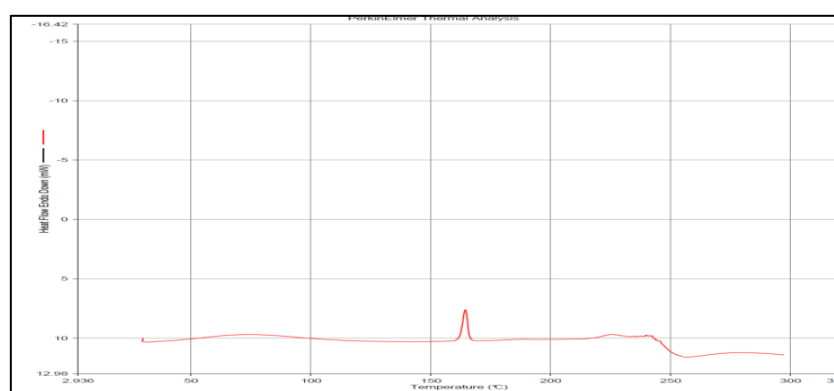


Fig 5: FTIR of Pure drug and Physical Mixture

3.1.5 Micrometric Evaluation

The powder flow properties of pure Famotidine, as presented in Table 4, indicate poor flowability. The angle of repose averaged 48.76° , which is higher than the standard range for good flow ($<40^\circ$). The bulk density (0.208 g/mL) and tapped density (0.478 g/mL) show a significant difference, resulting in a high compressibility index of 56.34% and a Hausner's ratio of 2.29, both of which strongly indicate poor flow characteristics. These findings suggest that Famotidine requires the use of flow-enhancing excipients or granulation techniques for optimal processing during tablet formulation.

Table 4: Powder Flow Properties of Pure Drug (Famotidine)

SI No.	Angle of Repose ($^\circ$)	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

3.1.6 Particle Size determination in Malvern Analyzer

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

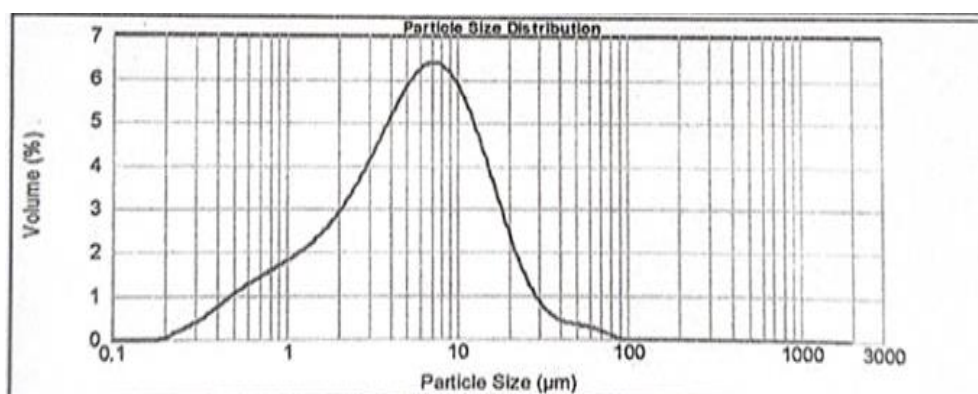


Fig.6: Particle Size Distribution of famotidine

3.1.7 Moisture content

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

3.1.8 Formulation of Mucoadhesive Tablets

Microcrystalline cellulose (MCC), used at concentrations ranging from 20–90%, was selected as a multifunctional excipient owing to its excellent binding, diluting, and compressibility characteristics suitable for both wet granulation and direct compression. Among its various grades, Avicel PH102 was chosen due to its granular form, which has been reported to improve tableting by offering lower crushing strength and faster disintegration times. Xanthan gum, a hydrophilic polysaccharide, was incorporated for its mucoadhesive and controlled-release properties. The flow property of the initial blend was found to be moderate, with a Hausner's ratio of approximately 1.3, indicating the need for flow enhancement. Therefore, talc (1.0–10%) was added as a glidant, and magnesium stearate (0.5%) was included as a lubricant to improve flowability and compression characteristics during tablet formulation.

3.1.9 Evaluation of Famotidine Tablets

The average weight of the tablets ranged from 249.6 mg (F2) to 252.6 mg (F4), indicating excellent weight uniformity and consistent die filling during compression. Tablet thickness values were within 3.12 to 3.32 mm, suggesting uniform compression across all formulations. Hardness values, which ranged between 5.1 and 5.7 kg/cm², indicate that the tablets had adequate mechanical strength to withstand handling without compromising drug release. Friability for F1 was measured and found to be 0.1% after 200 rotations, well within acceptable limits (<1%), confirming tablet robustness; while other formulations also exhibited similar resistance to abrasion. The percentage drug content ranged from 95.6% (F4) to 98.8% (F5), reflecting good content uniformity and appropriate drug distribution throughout the tablet matrix. These physical evaluations confirm that all formulations met Pharmacopoeial standards for tablet quality (Table 5).

Table 5: Physical Characteristics of Famotidine Mucoadhesive Tablets

Formulation Code	Average Weight (mg)	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)	% Drug Content
F1	251.2	3.32	5.5	0% after 100 rotations & 0.1% after 200	98.3
F2	249.6	3.12	5.1	–	96.69
F3	250.1	3.25	5.4	–	98.13
F4	252.6	3.28	5.2	–	95.6
F5	251.8	3.17	5.3	–	98.8
F6	250.8	3.30	5.7	–	97.9

3.1.10 In vitro drug release of mucoadhesive tablets

As shown in Table 6, all Famotidine mucoadhesive formulations (F1–F6) demonstrated sustained drug release over 24 hours. Initial release at 30 minutes ranged from 14.1% to 15.9%, indicating minimal burst effect. By 6 hours, more than 50% of drug release was



achieved in most formulations. F3 exhibited the most controlled and extended release, reaching 98.4% at 24 hours, making it the most effective in maintaining prolonged drug delivery. Formulations F5 and F6 also performed well with final drug releases of 88.5% and 86.5%, respectively. In contrast, F4 showed a relatively slower release (77.9% at 24 hr). These results suggest that the combination of HPMC K15M, Carbopol, and Xanthan Gum in F3 provided optimal matrix integrity and mucoadhesive control, supporting its potential for once-daily gastroretentive delivery. (Figure 7)

Table 6: Dissolution Data of Famotidine Mucoadhesive Tablets

Time (hr)	F1	F2	F3	F4	F5	F6
0.5	14.1	14.5	15.1	14.4	15.9	14.3
1	21.7	21.9	22.7	17.2	23.3	21.1
2	31.6	33.1	35.9	26.4	34.0	33.4
4	44.7	49.3	44.2	47.6	51.2	51.6
6	52.1	54.8	58.6	50.9	54.9	55.9
8	56.7	58.4	69.5	58.9	59.4	61.4
10	61.8	61.9	76.6	64.8	61.8	65.7
12	66.1	66.3	83.8	69.7	66.1	68.2
16	74.3	73.9	89.7	74.6	74.0	74.1
20	81.2	79.6	95.3	76.5	82.6	79.5
24	87.6	84.7	98.4	77.9	88.5	86.5

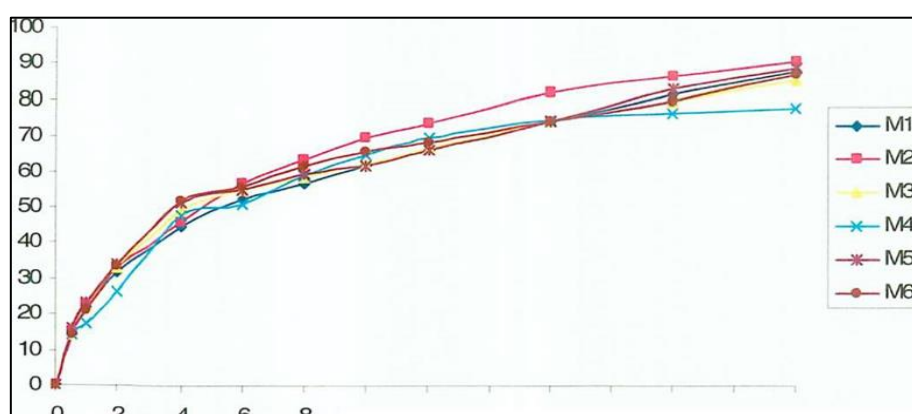


Fig.7: In vitro drug release of Mucoadhesive tablet

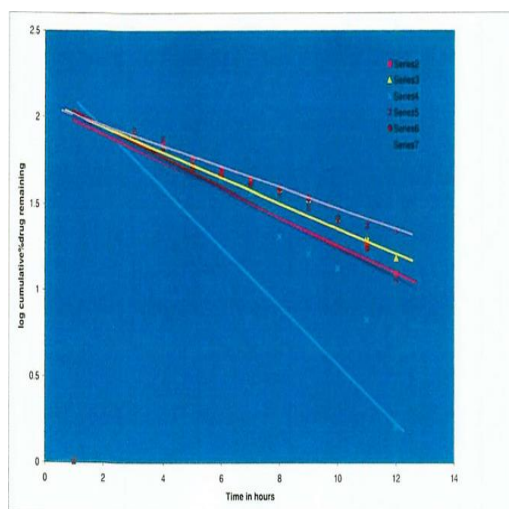
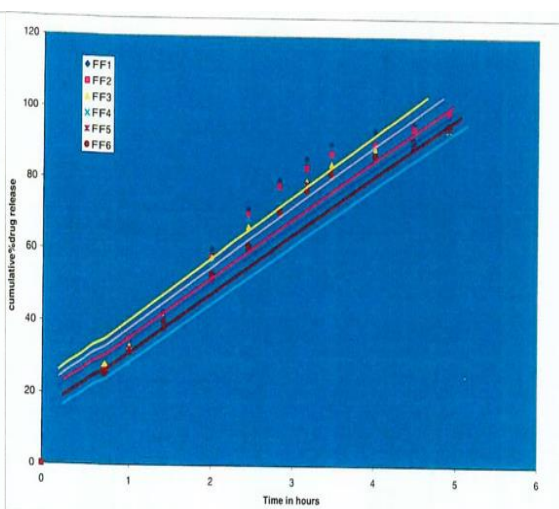
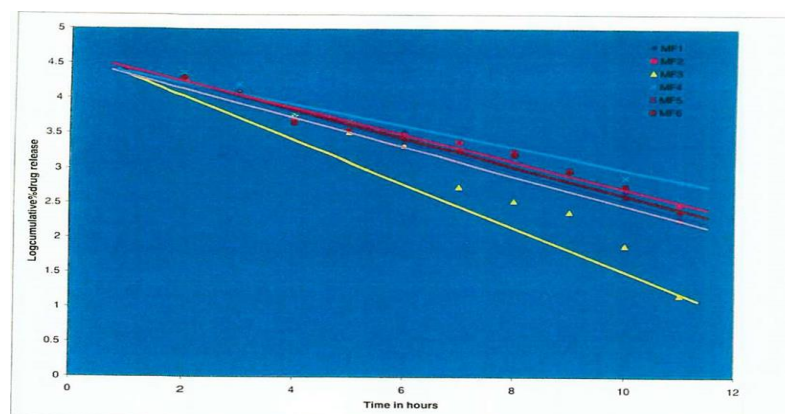
3.1.11 Release Kinetics Data

The release kinetics data of Famotidine mucoadhesive tablets were evaluated using First Order, Higuchi, and Hixson–Crowell models to understand the mechanism of drug release. Among the models, the First Order model showed a good fit for most formulations, particularly F4 ($R^2 = 0.983$), F2 ($R^2 = 0.973$), and F6 ($R^2 = 0.969$), indicating a concentration-dependent release profile, where the drug release rate is proportional to the remaining drug content. The Higuchi model, which is based on diffusion-controlled release, showed the best overall correlation for all formulations, with R^2 values ranging from 0.943 to 0.980. Notably, F1 ($R^2 = 0.980$) and F3 ($R^2 = 0.975$) fit particularly well, suggesting that drug release from the mucoadhesive matrix was predominantly governed by Fickian diffusion. In contrast, the Hixson–Crowell model yielded lower correlation coefficients ($R^2 = 0.502$ to 0.673), indicating that surface area or tablet erosion played a minimal role in the release process. The k values further support this, as they were comparatively lower and showed greater variability.

In summary, the Higuchi model was the best-fitting model overall, suggesting diffusion as the primary mechanism, while the First Order model supported concentration-dependent release, especially for F4 and F2. The Hixson–Crowell model was the least applicable, indicating that tablet geometry changes had little influence on the drug release rate (Table 7 & Figure 8).

**Table 7:** Release Kinetics Data of Famotidine Mucoadhesive Tablets

Formulation	First Order k	First Order R ²	Higuchi k	Higuchi R ²	Hixson–Crowell k	Hixson–Crowell R ²
F1	0.077	0.953	19.01	0.980	0.198	0.502
F2	0.0747	0.973	7.590	0.953	0.183	0.597
F3	0.148	0.887	8.786	0.975	0.308	0.571
F4	0.064	0.983	18.54	0.943	0.176	0.673
F5	0.077	0.935	19.00	0.955	0.195	0.592
F6	0.073	0.969	-0.0131	0.943	0.189	0.513

**First-order kinetics****Higuchi Model of swelling tablets****Hixson-Crowell of swelling tablets****Fig 8:** Release Kinetics of drug

4. Conclusion

The study successfully formulated mucoadhesive gastroretentive tablets of Famotidine to overcome its short half-life and limited bioavailability. By incorporating mucoadhesive polymers (HPMC, Carbopol, Xanthan gum) and optimizing formulation parameters, tablets with good mechanical strength, Mucoadhesion, and controlled release were obtained. The Preformulation data confirmed the drug's compatibility and stability, while in vitro evaluations demonstrated that all tablets maintained structural integrity and released the drug over a prolonged period. Among the six formulations, F3 exhibited the most desirable release profile (98.4% at 24 hr) and adhered well to the Higuchi and First-order kinetic models, indicating a combination of diffusion and concentration-dependent



mechanisms. The formulation approach ensures prolonged gastric retention and once-daily dosing, enhancing patient convenience and therapeutic effectiveness. Overall, the developed mucoadhesive system presents a promising strategy for gastroretentive delivery of Famotidine and may be extended to other drugs requiring similar delivery profiles.

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