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Original Research Article

In-Vitro and In-Vivo Characterization of Famotidine and Domperidone Raft Forming System

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Abstract:

Gastroesophageal reflux disease (GERD) is a common gastrointestinal disorder requiring prolonged and effective drug therapy. The present study aimed to develop and evaluate a raft-forming drug delivery system of Famotidine and Domperidone to enhance gastric retention and improve therapeutic efficacy. The formulation was prepared using the wet granulation method with sodium alginate and pectin as raft-forming polymers, along with Carbopol 934 and HPMC K4M as release-retarding agents. Preformulation studies confirmed compatibility between drugs and excipients, along with acceptable flow properties. The prepared formulations were evaluated for floating behavior, raft strength, swelling index, drug content, and in-vitro drug release. All batches exhibited rapid floating with lag time between 7–15 seconds and prolonged buoyancy exceeding 8–12 hours. Among the formulations, batch F6 demonstrated optimal performance with maximum raft strength and drug content. In-vitro dissolution studies revealed sustained drug release over 12 hours, with cumulative release of 96.85% for Famotidine and 97.10% for Domperidone. In-vivo pharmacokinetic studies in rabbits showed significantly improved bioavailability of the test formulation, with higher Cmax, delayed Tmax, increased AUC, prolonged half-life, and enhanced mean residence time compared to control and reference formulations. The results confirm that the developed raft-forming system effectively enhances gastric retention, provides sustained drug release, and improves the bioavailability of both drugs. Thus, it represents a promising gastro-retentive drug delivery approach for the effective management of GERD.

Keywords: Raft-forming system; Gastro-retentive drug delivery system (GRDDS); Famotidine; Domperidone; GERD; Floating drug delivery; Sustained release; Bioavailability; Pharmacokinetics.

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Introduction

Gastroesophageal reflux disease (GERD) is a prevalent gastrointestinal disorder characterized by the backflow of gastric contents into the esophagus, leading to symptoms such as heartburn, regurgitation, and mucosal irritation. Conventional oral dosage forms often provide limited therapeutic efficacy due to rapid gastric emptying and short residence time in the stomach. To overcome these limitations, gastro-retentive drug delivery systems (GRDDS), particularly raft-forming systems, have emerged as a promising approach for improving drug bioavailability and prolonging gastric residence time. [1-2]

Raft-forming systems are designed to form a viscous, cohesive gel (raft) that floats on the gastric fluid upon contact with acidic pH. This floating gel acts as a physical barrier, preventing reflux of gastric contents into the esophagus while simultaneously providing sustained drug release. The effectiveness of such systems largely depends on their physicochemical properties, gel strength, buoyancy, and drug release characteristics. [3] Famotidine, a histamine H_2 receptor antagonist, is widely used for the treatment of acid-related disorders due to its ability to inhibit gastric acid secretion. Domperidone, a dopamine D_2 receptor antagonist, enhances gastrointestinal motility and accelerates gastric emptying, thereby complementing the action of Famotidine. The combination therapy offers a synergistic effect in the management of GERD by both reducing acid secretion and improving gastric motility. However, both drugs exhibit limitations such as short half-life and reduced bioavailability when administered through conventional dosage forms, necessitating the development of an advanced delivery system. [4]

The development of a raft-forming system containing Famotidine and Domperidone aims to enhance gastric retention, provide localized drug action, and improve therapeutic outcomes. For the successful formulation of such a system,

comprehensive characterization through both in-vitro and in-vivo studies is essential. [5-7] In-vitro characterization plays a critical role in evaluating the formulation's physicochemical properties, including tablet integrity, buoyancy behavior, raft strength, swelling capacity, and drug release profile. Parameters such as floating lag time, total floating duration, acid neutralization capacity, and gel-forming ability provide insight into the formulation's performance in simulated gastric conditions. Additionally, drug release kinetics help in understanding the mechanism of drug release, whether diffusion-controlled, erosion-controlled, or a combination of both.

In-vivo characterization, on the other hand, is essential to establish the pharmacokinetic performance and therapeutic efficacy of the developed system. Animal studies, typically conducted in suitable models such as rabbits, provide valuable data on parameters like peak plasma concentration (Cmax), time to reach peak concentration (Tmax), area under the curve (AUC), and mean residence time (MRT). These parameters help in correlating the in-vitro findings with actual biological performance, thereby establishing an in-vitro–in-vivo correlation (IVIVC). [8-10]

Furthermore, the integration of Quality by Design (QbD) principles in formulation development ensures systematic optimization and robust performance of the raft-forming system. Stability studies under accelerated conditions further confirm the formulation's reliability and shelf-life.

In conclusion, the combined in-vitro and in-vivo characterization of the Famotidine and Domperidone raft-forming system is crucial for evaluating its potential as an effective gastro-retentive drug delivery system. This approach not only enhances drug bioavailability and therapeutic efficacy but also offers a patient-friendly alternative for the management of GERD and related disorders.

Materials and Methods

Materials: Famotidine (H_2 receptor antagonist) and Domperidone (dopamine receptor antagonist) were selected as the active pharmaceutical ingredients for the study. Sodium alginate and pectin were utilized as natural polymers to facilitate raft and gel formation. Carbopol 934 and HPMC K4M were incorporated as viscosity-enhancing and release-retarding agents. Calcium carbonate was included as a gas-generating agent to impart buoyancy, while sodium citrate functioned as a buffering agent for pH regulation. Lactose monohydrate was used as a diluent, whereas Aerosil (colloidal silicon dioxide) and magnesium stearate served as glidant and lubricant, respectively. All solvents and chemicals, including methanol, acetonitrile, ethanol (HPLC/analytical grade), orthophosphoric acid, hydrochloric acid, sodium hydroxide, potassium bromide, and distilled water, were of analytical or HPLC grade.

Preformulation Studies: Preformulation investigations were performed to assess the physicochemical characteristics and compatibility of Famotidine and Domperidone with selected excipients, ensuring the development of a stable formulation. Drug–excipient compatibility was evaluated using Fourier Transform Infrared (FTIR) spectroscopy by analyzing pure drugs, individual excipients, and their physical mixtures over a spectral range of 4000–400 cm^{-1} to identify potential interactions. [11]

The flow behavior of the powder blends was assessed by determining parameters such as angle of repose (using the funnel method), bulk density, tapped density, Hausner's ratio, and Carr's index. Bulk and tapped densities were measured using the graduated cylinder method, and the derived values were used to calculate Hausner's ratio and compressibility index, providing insight into flowability and packing properties. These studies were essential for optimizing the formulation process and ensuring uniformity and stability of the final dosage form.

Formulation Methodology of Raft-Forming System: The tablets were prepared using the wet granulation technique. Precisely weighed quantities of the drug, polymers, and excipients (excluding binder, volatile components, and lubricant) were blended uniformly. Polyvinylpyrrolidone (PVP K30) was dissolved in isopropyl alcohol and gradually incorporated into the powder blend to form a cohesive wet mass. The wet mass was passed through a 22# sieve to produce granules, which were subsequently dried in a hot air oven. The dried granules were then passed through a 40# sieve to obtain uniform particle size distribution. Finally, the remaining excipients, including lubricants, were added and mixed thoroughly. The prepared granules were compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches (Table 1.) [12-14]

Table 1: Formulation Composition

Ingredient	Range (mg)	Function
Famotidine	20	Anti-ulcer agent
Domperidone	10	Prokinetic agent
Sodium Alginate	75 – 150	Raft-forming polymer
Pectin	50 – 150	Gel-forming agent
Calcium Carbonate	30	Gas-generating agent
Carbopol 934	40	Viscosity enhancer
HPMC K4M	40	Release retardant
Sodium Citrate	20	Buffering agent
Aerosil (Colloidal Silicon Dioxide)	5	Glidant
Magnesium Stearate	5	Lubricant
Lactose Monohydrate	30 – 205	Diluent
Total Weight	**500 mg**	—

Evaluation of Raft Forming System [15-18]

In-vitro Floating Behavior: The floating characteristics of the tablets were evaluated in simulated gastric fluid (0.1 N HCl). The floating lag time (FLT), defined as the time taken for the tablet to rise to the surface, and the total floating time (TFT), defined as the duration for which the tablet remained buoyant, were recorded visually by placing the tablet in a beaker containing 100 mL of the medium.

Raft (Gel) Strength: The strength of the formed raft was determined using an L-shaped wire probe method. A tablet equivalent dose was introduced into 150 mL of 0.1 N HCl maintained at 37°C in a 250 mL beaker. The raft was allowed to form around the probe for 30 minutes. The force required to break the formed gel structure was recorded as an indicator of raft strength, reflecting the integrity and robustness of the gel barrier.

Swelling Index: The swelling behavior of the tablets was studied in 0.1 N HCl (pH 1.2) at 37 ± 0.5°C. Tablets were initially weighed (W_0) and then immersed in the medium. After a specified time period (8 hours), the tablets were removed, excess surface moisture was carefully blotted, and the final weight (W_t) was recorded. The swelling index was calculated using the formula: Swelling Index = $[(W_t - W_0)/W_0] \times 100$. This parameter indicates the hydration capacity and gel-forming ability of the polymers.

Drug Content Analysis: The drug content of Famotidine and Domperidone in the formulated tablets was determined using a validated High-Performance Liquid Chromatography (HPLC) method. A Phenomenex C18 column (250 mm × 4.6 mm, 5 µm) was used, with a mobile phase consisting of methanol and 0.1% orthophosphoric acid in a ratio of 55:45 (v/v), at a flow rate of 1.0 mL/min. Detection was carried out at 280 nm. The mobile phase was filtered and sonicated prior to use. Standard and sample solutions were prepared, and drug content was calculated based on peak area.

In-vitro Dissolution Study: The in-vitro drug release study was performed using USP Apparatus II (paddle method). The dissolution medium consisted of 900 mL of simulated gastric fluid (0.1 N HCl, pH 1.2) maintained at 37 ± 0.5°C, with a paddle rotation speed of 50 rpm. A tablet equivalent was introduced into the medium, and samples of 10 mL were withdrawn at predetermined time intervals, filtered, and analyzed using HPLC at 280 nm. An equal volume of fresh dissolution medium was replaced after each sampling to maintain sink conditions. The cumulative percentage drug release was calculated to evaluate the release profile of the formulation.

In Vivo Pharmacokinetic Study: The in vivo pharmacokinetic evaluation of the raft-forming system containing Famotidine and Domperidone was conducted using twelve healthy male rabbits (2.0–2.5 kg). Animals were acclimatized for one week under controlled environmental conditions (20 ± 2°C, 50 ± 10% RH, 12 h light/dark cycle) with free access to food and water. The study was designed as a single-dose experiment, and animals were randomly divided into three groups (n = 4): test formulation (raft-forming system), reference formulation (marketed tablet suspension), and control (aqueous drug solution).

Following overnight fasting (12 h), formulations were administered orally, and food was provided 4 hours post-dosing. Blood samples (~1.5 mL) were collected from the marginal ear vein at predetermined intervals (0–24 h) into heparinized tubes. Plasma was separated by centrifugation at 3500 rpm for 10 min at 4°C and stored at –80°C until analysis.

Drug concentrations were determined using a validated HPLC method with UV/PDA detection. Pharmacokinetic parameters, including Cmax, Tmax, $AUC_{0–t}$, $AUC_{0–\infty}$, half-life, and mean residence time, were calculated using non-compartmental analysis. Statistical analysis was performed using ANOVA, with $p < 0.05$ considered significant. All procedures were

conducted in accordance with institutional animal ethics guidelines.

Results and Discussion

Post Evaluation of Raft Forming System

Table 2: Post Evaluation of Raft Forming System batches (F1 To F9)

Batch	Floating Lag Time (sec)	Floating Time	Raft/Gel Strength (N/m²)	Drug Content (%) Famotidine	Drug Content (%) Domperidone
F1	13	>8 hr	4.28	92.85	93.42
F2	15	>8 hr	4.31	93.98	93.56
F3	11	>9 hr	5.05	94.22	94.10
F4	9	>12 hr	5.78	96.12	95.96
F5	14	>12 hr	5.69	97.35	96.18
F6	7	>12 hr	6.52	97.96	97.84
F7	9	>10 hr	5.15	94.88	94.35
F8	11	>10 hr	5.32	95.36	94.62
F9	8	>11 hr	5.71	95.18	95.26

The floating lag time (FLT) of all batches was found to be between 7 to 15 seconds, indicating rapid buoyancy due to effective gas generation. The total floating time (TFT) for all formulations exceeded 8 hours, with some batches showing buoyancy up to 12 hours, confirming excellent floating behavior and prolonged gastric retention.

The raft (gel) strength values were observed between 4.28 to 6.52 N/m², reflecting the ability of the formed gel to withstand mechanical stress in the gastric environment.

The drug content for both Famotidine and Domperidone across all batches was found to be within acceptable limits (approximately 92% to 98%), indicating uniform distribution of drug within the formulation.

Among all formulations, batch F6 exhibited comparatively superior performance, with optimum viscosity, highest raft strength, excellent floating behavior, and maximum drug content. The higher polymer concentration in this batch contributed to enhanced gel formation, prolonged floating time, and improved overall performance.

In-vitro Dissolution Studies: The in-vitro drug release study of the raft forming system was carried out to evaluate the release behavior of Famotidine and Domperidone from different formulation batches (F1–F9) in simulated gastric fluid (pH 1.2). The study was conducted for 12 hours to assess the sustained release characteristics of the formulations. (Table 3 & 4, Figure 1 & 2)

Table 3: In-Vitro Drug Release of Famotidine

Batch	Cumulative Drug Release at 1 hr	Cumulative Drug Release at 2 hr	Cumulative Drug Release at 4 hr	Cumulative Drug Release at 8 hr	Cumulative Drug Release at 10 hr	Cumulative Drug Release at 12 hr
F1	23.88 ± 0.210	42.75 ± 0.150	57.68 ± 1.180	75.94 ± 0.540	87.92 ± 1.300	94.12 ± 0.710
F2	25.90 ± 0.220	34.10 ± 0.130	55.72 ± 0.700	72.88 ± 1.200	88.75 ± 1.690	93.05 ± 0.940
F3	26.74 ± 0.500	38.10 ± 0.500	57.95 ± 0.320	78.20 ± 1.480	86.25 ± 1.400	92.90 ± 0.320
F4	21.95 ± 0.210	37.80 ± 0.400	58.60 ± 1.690	71.45 ± 0.710	85.10 ± 1.650	92.10 ± 0.820
F5	24.10 ± 0.420	34.80 ± 0.120	56.20 ± 0.420	70.85 ± 1.290	82.90 ± 1.470	94.30 ± 0.520
F6	28.80 ± 0.510	40.95 ± 0.230	55.10 ± 0.690	78.60 ± 0.880	86.40 ± 0.790	96.85 ± 0.690
F7	19.80 ± 0.520	37.60 ± 0.580	57.90 ± 0.480	77.95 ± 0.520	83.80 ± 0.210	95.10 ± 0.800
F8	30.25 ± 0.910	44.90 ± 0.220	65.20 ± 1.280	74.65 ± 1.850	80.75 ± 0.700	93.60 ± 0.320
F9	29.90 ± 1.420	46.60 ± 0.290	57.85 ± 1.180	72.95 ± 0.880	83.75 ± 0.600	92.95 ± 0.700

Table 4: In-Vitro Drug Release of Domperidone

Batch	Cumulative Drug Release at 1 hr	Cumulative Drug Release at 2 hr	Cumulative Drug Release at 4 hr	Cumulative Drug Release at 8 hr	Cumulative Drug Release at 10 hr	Cumulative Drug Release at 12 hr
F1	35.82 ± 0.150	43.80 ± 0.690	54.10 ± 1.550	74.95 ± 0.700	86.10 ± 0.420	95.90 ± 0.540
F2	34.95 ± 0.160	54.60 ± 0.600	65.40 ± 1.680	82.75 ± 0.150	92.85 ± 1.180	93.20 ± 0.880
F3	35.90 ± 0.180	46.90 ± 0.540	53.20 ± 1.690	75.95 ± 0.310	86.70 ± 0.430	94.80 ± 0.680
F4	32.80 ± 0.250	45.80 ± 0.690	53.75 ± 1.580	72.80 ± 0.150	86.10 ± 0.690	94.30 ± 0.820
F5	36.10 ± 0.600	57.90 ± 0.780	64.95 ± 1.280	86.95 ± 0.580	91.80 ± 0.450	92.90 ± 0.210
F6	34.90 ± 0.500	47.95 ± 0.620	52.90 ± 1.200	73.80 ± 0.580	82.10 ± 0.900	97.10 ± 0.250
F7	38.20 ± 0.090	54.80 ± 0.700	66.95 ± 1.480	80.95 ± 0.150	92.80 ± 1.400	94.00 ± 0.500

F8	32.95 ± 0.600	46.90 ± 0.350	54.70 ± 0.340	72.85 ± 0.580	89.10 ± 1.320	94.80 ± 0.120
F9	34.90 ± 0.210	42.60 ± 0.320	56.10 ± 0.200	74.10 ± 0.420	87.90 ± 0.300	93.10 ± 0.250

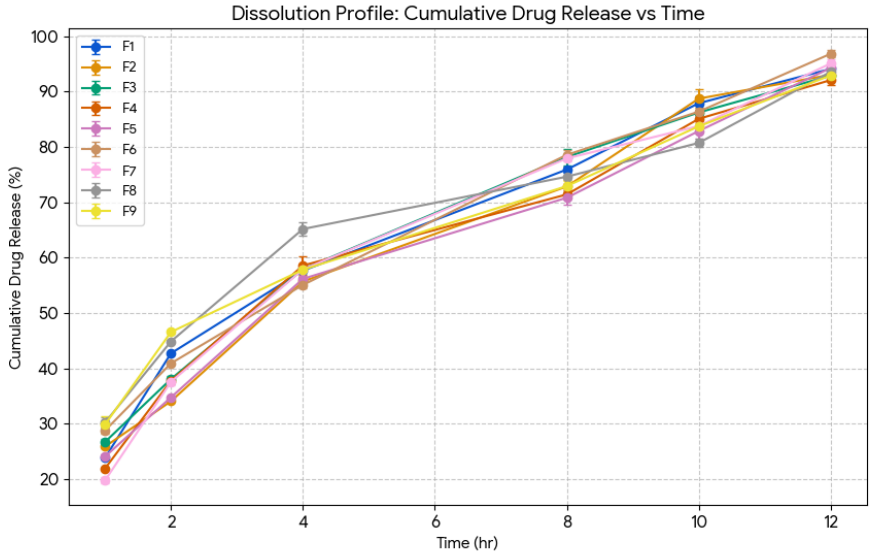

Figure 1: Dissolution Profile of Famotidine

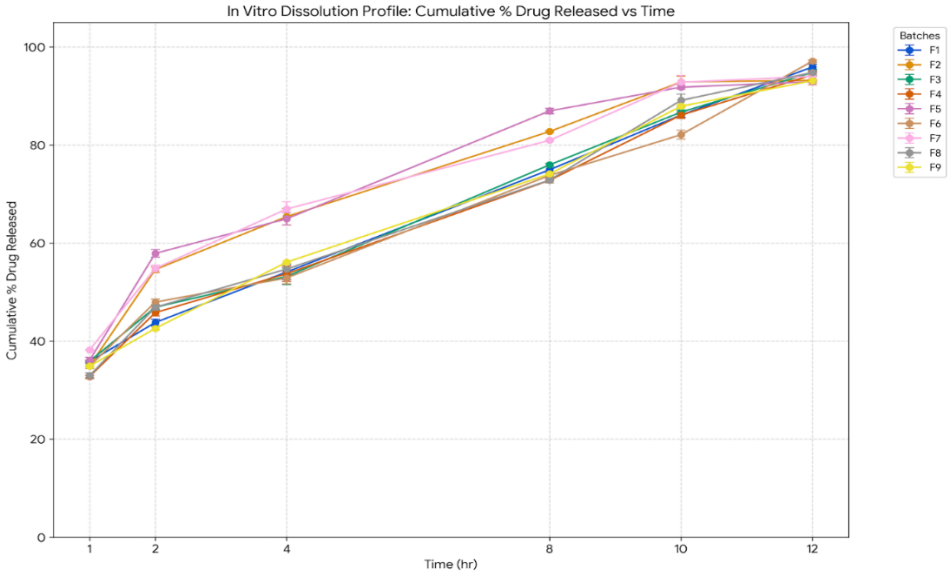

Figure 2: Dissolution Profile of Domperidone

Drug Release Behavior of Famotidine: All formulations exhibited a controlled and sustained release profile over 12 hours. The cumulative drug release for Famotidine ranged from approximately 92.10% to 96.85% at the end of 12 hours. Initial drug release (1 hour) was observed between 19.80% and 30.25%, indicating a moderate burst release which is beneficial for achieving therapeutic concentration quickly.

Among all batches, F6 showed the highest cumulative drug release (96.85%) at 12 hours, followed by F7 and F5. The sustained release behavior observed can be attributed to the presence of hydrophilic polymers such as sodium alginate and pectin, which form a gel barrier controlling drug diffusion.

Batches containing higher polymer concentration exhibited relatively slower release rates due to increased gel viscosity and diffusion path length. Conversely, formulations with lower polymer content showed comparatively faster drug release.

Drug Release Behavior of Domperidone: The release pattern of Domperidone also demonstrated sustained drug release, with cumulative release ranging from 92.90% to 97.10% over 12 hours. The initial release at 1 hour ranged from 32.80% to 38.20%, which is slightly higher compared to Famotidine, possibly due to differences in

solubility and drug-polymer interaction. Batch F6 again showed the highest drug release (97.10%) at 12 hours, indicating its superior formulation characteristics. Other batches such as F1 and F3 also exhibited satisfactory release profiles.

The slightly slower release of Domperidone in some batches can be attributed to its poor aqueous solubility, which limits its dissolution rate. However, the raft forming system effectively enhanced its release by maintaining prolonged gastric residence time.

In Vivo Pharmacokinetic Study – Results and Discussion: The plasma concentration–time profile showed significant differences among control, reference, and test formulations. The raft-forming system exhibited higher Cmax, delayed Tmax, and prolonged plasma drug levels, indicating sustained release and enhanced gastric retention. (Table 5 & 6)

Table 5: Pharmacokinetic Parameters of Famotidine

Parameter	Control	Reference	Test (Raft System)
Cmax (ng/mL)	185.4 ± 6.2	242.6 ± 8.4	318.9 ± 10.5
Tmax (hr)	1.0 ± 0.0	1.5 ± 0.2	2.5 ± 0.3
$AUC_{0–t}$ (ng·hr/mL)	820.5 ± 25.3	1125.7 ± 30.6	1584.3 ± 42.8
$AUC_{0–\infty}$ (ng·hr/mL)	910.2 ± 28.7	1210.6 ± 34.5	1675.2 ± 45.6
t½ (hr)	2.4 ± 0.3	3.1 ± 0.4	4.8 ± 0.5
MRT (hr)	3.2 ± 0.4	4.1 ± 0.5	6.3 ± 0.6

Table 6: Pharmacokinetic Parameters of Domperidone

Parameter	Control	Reference	Test (Raft System)
Cmax (ng/mL)	142.3 ± 5.8	198.7 ± 7.2	276.4 ± 9.3
Tmax (hr)	0.75 ± 0.1	1.25 ± 0.2	2.0 ± 0.2
$AUC_{0–t}$ (ng·hr/mL)	640.8 ± 20.6	910.5 ± 28.1	1325.7 ± 36.4
$AUC_{0–\infty}$ (ng·hr/mL)	710.4 ± 22.3	980.2 ± 30.4	1402.6 ± 39.2
t½ (hr)	2.1 ± 0.2	2.8 ± 0.3	4.2 ± 0.4
MRT (hr)	2.9 ± 0.3	3.8 ± 0.4	5.6 ± 0.5

The test formulation demonstrated improved bioavailability, with increased Cmax for Famotidine (318.9 ng/mL) and Domperidone (276.4 ng/mL) compared to control. The delayed Tmax (2.5 h and 2.0 h, respectively) confirmed controlled drug release. Higher AUC values indicated enhanced drug absorption, while increased half-life and mean residence time (MRT) suggested prolonged systemic circulation. These improvements are attributed to raft formation, prolonged gastric retention, and controlled drug diffusion. The raft-forming system significantly enhanced bioavailability and sustained release of both drugs, demonstrating its effectiveness as a gastro-retentive drug delivery system.

Conclusion

The present study successfully developed and evaluated a raft-forming drug delivery system of Famotidine and Domperidone aimed at improving gastric retention and therapeutic efficacy in the management of gastroesophageal reflux disease (GERD). The formulation demonstrated satisfactory physicochemical properties, indicating its suitability for oral administration. In-vitro evaluation confirmed rapid gel formation, desirable floating behavior, sufficient raft strength, and sustained drug release over an extended period. The optimized formulation exhibited controlled drug release kinetics, ensuring prolonged availability of the drugs in the gastric environment. In-vivo pharmacokinetic studies revealed a significant enhancement in bioavailability, as evidenced by increased Cmax and AUC, along with delayed Tmax, prolonged half-life, and increased mean residence time. These findings clearly indicate improved gastric retention and sustained drug release from the raft-forming system. Overall, the developed raft-forming system proved to be an effective gastro-retentive drug delivery approach for Famotidine and Domperidone, offering improved therapeutic performance and potential for enhanced patient compliance. This study supports the application of raft-forming systems as a promising strategy for the treatment of GERD and related acid reflux disorders.

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