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FORMULATION AND EVALUATION OF GASTRORETENTIVE FLOATING TABLETS OF FAMOTIDINE FOR ENHANCED ANTI-ULCER ACTIVITY

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ABSTRACT

The objective of the present study was to formulate and evaluate gastroretentive floating tablets of Famotidine for prolonged gastric retention and sustained drug release in the treatment of peptic ulcer disease. Floating tablets were prepared using the wet granulation method employing Xanthan gum, Eudragit, and Carbopol 940 as release-retarding polymers and sodium bicarbonate as a gas-generating agent. Preformulation studies including organoleptic characterization, solubility analysis, determination of λmax, calibration curve preparation, and FTIR compatibility studies were carried out. The prepared formulations were evaluated for pre-compression parameters, post-compression parameters, floating behavior, swelling index, in-vitro drug release, and stability studies. Results demonstrated satisfactory flow properties and tablet characteristics. Floating lag time ranged from 30–55 seconds, while total floating time extended up to 18 hours. Formulations F5 and F6 exhibited superior swelling behavior and sustained drug release. Among all formulations, F5 was identified as the optimized formulation due to its balanced floating characteristics, controlled drug release, and stability. The study concluded that gastroretentive floating tablets of Famotidine can effectively prolong gastric residence time and improve therapeutic efficacy in anti-ulcer treatment.

KEYWORDS: Famotidine, Gastroretentive Drug Delivery System, Floating Tablets, Anti-Ulcer Activity, Xanthan Gum, Carbopol 940, Sustained Release.

INTRODUCTION

Peptic ulcer disease is a common gastrointestinal disorder characterized by erosion of the gastric or duodenal mucosa resulting from an imbalance between aggressive factors such as gastric acid, pepsin, and Helicobacter pylori and protective mucosal defenses. Conventional oral dosage forms often exhibit reduced efficacy because of rapid gastric emptying and short residence time in the stomach.

Gastroretentive drug delivery systems (GRDDS) have emerged as an effective approach to enhance gastric residence time, improve bioavailability, and provide sustained drug release. Floating drug delivery systems are among the most widely investigated GRDDS because they remain buoyant in gastric fluid for extended periods and release the drug in a controlled manner.

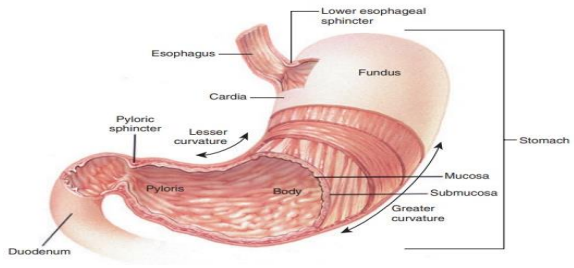

Figure 1: Structure of the Stomach.

Famotidine is a Histamine H_2-receptor antagonist used for the treatment of peptic ulcer disease and gastroesophageal reflux disease. Due to its short biological half-life and absorption characteristics, it is considered a suitable candidate for gastroretentive delivery.

Table 1: Classification of Gastroretentive Drug Delivery Systems.

Type of System	Working Principle
Floating systems	Low density enables buoyancy
Mucoadhesive systems	Adhesion to gastric mucosa
Swelling systems	Increase in size prevents passage
High-density systems	Sink to bottom of stomach
Magnetic systems	External magnetic control

Therefore, the present study aimed to develop floating tablets of Famotidine using hydrophilic polymers to achieve prolonged gastric retention and sustained drug release.

MATERIALS AND METHODS

Materials

1.1 Active Pharmaceutical Ingredient (API)

Famotidine is a Histamine H_2-receptor antagonist widely used in the treatment of peptic ulcer disease, gastroesophageal reflux disease (GERD), and Zollinger–Ellison syndrome. It works by inhibiting the action of histamine on H_2 receptors present in the gastric parietal cells, thereby reducing gastric acid secretion.

1.2 Polymers

- HPMC K4M / HPMC K15M / HPMC K100M
- Carbopol 934P
- Xanthan Gum

1.3 Gas Generating Agents

- Sodium bicarbonate
- Citric acid

1.4 Binders

- PVP K30 (Polyvinylpyrrolidone)
- Starch paste (alternative)

1.5 Diluents

- Microcrystalline Cellulose (MCC)

1.6 Lubricants and Glidants

- Magnesium stearate
- Talc

1.7 Chemicals for Evaluation

- 0.1N HCl (pH 1.2)
- Distilled water

METHODS

A. Preformulation Studies

2.1 Organoleptic Properties

The organoleptic properties of the drug were evaluated to assess its physical characteristics. The color of the drug was visually observed under normal lighting conditions to ensure uniformity and absence of discoloration. The odor of the drug was checked by gentle smelling to identify any characteristic or unpleasant smell. The physical appearance, including texture and crystalline nature, was examined to confirm purity and quality of the

drug sample. These parameters help in preliminary identification and quality assessment of the drug.

2.2 Solubility Study

The solubility of the drug was determined in different solvents to understand its dissolution behavior. An excess amount of drug was added separately to water, 0.1N hydrochloric acid, and phosphate buffer. The mixtures were shaken continuously using a mechanical shaker for a specific period until equilibrium was reached. The solutions were then filtered, and the concentration of dissolved drug was analyzed. This study helps in selecting a suitable dissolution medium and understanding drug release characteristics.

2.3 Determination of λmax

The maximum wavelength (λmax) of the drug was determined using a UV-visible spectrophotometer. The drug was dissolved in 0.1N hydrochloric acid to prepare a suitable solution. The solution was scanned over a wavelength range of 200–400 nm. The wavelength at which maximum absorbance was observed was recorded as λmax. This value is essential for further analytical studies such as calibration curve and drug content estimation.

2.4 Calibration Curve

A calibration curve was prepared to establish a relationship between drug concentration and absorbance. Standard solutions of the drug were prepared in the concentration range of 2–20 µg/ml using 0.1N hydrochloric acid. The absorbance of each solution was measured at the determined λmax using a UV spectrophotometer. This calibration curve was used for quantitative analysis of drug content and dissolution samples.

2.5 Drug–Excipient Compatibility Study

The compatibility between the drug and excipients was studied using Fourier Transform Infrared (FTIR) spectroscopy. Samples of pure drug and physical mixtures of drug with excipients were prepared and analyzed. The FTIR spectra were recorded and compared for characteristic peaks. Any significant shift, disappearance, or appearance of new peaks indicated possible interaction. This study ensures stability and compatibility of the formulation components.

B. Formulation of Floating Tablets

Table No. 1: Composition of the Floating Tablets.

Sr no.	Ingredients	F1	F2	F3	F4	F5	F6
1	Famotidine	20	20	20	20	20	20
2	Xanthan gum	20	20	20	40	40	40
3	Eudragit	10	20	30	10	20	30

4	Carbopol 940	20	20	20	20	20	20
5	Microcrystalline cellulose	95	85	75	75	65	55
6	Sodium bicarbonate	30	30	30	30	30	30
7	Magnesium stearate	3	3	3	3	3	3
8	Talc	2	2	2	2	2	2
9	**Total (mg)**	**200**	**200**	**200**	**200**	**200**	**200**

Method: Wet Granulation Technique

Floating tablets were prepared using the wet granulation method to improve flow and compressibility of the powder blend.

3.1 Preparation of Binder Solution

A binder solution was prepared by dissolving the required quantity of PVP K30 in isopropyl alcohol or distilled water. The solution was stirred continuously until a clear and uniform solution was obtained. This binder solution helps in forming cohesive granules during wet massing.

3.2 Preparation of Granules

In the first step, accurately weighed quantities of drug, polymer, and diluent were passed through sieve #60 to ensure uniform particle size. These ingredients were then mixed thoroughly for about 10 minutes to obtain a uniform dry blend.

In the second step, the binder solution was added slowly to the powder blend with continuous mixing until a cohesive wet mass was formed. Care was taken to avoid overwetting.

The wet mass was then passed through sieve #16 to produce granules of uniform size. These granules were dried in a hot air oven at 40–45°C for 1–2 hours until the moisture content was minimized.

After drying, the granules were passed through sieve #20 to break lumps and obtain uniform granules. The dried granules were then blended with previously dried sodium bicarbonate and citric acid, followed by addition of magnesium stearate and talc. The final blend was mixed gently for 5 minutes.

3.3 Compression of Tablets

The prepared granules were compressed into tablets using a rotary tablet compression machine. The compression force was adjusted to obtain tablets with a hardness of 5–7 kg/cm². Proper compression ensures adequate mechanical strength and floating ability of the tablets.

3. Evaluation of Granules (Pre-Compression Parameters)

3.1 Angle of Repose

The angle of repose was determined by the fixed funnel method to assess the flow property of granules. A funnel was fixed at a certain height above a flat horizontal surface. The granules were allowed to flow freely through the funnel orifice onto the surface, forming a conical heap. Care was taken to ensure that the funnel tip remained at a constant height and the powder flowed without interruption. The height (h) of the formed heap and the radius (r) of its base were measured.

The angle of repose (θ) was calculated using the formula:

$\tan\theta = h/r$

3.2 Bulk Density

Bulk density was determined by transferring a known quantity of granules into a clean, dry graduated measuring cylinder without compacting. The volume occupied by the granules (bulk volume) was noted. The weight of the granules was already known.

Bulk density was calculated using the formula:

Bulk Density=Weight of granules/Bulk volume

3.3 Tapped Density

Tapped density was determined by placing the measuring cylinder containing the granules on a tapped density apparatus. The cylinder was tapped mechanically (usually 500–1000 taps) until no further change in volume was observed. The final tapped volume was recorded.

Tapped density was calculated using the formula:

Tapped Density=Weight of granules/Tapped volume

3.4 Carr's Index

Carr's Index was calculated using the values of bulk density and tapped density obtained from the above experiments.

Carr's Index = [(Tapped density – Bulk density) / Tapped density] × 100

3.5 Hausner Ratio

Hausner ratio was calculated using bulk density and tapped density values.

Hausner Ratio = Tapped density / Bulk density

4. Evaluation of Tablets (Post-Compression Parameters)

4.1 Appearance

- Visual inspection.

4.2 Weight Variation

- 20 tablets weighed individually and average weight calculated.

4.3 Thickness

- Measured using Vernier caliper.

4.4 Hardness

- Measured using Monsanto hardness tester.

4.5 Friability

- Tested using Roche friabilator at 25 rpm for 4 minutes.

4.6 Drug Content Uniformity

- Tablets powdered and analyzed using UV spectrophotometer.

5. Floating Properties Evaluation

A. Floating Lag Time (FLT)

The floating lag time of the prepared tablets was determined using simulated gastric fluid. A tablet was placed gently in a beaker containing 100 ml of 0.1N hydrochloric acid maintained at a temperature of 37 ± 0.5°C. The medium was kept undisturbed to simulate gastric conditions. The time taken by the tablet to rise from the bottom of the beaker to the surface of the dissolution medium was recorded using a stopwatch. This time was noted as the floating lag time (FLT). The test was performed for all formulations, and the average value was calculated. A shorter floating lag time indicates better floating ability and faster buoyancy of the tablet.

B. Total Floating Time (TFT)

The total floating time was determined by observing the duration for which the tablet remained buoyant on the surface of the dissolution medium. After measuring the floating lag time, the tablet was continuously observed in the same medium (0.1N HCl at 37 ± 0.5°C). The total time during which the tablet remained floating without sinking or disintegrating was recorded as the total floating time (TFT).

6. Swelling Study

A tablet from each formulation was accurately weighed (initial weight W_0) and placed in a petri dish containing 0.1N hydrochloric acid maintained at 37 ± 0.5°C. At predetermined time intervals (such as 1, 2, 4, 6, and 8 hours), the tablet was removed carefully from the medium, and excess surface liquid was gently blotted using filter paper to remove adhering fluid without disturbing the swollen matrix. The tablet was then weighed again (final weight Wt).

The swelling index (SI) was calculated using the following formula:

Swelling Index (SI)=Wt−W0/W0×100

7. In-vitro Dissolution Study

Apparatus:

- USP Dissolution Apparatus Type II (Paddle)

Conditions:

- 900 ml dissolution medium
- 0.1N HCl for first 2 hours
- Phosphate buffer pH 6.8 for remaining time
- Temperature: 37 ± 0.5°C
- Speed: 50–75 rpm

Sampling:

- 5 ml samples withdrawn at predetermined intervals (1, 2, 4, 6, 8, 10, 12 hours)
- Replaced with fresh medium
- Analyzed using UV spectrophotometer

8. Stability Studies

- Conducted as per ICH guidelines under:
- 40°C ± 2°C
- 75% ± 5% RH
- Duration: 3 months

Parameters evaluated:

- Drug content
- Hardness
- Dissolution profile

3. RESULTS AND DISCUSSION

A. Preformulation Studies

2.1 Organoleptic Properties

The organoleptic evaluation confirmed that the drug was white to off-white in color, odorless, and present in crystalline powder form, indicating good purity and suitability for formulation development.

Table 1: Organoleptic Properties.

Parameter	Observation
Color	White to off-white
Odor	Odorless
Physical Appearance	Crystalline powder

2.2 Solubility Study

The solubility study revealed that the drug is freely soluble in 0.1N hydrochloric acid, which indicates that it has better solubility in acidic medium. This supports its suitability for gastroretentive and floating drug delivery systems, as the drug will dissolve efficiently in the gastric environment.

Table 2: Solubility Study.

Solvent	Solubility
Water	Slightly soluble
0.1N HCl	Freely soluble
Phosphate buffer (pH 6.8)	Moderately soluble

2.3 Determination of λmax

Table 3: Determination of λmax.

Parameter	Observation
Solvent used	0.1N HCl
λmax	265 nm

2.4 Calibration Curve

Table 4: Calibration Curve Data.

Concentration (µg/ml)	Absorbance
2	0.110
4	0.215
6	0.325
8	0.430
10	0.540

The λmax of the drug was found to be 265 nm in 0.1N HCl, which was used for further analytical studies. The calibration curve showed a linear relationship between concentration and absorbance in the range of 2–20 µg/ml, confirming compliance with Beer-Lambert's law. This ensures accuracy in drug estimation during dissolution and content uniformity studies.

3. Evaluation of Granules (Pre-Compression Parameters)

Table 5: Pre-compression Parameters.

Formulation	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Carr's Index (%)	Hausner Ratio
F1	28	0.42	0.52	19.2	1.23
F2	27	0.43	0.53	18.8	1.22
F3	26	0.44	0.54	18.5	1.21
F4	25	0.45	0.55	18.1	1.20
F5	25	0.46	0.56	17.8	1.19
F6	24	0.47	0.57	17.5	1.19

4. Evaluation of Tablets (Post-Compression Parameters)

Table 6: Post-compression Evaluation.

Formulation	Hardness (kg/cm²)	Friability (%)	Thickness (mm)	Weight (mg)	Drug Content (%)
F1	5.0	0.65	4.2	200	97.8
F2	5.2	0.60	4.3	200	98.5
F3	5.4	0.55	4.4	200	99.0
F4	5.6	0.50	4.5	200	99.5
F5	5.8	0.45	4.6	200	99.2
F6	6.0	0.40	4.7	200	99.0

Post-compression evaluation showed that all tablets possessed acceptable hardness (5–6 kg/cm²) and low friability (<1%), indicating good mechanical strength. Drug content was found to be within acceptable limits (97–99%), confirming uniform distribution of Famotidine.

5. Floating Properties Evaluation

Table 7: Floating Properties.

Formulation	Floating Lag Time (sec)	Total Floating Time (hrs)
F1	55	8
F2	50	10
F3	45	12
F4	40	14
F5	35	16
F6	30	18

The floating study demonstrated that all formulations exhibited good buoyancy. Floating lag time decreased from F1 to F6, which may be due to increased polymer concentration and better entrapment of CO_2 generated by sodium bicarbonate. Total floating time increased

significantly, with F4–F6 showing more than 12 hours of floating, indicating excellent gastroretentive behavior.

6. Swelling Study

Table 8: Swelling Index. (%)

Time (hrs)	F1	F2	F3	F4	F5	F6
1	75	85	95	110	120	130
2	100	120	140	160	180	200
4	130	150	170	200	220	240
6	150	170	190	220	250	270
8	170	190	210	240	270	300

The swelling study revealed that swelling index increased with polymer concentration. Formulations containing higher amounts of Xanthan gum and Eudragit (F4–F6) showed greater swelling due to enhanced water uptake and gel formation. This swelling contributes to prolonged drug release and improved floating behavior.

7. In-vitro Dissolution Study

Table 9: In-vitro Drug Release. (%)

Time (hrs)	F1	F2	F3	F4	F5	F6
1	25	22	20	18	15	12
2	40	35	32	28	25	22
4	60	55	50	45	40	35
6	75	70	65	60	55	50
8	90	85	80	75	70	65
10	100	95	90	85	80	75

In-vitro drug release studies indicated that F1 showed faster drug release, while F6 showed sustained release up to 10 hours. This is due to increased polymer concentration forming a thicker gel barrier, which slows drug diffusion. Formulation F5 and F6 showed the best sustained release profile.

8. Stability Studies

Table 10 Stability Study Results. (Optimized Formulation F5)

Storage Conditions: 40°C ± 2°C / 75% ± 5% RH

Parameter	Initial	1 Month	2 Months	3 Months
Drug Content (%)	99.2	98.9	98.5	98.1
Hardness (kg/cm²)	5.8	5.7	5.6	5.5
% Drug Release at 10 hrs	80	79	78	77

4. CONCLUSION

The present investigation successfully developed gastroretentive floating tablets of Famotidine using Xanthan Gum, Carbopol 940, and Eudragit polymers. The prepared tablets exhibited satisfactory physicochemical properties, prolonged floating behavior, enhanced swelling characteristics, and sustained drug release. Among all formulations, F5 demonstrated the most desirable performance with optimum floating lag time, prolonged floating duration, controlled drug release, and acceptable stability. The developed gastroretentive floating tablet system may provide improved therapeutic efficacy and patient compliance in the management of peptic ulcer disease.

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