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Formulation and Evaluation of Gastro- Retentive Floating Tablet in Ulcer Activity

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ABSTRACT

This study developed and evaluated Gastro-retentive famotidine Microballoons for enhanced peptic ulcer treatment. Nine formulations (F1–F9) were prepared using HPMC K4M by emulsion solvent diffusion, varying polymer ratios (1:1–1:3) and stirring speeds (900–1500 rpm). The Microballoons exhibited excellent micromeritic properties (angle of repose: 22.14°–27.19°; Carr's index: 7.93–13.11%), sustained buoyancy (>12 h, 64.17–83.21%), and high drug encapsulation (63.47–70.34%). FTIR/DSC confirmed drug-excipient compatibility, while SEM revealed porous spherical structures facilitating flotation. *In vitro* release followed Korsmeyer-Peppas (F1,F4–F5,F7–F9), Higuchi (F2,F6), or zero-order kinetics (F3), with anomalous transport ($0.45<n<0.89$) predominating. Optimized formulation F3 demonstrated superior performance: highest buoyancy (83.21±1.07%), encapsulation (70.34±0.98%), and zero-order release (R^2=0.9954). The system's prolonged gastric retention and controlled release address famotidine's short half-life (2.5–4 h), potentially improving therapeutic efficacy in acid-related disorders.

Keywords: *Famotidine, Microballoons, Gastroretentive, Korsmeyer-Peppas, HPMC K4M, peptic, ulcer.*

1. INTRODUCTION

Peptic ulcer disease (PUD) is a common gastrointestinal disorder characterized by erosions in the stomach or duodenal lining, primarily caused by *Helicobacter pylori* infection or prolonged use of nonsteroidal anti- inflammatory drugs (NSAIDs). The condition leads to symptoms such as abdominal pain, bloating, nausea, and, in severe cases, bleeding or perforation. Acid-suppressive therapy remains a cornerstone in PUD management, with histamine H_2-receptor antagonists (H_2RAs) like famotidine playing a crucial role. Famotidine, a potent H_2RA, competitively inhibits histamine receptors on gastric parietal cells, reducing gastric acid secretion. However, conventional immediate-release (IR) formulations of famotidine have limitations, including a short half-life (~3–4 hours) and rapid gastric emptying, leading to frequent dosing and fluctuating plasma concentrations. To overcome these challenges, gastroretentive drug delivery systems (GRDDS) have been explored to prolong gastric residence time, enhance bioavailability, and sustain therapeutic drug levels at the target site.

2. MATERIALS AND METHODS MATERIALS

- **Drug**: Famotidine (procured from a certified pharmaceutical supplier) was used as the model drug for formulation.
- **Polymer**: Hydroxypropyl methylcellulose (HPMC K4M) was selected due to its hydrophilic nature, high viscosity, and excellent matrix-forming ability.
- **Solvents**: Ethanol and dichloromethane were used in a 1:1 ratio as the organic phase for drug and polymer solubilization.
- **Surfactant**: Tween 80 (0.01%) was employed to stabilize the emulsion during the solvent diffusion process.

Other chemicals: All reagents and solvents used were of analytical grade and purchased from verified suppliers.

Preparation of Famotidine Microballoons

The microballoons were prepared by the **emulsion solvent diffusion technique**, a well-established method fabricating hollow microspheres.

Procedure:

- **Organic Phase Preparation**: A known quantity of famotidine and HPMC K4M were dissolved in a 1:1 v/v mixture of ethanol and dichloromethane to obtain a clear solution.
- **Aqueous Phase Preparation**: A 200 mL aqueous solution containing 0.01% Tween 80 was prepared in a beaker.
- **Emulsification**: The organic phase was added dropwise into the aqueous phase under continuous stirring using a mechanical stirrer at varying speeds (900, 1100, 1300, 1500 rpm).
- **Effusion and Evaporation**: The system was stirred for 2–3 hours at room temperature to allow for complete diffusion of the organic solvents into the aqueous phase, resulting in the formation of hollow, porous microballoons.
- **Filtration and Drying**: The resulting microballoons were filtered using Whatman filter paper, washed with distilled water, and dried at room temperature in a desiccator.

Preformulation Studies

Preformulation studies are critical to understanding the physical and chemical properties of the drug substance.

Melting Point Determination

The melting point of famotidine was determined using a capillary method. Approximately 0.5 cm of powdered drug was placed in a sealed capillary tube and heated gradually. The temperature at which the drug transitioned from solid to liquid was recorded.

Solubility Study

Solubility was evaluated in various media (purified water, 0.1N HCl, phosphate buffers of pH 4.5, 6.8). A known amount of drug was added to 10 mL of each solvent, shaken for 24 hours at 37°C, filtered, and analyzed by UV spectrophotometry at 266 nm.

Loss on Drying (LOD)

LOD was measured by placing a known weight of the drug in a hot air oven at 105°C until a constant weight was achieved.

Flow Properties

- **Bulk Density (ρb)** = Weight of sample / Bulk volume
- **Tapped Density (ρt)** = Weight of sample / Tapped volume
- **Carr's Index** = $[(\rho t - \rho b) / \rho t] \times 100$
- **Hausner Ratio** = $\rho t / \rho b$
- **Angle of Repose (θ)** = $\tan^{-1}(h/r)$, where h is the height and r is the radius of the powder cone.Identification, melting point (165–170°C), LOD (<0.5%), bulk/tapped density (0.35/0.45 g/cm³), compressibility index (22.2%), angle of repose (28°), particle size (25–50 µm), calibration curve (R^2=0.999), solubility (pH-dependent, 1.1 mg/mL in water).

Compressibility index:

The compressibility index (Carr's Index) was determined as a quantitative measure of powder flowability by comparing bulk and tapped density values. Using the standard formula:

Carr's Index (%) = [(Tapped Density - Bulk Density) / Tapped Density] × 100

Table 1 Correlation Between Compression Percentage and Powder Flow Characteristics

Compression Percentage Range	Flow Behavior Description
5-15%	Superior (effortlessly flowing granules)
12-16%	Favorable (easily flowing powdered granules)
18-21%	Moderate (standard powdered granules)
23-28%	Limited (highly mobile powders)
28-35%	Restricted (cohesive particulate systems)
35-38%	Minimal flow capacity
>40%	Exceptionally inadequate flow properties

Angle of Repose (θ): Measured by pouring powder through a funnel onto a flat surface, then calculating**: θ arctan(h/r)** where *h* = pile height, *r* = base radius. Lower θ indicates better flowability.

Table 2: Powder Flow Characteristics Based on Angle of Repose Measurements

Angle of Repose Range (°)	Flow Property Classification
<25	**Outstanding flow characteristics**
25-30	**Satisfactory flow performance**
30-40	**Considerable flow limitations**
>40	**Marginal flow capability**

Calibration Curve of Famotidine in 0.1 N HCl, pH 1.20

A calibration curve for famotidine was prepared in 0.1 N HCl (pH 1.20) using standard solutions (5-25 µg/mL). Absorbance was measured at 266 nm by UV spectrophotometry, with linear regression ($R^2 \geq 0.999$) validating the method.

Linearity and Range

The calibration curve was established by measuring absorbance at 266 nm of famotidine standards (5-30 µg/mL) in 0.1N HCl (pH 1.20), showing excellent linearity ($R^2 \geq 0.999$) with a regression equation (y=mx+c).

Precision

Method precision was verified through repeatability (3 replicates), intraday (triplicate measurements), and interday (3 consecutive days) studies of 5-20 µg/mL solutions, showing excellent reproducibility (RSD <2% intraday, <3% interday).

***In- Vitro* Buoyancy Study**

The in-vitro buoyancy study was conducted by placing the floating tablets in 900 mL 0.1N HCl (pH 1.2, 37±0.5°C) in USP dissolution apparatus II (50 rpm). Floating lag time and total floating duration were recorded visually.

$$Buoyancy(\%) = \frac{Q_f}{Q_f + Q_s} \times 100$$

Where, Q_f is weight of floating microballoons and Q_s is weight of settled microballoons respectively.

***In-Vitro* Dissolution Study**

The in-vitro dissolution study was performed using USP Apparatus II (paddle) at 50 rpm in 900 mL 0.1N HCl (pH 1.2, 37±0.5°C). Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically at 266 nm.

Kinetic Modeling of Drug Release

The drug release kinetics were evaluated by fitting dissolution data to various models (zero-order, first- order, Higuchi, Korsmeyer-Peppas). The best-fit model was selected based on highest correlation coefficient (R^2) value.

3. RESULT AND DISCUSSION

Preformulation Studies of Famotidine

Famotidine's physical properties were characterized through identification tests, melting point determination, loss on drying, bulk/tapped density measurements, compressibility index, angle of repose, particle size analysis, calibration curve development, and solubility studies in various media.

Drug Identification Tests Chemical Test

The drug was identified as famotidine by developing a violet-blue color upon reaction with phenylenediamine dihydrochloride, zinc powder, and ferric ammonium sulfate in acidic medium, following standard pharmacopeial identification procedures.

Thin Layer Chromatographic Studies (TLC)

TLC analysis using two solvent systems (ethyl acetate:methanol:toluene:ammonia 40:25:20:2 and chloroform:methanol 9:1) confirmed famotidine purity with single spots (Rf 0.613±0.036 and 0.569±0.018 respectively), matching literature values (Rf 0.539).

UV Spectrophotometric Studies

UV spectrophotometric analysis of famotidine in phosphate buffers (pH 2.50, 3.50) and 0.1N HCl (pH 1.20) showed characteristic λ values (200-400 nm) matching literature data, confirming proper solvent selection for analysis.

Table 3: Spectral Analysis of Famotidine in Various Solvent Systems

En try	Solvent Composition	λ_{max} (nm)
1	Phosphate buffer solution (pH 2.50)	265.5
2	0.1N hydrochloric acid (pH 1.20)	266.0
3	Phosphate buffer solution (pH 3.50)	265.5

Fourier Transform Infrared Radiation

The FTIR spectrum confirmed famotidine's identity, with characteristic peaks matching reference standards (Fig.1). Key functional groups were identified (Table 4), verifying the drug's purity and molecular structure through vibrational band analysis.

Table 4: FTIR Spectral Signature Analysis of Famotidine

Peak Position (cm^{-1})	Molecular Vibration Assignment
3506.59, 3398.57, 3240.41	N-H stretching vibrations (amine groups)
3375.43-3240.41	Sulfonamide (SO_2-NH_2) characteristic
2939.52	Aliphatic C-H stretching
1639.49	Aromatic C=C ring stretching
1597.06	N-H out-of-plane deformation
1492.90	Sulfoxide (S=O) stretching
1284.59	SO_2 asymmetric stretching
1149.57	SO_2 symmetric stretching
1203.58	C-H bending modes
1114.86	Thiocarbonyl (C=S) stretching
983.70, 887.26, 779.24	N-H bending vibrations
609.51	=C-H out-of-plane bending

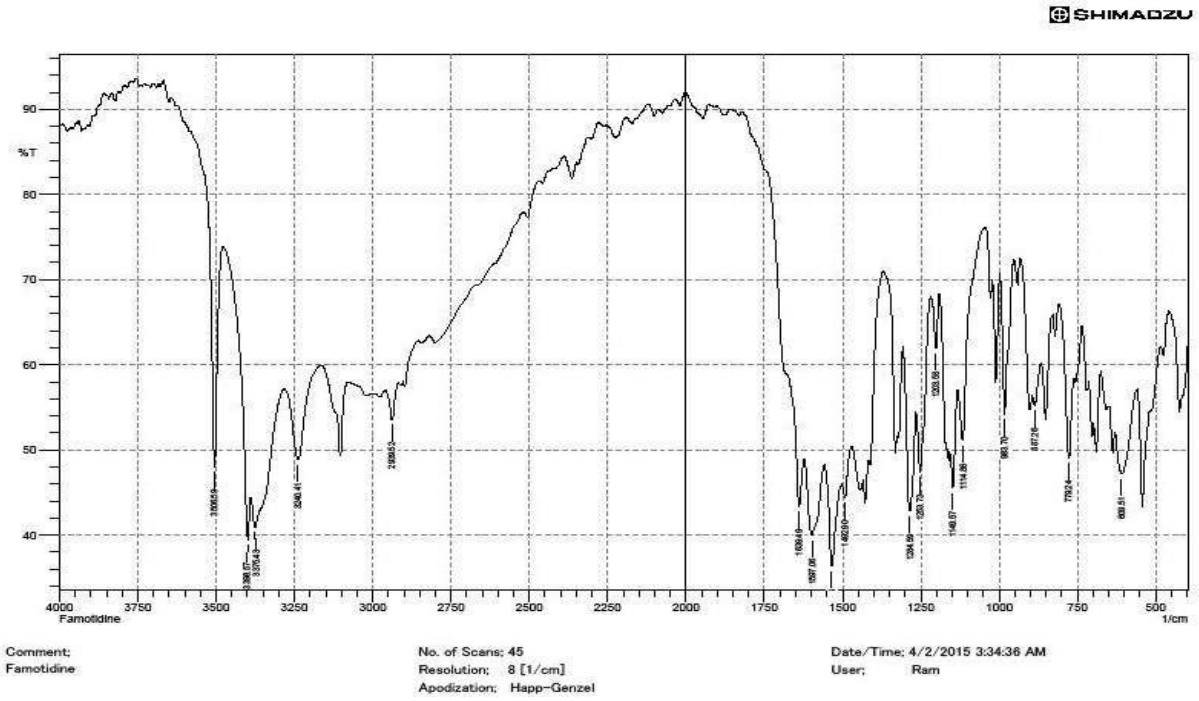


Fig 1: FTIR spectra of famotidine

Loss on Drying

The drug's loss on drying (0.096%) complied with pharmacopeial specifications (<0.5%), confirming appropriate moisture content for formulation processing without compromising stability or quality.

Determination of Particle Size

Microscope calibration established 1 eyepiece division = 14 µm. Famotidine's mean particle size measured 78.977 µm (0.078977 mm), confirming appropriate micronization for formulation processing.

Solubility Determination

Famotidine exhibited pH-dependent solubility, with highest solubility in 0.1N HCl (pH 1.20, 27.6±1.34 mg/mL), matching gastric pH and confirming suitability for gastroretentive formulations, while showing reduced solubility in neutral buffers (pH 6.80).

Table 5: Equilibrium Solubility Profile of Famotidine in Various Solvent Systems (37°C)

Medium	Solubility (mg/mL) (Mean ± SD, n=3)	Relative Solubility Enhancement
Distilled water	1.00 ± 0.078	(Baseline)
0.1N HCl (pH 1.20)	27.60 ± 1.34	27.6-fold increase
Phosphate Buffer (pH 3.50)	18.73 ± 1.13	18.7-fold increase
Phosphate Buffer (pH 6.80)	6.18 ± 0.68	6.2-fold increase

Calibration Curve of Famotidine in 0.1 N HCl, pH 1.20

Famotidine showed maximum absorbance at 266 nm in 0.1N HCl (pH 1.20), enabling accurate spectrophotometric detection. A linear calibration curve (5-30 µg/mL) was established with 0.1N HCl as blank, confirming method suitability for quantitative analysis.

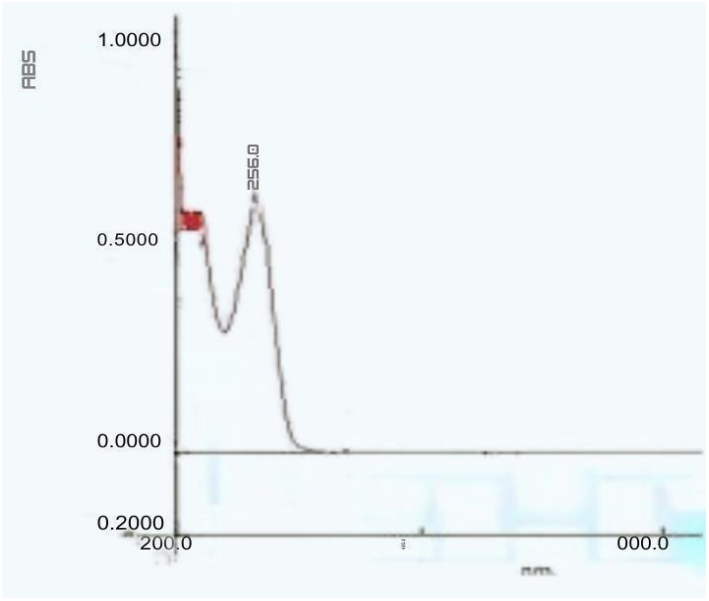


Fig. 2. UV spectra of famotidine in 0.1 N HCl (pH 1.20)

Table 6: Spectrophotometric Calibration Data for Famotidine in 0.1N HCl (pH 1.20)

Standard Concentration (µg/mL)	**Mean Absorbance at 266 nm (±SD)**	**Regression Analysis Parameters**
0 (Blank)	0.000 ± 0.000	**Equation:** y = 0.0364x + 0.0007
5	0.182 ± 0.0018	**Correlation (R^2):** 0.9998
10	0.373 ± 0.0041	**Linear Range:** 5-30 µg/mL
15	0.543 ± 0.0054	**LOD:** 0.152 µg/mL
20	0.720 ± 0.0057	**LOQ:** 0.461 µg/mL
25	0.912 ± 0.0027	
30	1.096 ± 0.0021	

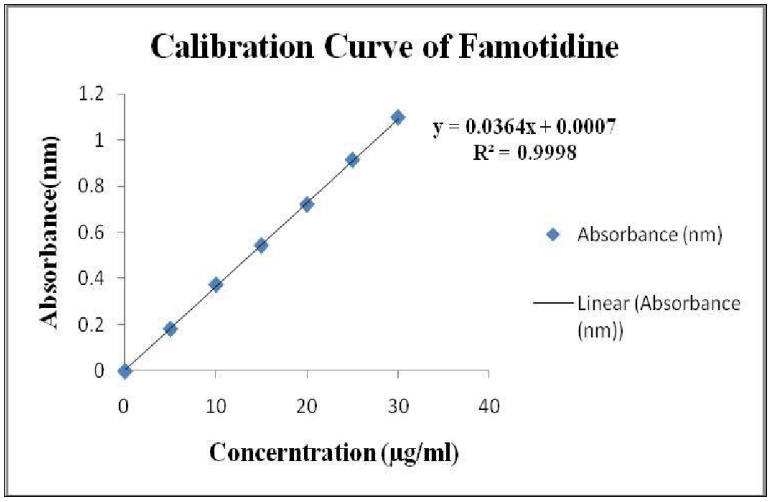


Fig. 3. Calibration curve of Famotidine Precision

The method demonstrated excellent precision with intraday (same-day) and interday (three-day) RSD values <1% across all concentrations, confirming high reproducibility under variable testing conditions as per ICH guidelines.

Table 7: Precision Evaluation of Famotidine Assay Method

Nominal Concentration (µg/mL)	Intraday Precision (n=3)			Interday Precision (n=3)		
	Measured (µg/mL)		%RSD	Measured (µg/mL)		%RSD
5	4.94 0.047	±	0.96	4.95 0.030	±	0.62
10	9.98 0.030	±	0.31	9.97 0.025	±	0.25
20	19.94 0.080	±	0.40	19.94 0.065	±	0.33

Stability Study

The famotidine solution demonstrated excellent bench-top stability for 20 hours at room temperature, with %RSD <1%, confirming short-term stability for analytical processing without significant degradation.

Drug Excipient Compatibility Studies

FTIR and DSC techniques confirmed drug-excipient compatibility, with FTIR identifying functional group interactions and DSC detecting thermal behavior changes, ensuring formulation stability before development.

Fourier-Transform Infrared Spectroscopy (FTIR)

FTIR analysis confirmed famotidine-excipient compatibility in microballoon formulations, with preserved drug

characteristic peaks in physical mixtures (Figs. 4-7). No peak shifts/disappearances indicated absence of interactions, validating excipient selection for therapeutic efficacy.

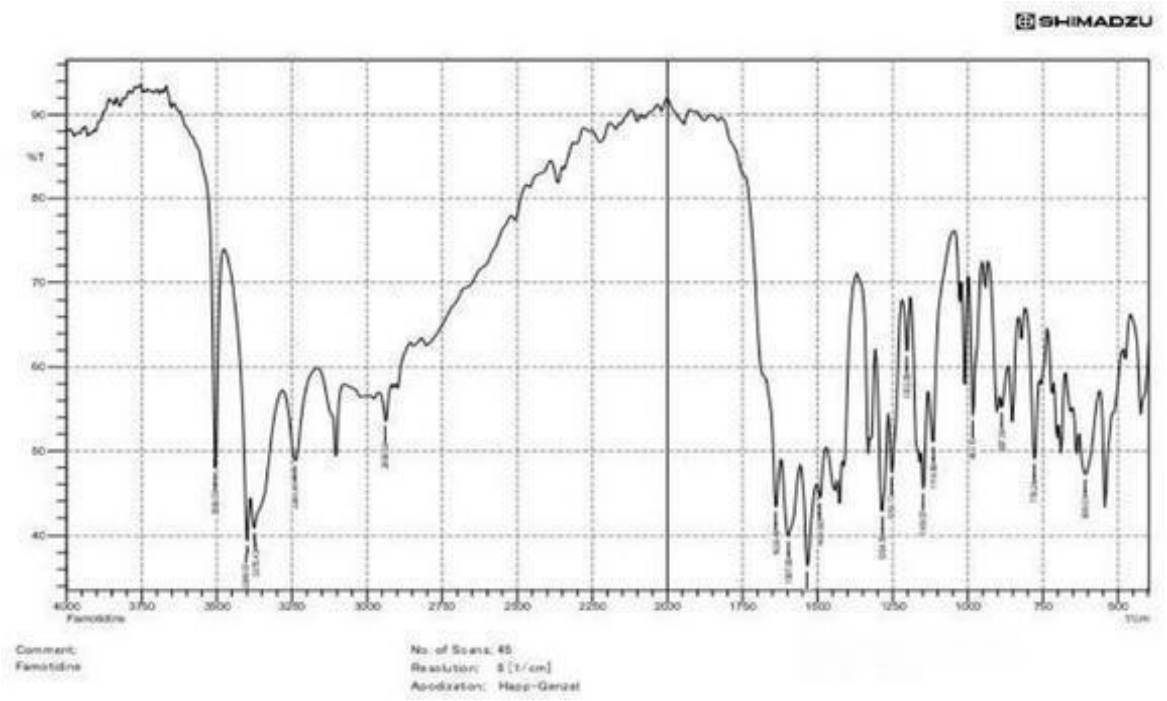


Fig.4. FTIR Spectra of Famotidine

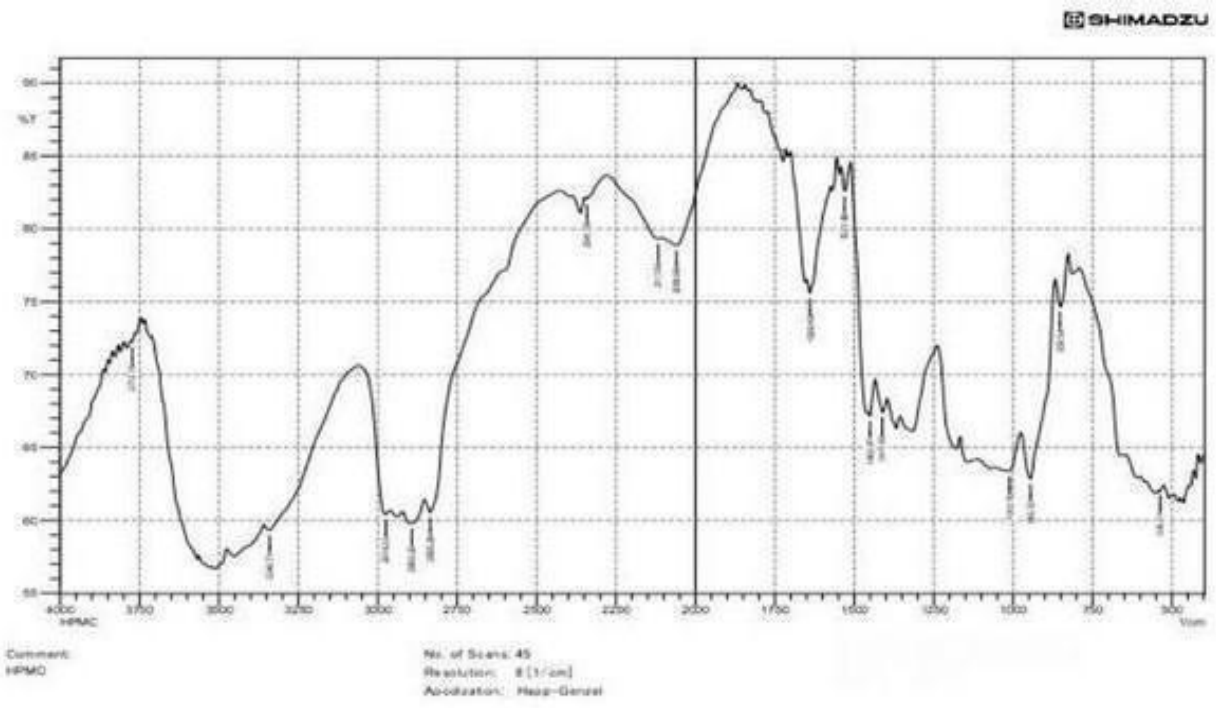


Fig. 5: FTIR spectra of HPMC K4M

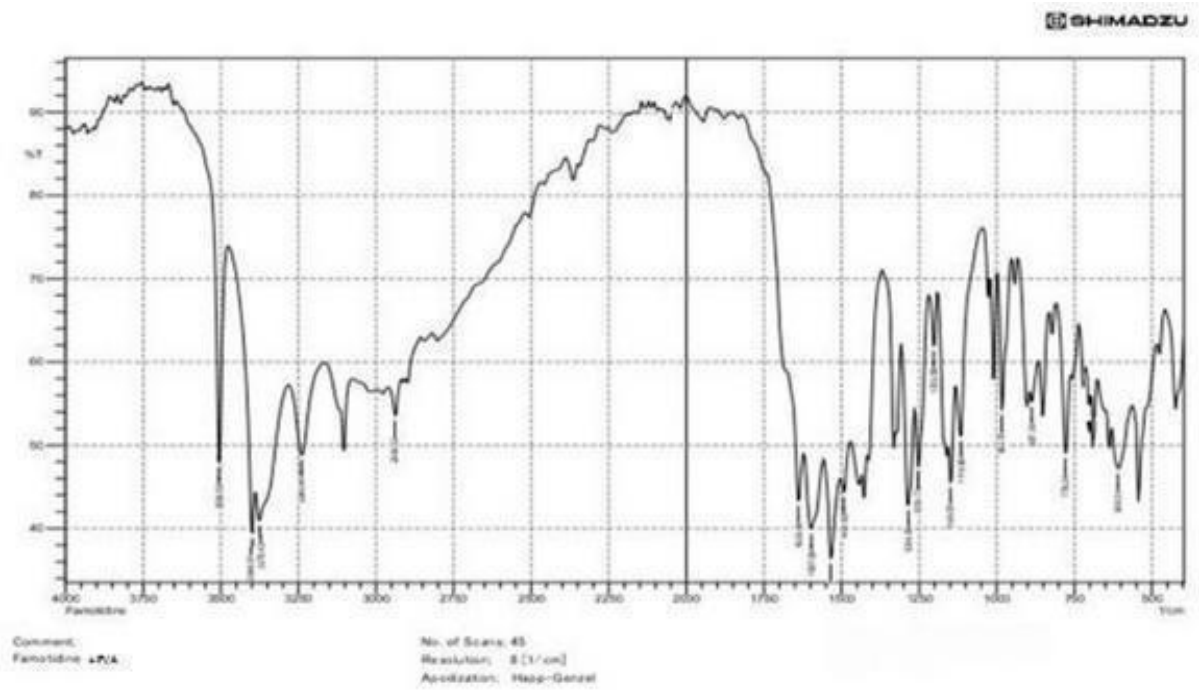


Fig. 6: FTIR spectra of Famotidine and HPMC K4M

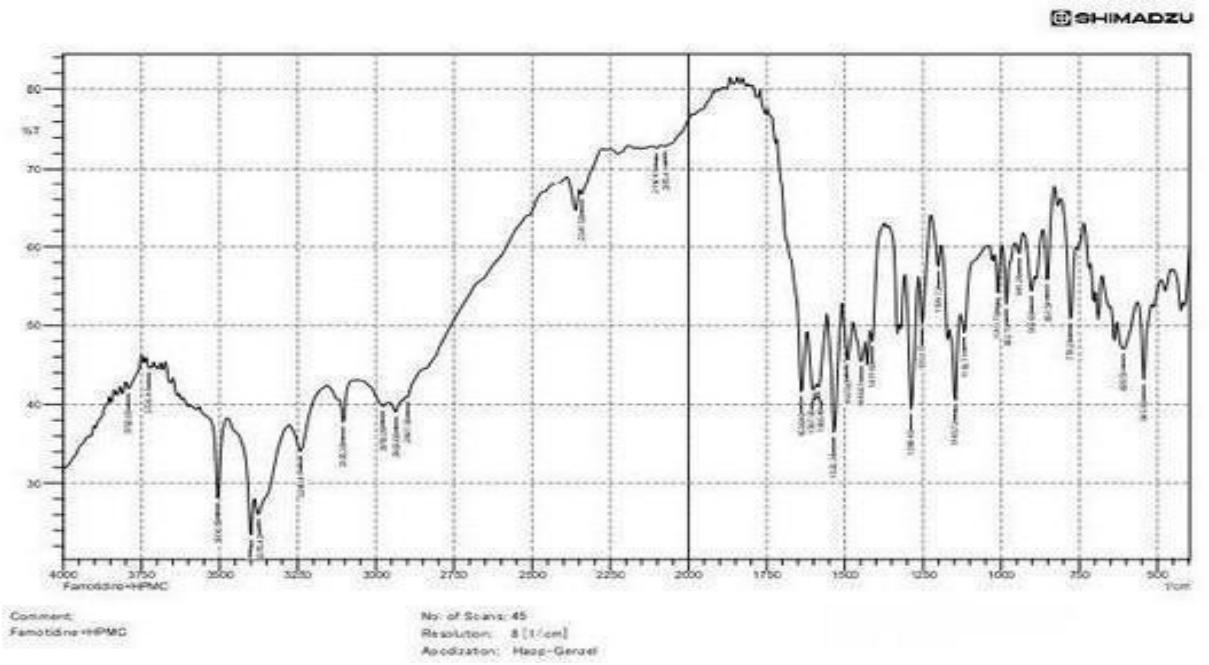


Fig. 7. FTIR spectra of Famotidine and PVA

Differential Scanning Calorimetry

DSC analysis confirmed famotidine-excipient compatibility, with the drug's characteristic endothermic peak (158°C, ΔH 99.1 mJ/mg) remaining unchanged in physical mixtures, demonstrating no physicochemical interactions (Fig. 8).

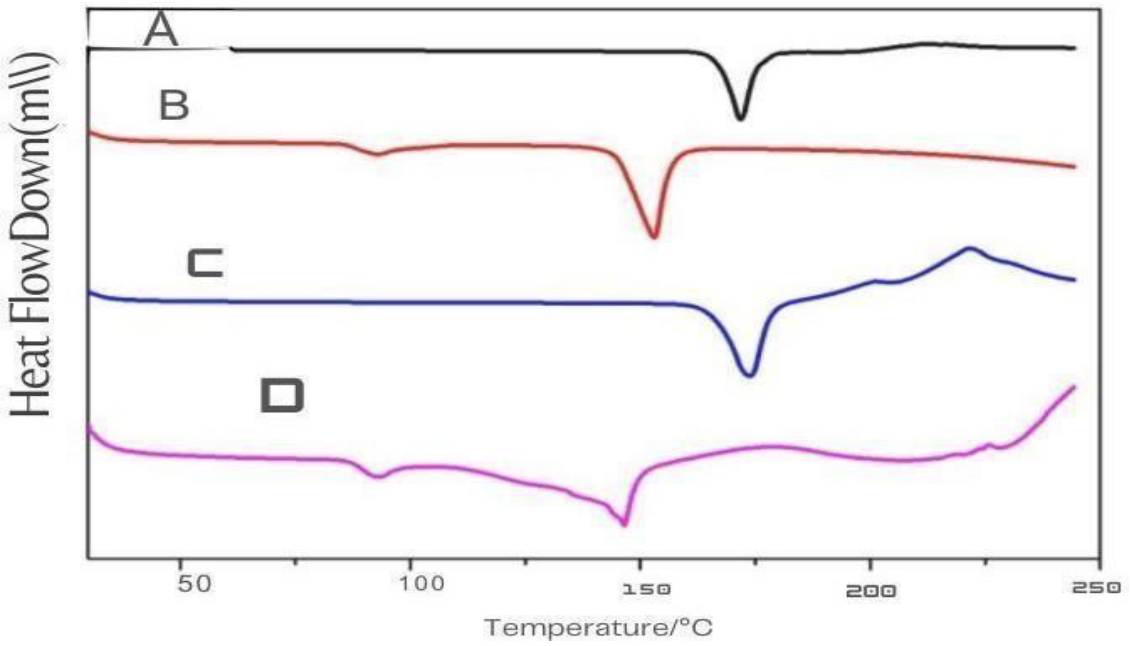


Fig. 8.DSC Thermograms of pure drug and physical mixture Angle of Repose

All nine famotidine microballoon batches exhibited excellent flow properties, with angle of repose values ranging from 22.14°±0.67 to 27.19°±0.62, confirming free-flowing characteristics and smooth particle surfaces.

Bulk Density

The nine microballoon batches showed low bulk densities (0.49±0.24 to 0.69±1.06 g/cm³), significantly below gastric fluid density (1.004 g/cm³), ensuring immediate floatation due to enhanced porosity and buoyancy

Tapped Density

The tapped density of all microballoon formulations ranged from 0.55±0.58 to 0.76±0.45 g/cm³, confirming their suitability as floating systems due to lower density than gastric fluid (0.997 g/cm³).

Carr's Compressibility Index

All nine microballoon formulations exhibited excellent flow and compressibility, with Carr's index values ranging from 7.94±0.0009% to 13.11±0.0003%, facilitating easy capsule filling compared to pure drug.

Hausner Ratio

All nine microballoon formulations demonstrated improved flow properties (Hausner ratio: 1.08- 1.15) compared to pure drug (1.33), confirming enhanced powder flow characteristics essential for capsule filling.

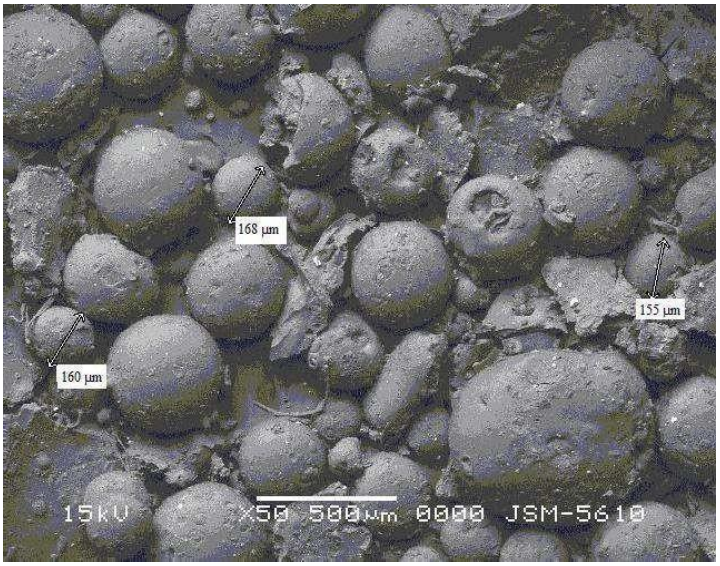
Table 8: Micromeritic Characterization of Famotidine Microballoon Formulations

Formulation	Angle of	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Compressibility Index (%)	Hausner Ratio	Flow Characterization
F1	22.24 ± 0.57	0.20 ± 0.14	0.45 ± 0.48	11.20	1.02	Excellent flow
F2	23.22 ± 0.52	0.52 ± 0.53	0.51 ± 0.38	12.12	1.05	Good flow

F3	25.18 ± 0.51	0.62 ± 0.62	0.57 ± 0.25	9.95	1.19	Excellent flow
F4	23.32 ± 0.27	0.43 ± 0.47	0.48 ± 0.57	9.62	1.09	Excellent flow
F5	23.94 ± 1.84	0.58 ± 0.29	0.55 ± 0.43	10.23	1.00	Excellent flow
F6	26.24 ± 0.59	0.58 ± 0.32	0.66 ± 0.35	11.52	1.01	Excellent flow
F7	23.78 ± 0.78	0.48 ± 0.72	0.53 ± 0.18	8.93	1.18	Excellent flow
F8	24.62 ± 0.49	0.59 ± 1.16	0.65 ± 0.36	7.00	1.18	Excellent flow
F9	27.29 ± 0.52	0.52 ± 0.66	0.58 ± 0.63	7.82	1.19	Excellent flow

Surface Morphology

SEM analysis revealed spherical famotidine microballoons with smooth, dense surfaces and highly porous cores (Figs. 6, explaining their excellent buoyancy and controlled drug release properties



.Fig. 9. SEM photographs of range of floating microballoon

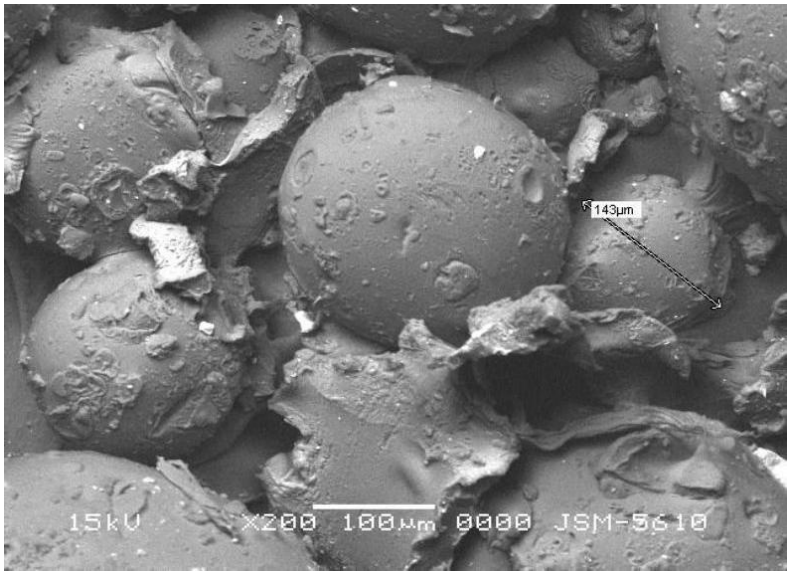


Fig. 10. SEM photographs of smooth texture of floating microballoons

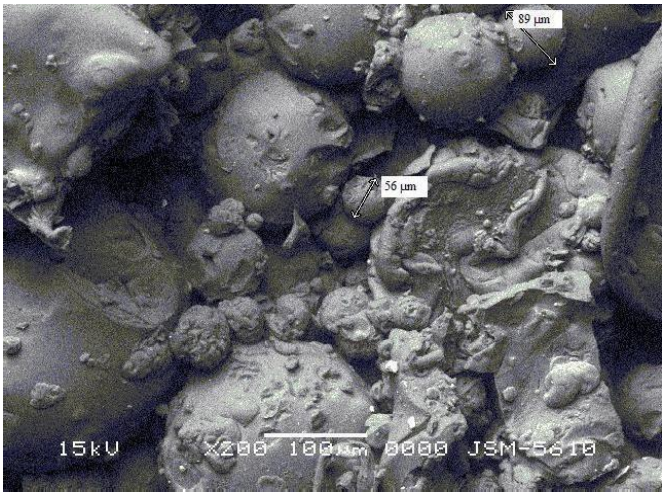


Fig.11. SEM photographs of porous external surface of floating microballoons

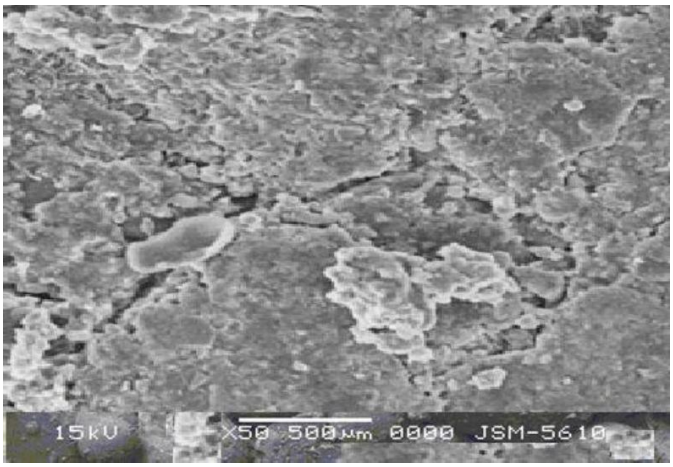


Fig. 12. SEM photographs of porous internal surface of floating microballoon Drug Entrapment Efficiency

Table 9: Drug Encapsulation Efficiency of Famotidine Microballoon Formulations

Formulation	Encapsulation Efficiency (% ± SD)	Performance Classification	Key Influencing Factor
F1	64.14 ± 1.26	Moderate	Base polymer concentration
F2	67.62 ± 1.04	Good	Optimized stirring speed
F3	70.34 ± 0.98	Excellent (Highest)	High HPMC K4M content
F4	67.25 ± 1.36	Good	Balanced composition
F5	69.15 ± 1.73	Excellent	Intermediate polymer ratio
F6	67.63 ± 1.06	Good	Process optimization
F7	66.81 ± 1.22	Good	Stabilized emulsion
F8	65.35 ± 1.91	Moderate	Variable crosslinking
F9	63.47 ± 1.46	Moderate (Lowest)	Minimal polymer content

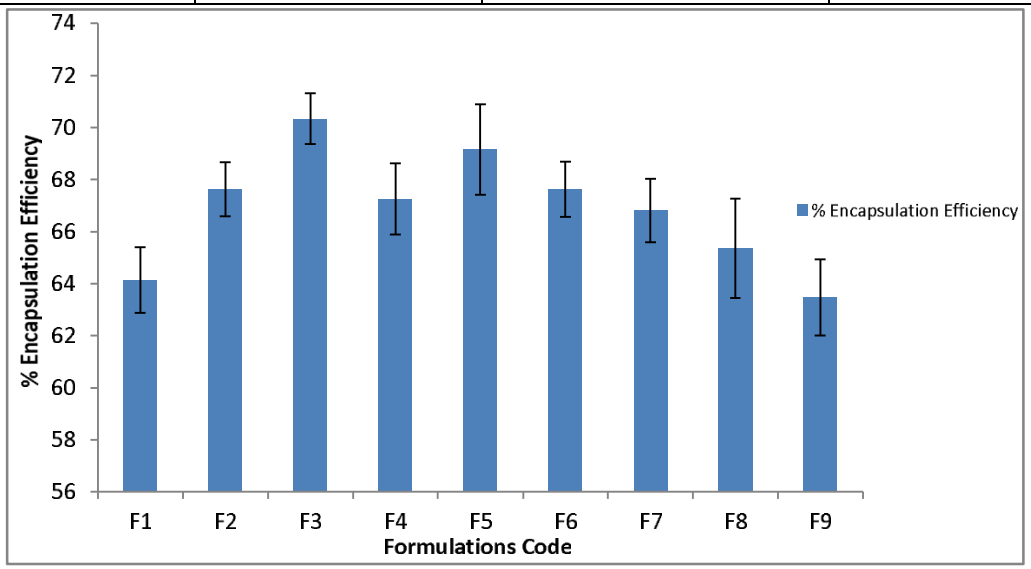


Fig.13.Comparative chart of % encapsulation efficiency of different formulations of famotidine

microballoons

***In-Vitro* Buoyancy Study**

All nine famotidine microballoon formulations (F1-F9) demonstrated sustained 12-hour buoyancy (64.17±1.16% to 83.21±1.07%), with buoyancy increasing proportionally with HPMC K4M concentration and particle size (F3: 160.58±0.73µm, 83.21% buoyancy) but inversely with stirring speed.

Table 10:Buoyancy Profile of Famotidine Microballoon Formulations

Formulation	% Buoyancy (Mean ± SD)	Floating Duration (h)	Key Influencing Factor
F1	68.53 ± 1.96	>12	Moderate porosity
F2	75.45 ± 2.14	>12	Optimized density (0.53 g/cm³)
F3	**83.21 ± 1.07**	**>12**	**Highest porosity + large particle size (160.58 µm)**
F4	65.38 ± 1.76	>12	Lower polymer ratio
F5	74.65 ± 1.08	>12	Balanced excipient blend
F6	80.14 ± 1.14	>12	Enhanced cavity formation
F7	64.17 ± 1.16	>12	Smaller particle size (109.43 µm)
F8	70.52 ± 0.96	>12	Intermediate density
F9	78.61 ± 1.59	>12	High HPMC content

* All values are expressed as mean ± S.D., n =3

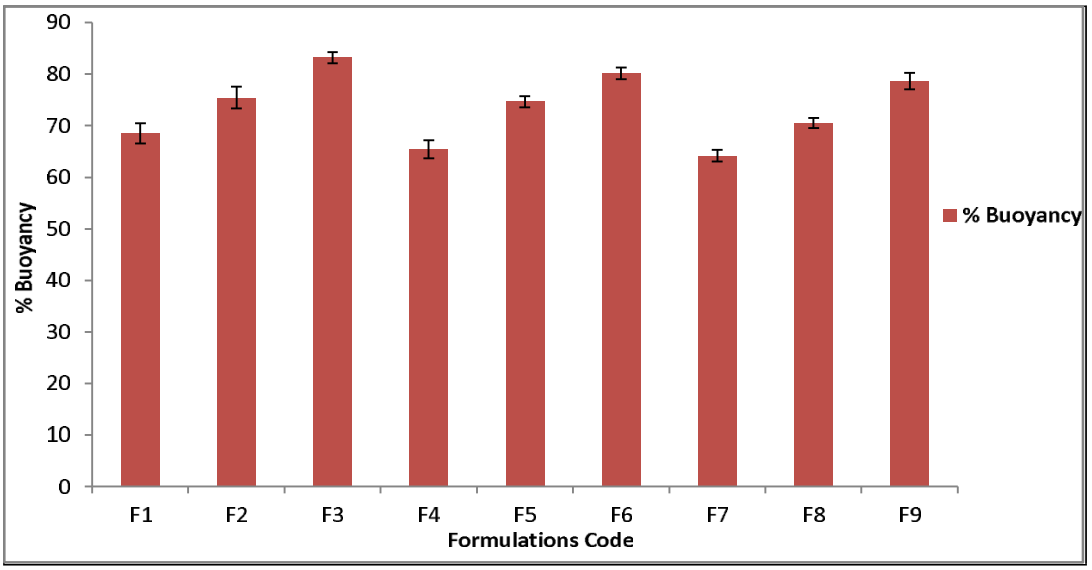


Fig.14. Comparative chart of % buoyancy of different formulations of famotidine microballoons *In-Vitro* Dissolution Study

The in vitro drug release of famotidine-loaded microballoons in 0.1N HCl (pH 1.20) exhibited an initial burst release (≤1 hour) from surface-associated drug, followed by sustained release (Fig. 8. Higher HPMC K4M concentrations reduced release rates by increasing matrix stiffness and diffusional path length, while lower polymer concentrations produced smaller microballoons with faster release due to larger surface area. Increased stirring speed (900-1500 rpm) accelerated release by disrupting microballoon integrity, whereas lower speeds maintained sustained release. Formulations with optimal HPMC K4M content (F3: 160.58µm) demonstrated prolonged release over 12 hours, confirming their gastroretentive potential through combined buoyancy and controlled release mechanisms.

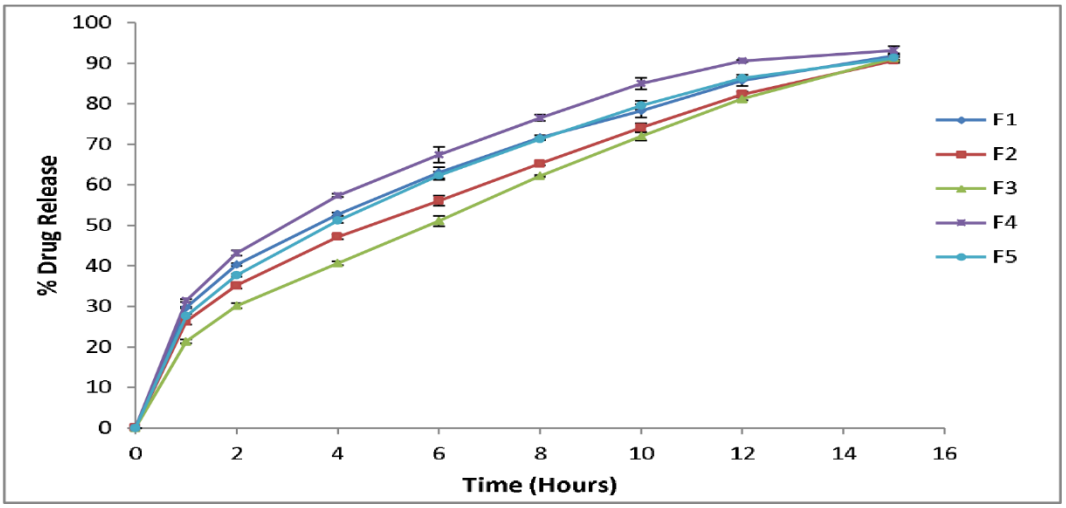


Fig. 15. *In* vitro drug release profile of famotidine microballoons for batch F1 to F5

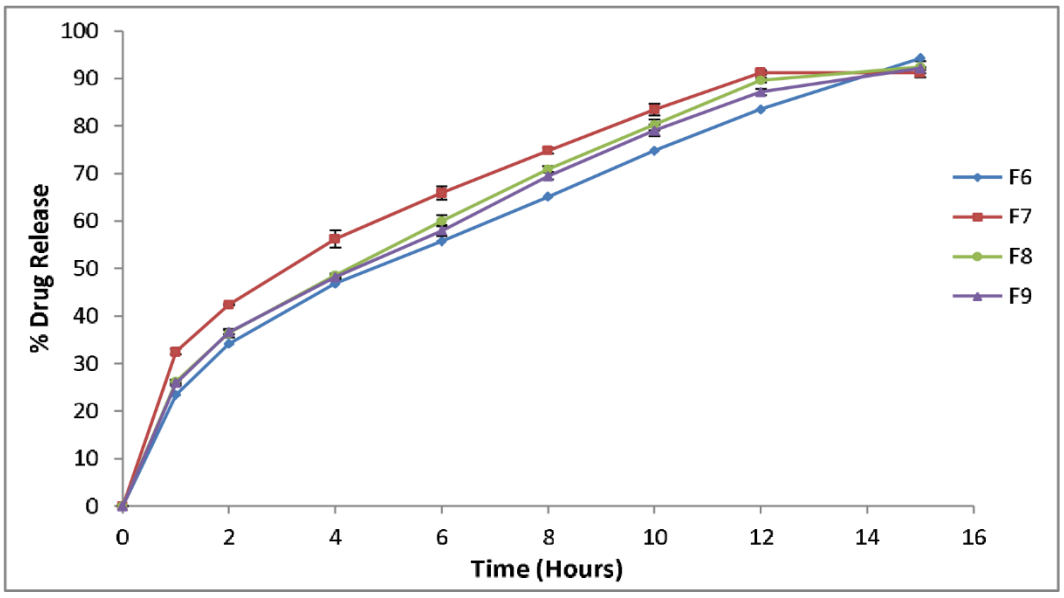


Fig. 16. *In vitro* drug release profile of famotidine microballoons for batch F6 to F9

4. CONCLUSION

Gastroretentive drug delivery systems (GRDDS) for famotidine present a significant advancement in the treatment of peptic ulcer disease (PUD) by overcoming the limitations of conventional dosage forms. The short half-life and rapid gastric transit of famotidine necessitate frequent dosing, which can lead to patient non-compliance and suboptimal therapeutic outcomes. By employing gastroretentive strategies such as floating systems, mucoadhesive formulations, expandable/swellable matrices, and high-density systems, famotidine can be retained in the stomach for prolonged periods, ensuring sustained drug release and enhanced bioavailability.

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