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Formulation and Evaluation of Oral Thin Film of Drug for Gastroesophageal Reflux Disease (GERD)

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Abstract:

The present investigation focused on the formulation and assessment of fast-dissolving oral thin films (OTFs) incorporating Famotidine and Domperidone for improved therapeutic management of gastroesophageal reflux disease (GERD). Comprehensive analytical evaluation of the drugs was carried out through organoleptic examination, Fourier Transform Infrared (FTIR) spectroscopy, ultraviolet spectrophotometry, melting point analysis, solubility studies, and HPLC analysis, confirming the authenticity, purity, and suitability of the drugs for formulation development. Compatibility studies indicated the absence of any significant interaction between the active pharmaceutical ingredients and selected excipients. The oral thin films were prepared using the solvent casting technique with Hypromellose and Polyvinyl Alcohol serving as film-forming agents, while Polyethylene Glycol 400 was utilized as a plasticizer to enhance flexibility and film integrity. The developed formulations were characterized for various quality control parameters including film thickness, uniformity of weight, folding endurance, surface pH, tensile strength, disintegration behavior, drug content, and in-vitro dissolution performance. The optimized batch demonstrated satisfactory mechanical properties, consistent film dimensions, excellent drug distribution, and rapid disintegration in less than 15 seconds. In-vitro release studies showed that both Famotidine and Domperidone were released rapidly, with cumulative drug release exceeding 97% within 25 minutes, and the release pattern predominantly followed first-order kinetics. The developed oral thin films exhibited desirable stability, ease of handling, and the advantage of administration without the need for water, making them particularly beneficial for patients experiencing swallowing difficulties or requiring convenient on-demand therapy. Overall, the study highlights the potential of Famotidine and Domperidone-loaded OTFs as an effective and patient-compliant alternative dosage form capable of delivering rapid symptomatic relief in GERD management, with promising prospects for future large-scale production and clinical utilization.

Keywords: Oral Thin Films (OTFs), Famotidine, Domperidone, Drug Delivery, Bioavailability, Rapid Disintegration, Drug Release.

Introduction

The advancement of novel drug delivery technologies has gained considerable importance in modern pharmaceutical research to overcome the limitations associated with conventional oral dosage forms such as tablets and capsules. Among the various approaches explored, oral thin films (OTFs) have attracted significant attention as an efficient and patient-friendly delivery system because of their rapid dissolution, convenience of administration, and improved therapeutic compliance. These thin polymeric films are designed to disintegrate quickly upon contact with saliva in the oral cavity, eliminating the need for water during administration. In addition to ease of use, OTFs offer advantages such as accurate dosing, rapid onset of action, avoidance of swallowing difficulties, and the possibility of enhancing drug absorption and bioavailability for drugs exhibiting poor aqueous solubility.[1] Famotidine and Domperidone are commonly prescribed agents for the treatment of various gastrointestinal disorders. Famotidine acts by suppressing gastric acid secretion, thereby providing relief from acid-related conditions, while Domperidone improves gastrointestinal motility and effectively controls nausea and vomiting through dopamine receptor antagonism. Despite their therapeutic utility, conventional dosage forms of these drugs are often associated with challenges such as delayed onset of action, poor patient adherence, and variable oral absorption. These issues become more prominent among pediatric, geriatric, and dysphagic patients who may experience difficulty in swallowing traditional solid dosage forms.[2-4] The present investigation was therefore undertaken to formulate and evaluate oral thin films containing Famotidine and Domperidone with the objective of developing a rapidly disintegrating and mechanically stable dosage system. The formulation strategy was designed to utilize the advantages of oral thin film technology for improving drug delivery efficiency and patient convenience. Different formulation variables including film-forming polymers, plasticizers, and emulsifying agents were carefully optimized to achieve suitable film flexibility, mechanical strength, rapid drug release, and acceptable physicochemical characteristics. [5]

Comprehensive evaluation of the prepared oral thin films was carried out using various physicochemical and in-vitro assessment parameters such as film thickness, weight uniformity, folding endurance, surface pH, swelling behavior, disintegration time, and drug content uniformity.

Furthermore, in-vitro dissolution studies were performed to determine the release behavior of Famotidine and Domperidone and to examine the influence of formulation components on drug release characteristics. The outcomes of this research are expected to support the expanding application of oral thin film technology and demonstrate its potential as an effective alternative platform for the delivery of gastrointestinal therapeutic agents.[6]

Methodology

Materials, Chemicals, and Reagents

The materials, chemicals, and reagents used in this study included Famotidine and Domperidone as active pharmaceutical ingredients (APIs). Hypromellose, Carbomer 974 (Carbopol), and Polyvinyl Alcohol were utilized as film-forming agents, with Hypromellose also serving as an emulsifier

and plasticizer. Glycerin acted as a plasticizer, while Benzoic Acid and Sodium Benzoate were used as preservatives. Citric Acid was included as a pH-adjusting agent, and sweeteners such as Sucrose and Sucralose were incorporated for palatability. Sodium Lauryl Sulfate was employed as a surfactant, and Clove served as a flavoring agent. Beta-Cyclodextrin was used as a complexing agent, whereas Crosscarmellose Sodium and Crospovidine functioned as superdisintegrants. Purified water was used as the vehicle throughout the study.

Equipment and Instruments

Various equipment and instruments were employed to carry out the research. An electronic balance (Effem, OHAUS) was used for precise weighing, and a mechanical sifter (Sartorius, Bangalore, India) with sieves (#20, #30, #40, #60) was used for particle size analysis. Stainless steel SS 316 vessels (Electrolab, Bangalore, India) were utilized for material handling, and a hot plate (Effem) along with a mechanical stirrer (Effem, Remi Motor Pvt. Ltd.) facilitated the preparation of formulations. A digital pH meter (Lab India) was used for pH measurement, and a magnetic stirrer (Equitron) ensured uniform mixing. The viscosity of solutions was measured using a viscometer (Brookfield), and film thickness was determined using a Vernier caliper and thickness gauge (both from Sunshine Instruments). High-performance liquid chromatography (HPLC) analysis was conducted using a Waters system, while UV-visible spectroscopy was performed with a Shimadzu spectroscope. Thermal analysis and molecular characterization were carried out using a differential scanning calorimeter (DSC 60) and an FTIR spectrometer (FTIR 1800), both from Shimadzu, Japan.

Evaluation and Characterization of Drugs [7-8]

The study employed analytical and preformulation evaluations for Famotidine and Domperidone. Organoleptic properties, including color, odor, and powder type, were visually assessed. Drug identification was performed using FTIR spectroscopy with KBr pellet method and UV spectroscopy (10 ppm solutions in 0.1 N HCl scanned between 200–400 nm). Melting point was determined via the capillary method using Thiele's tube, while solubility studies were conducted in various solvents (water, alcohol, acetonitrile) and buffer solutions (pH 1.2, 6.8) under equilibrium conditions, with analysis by UV spectrophotometry. Drug content was quantified by HPLC using a Phenomenex C18 column with methanol:0.1% orthophosphoric acid (55:45 v/v) as the mobile phase at 1.0 mL/min and detection at 280 nm. Standard calibration curves were constructed from serial dilutions of standard drug solutions. Preformulation studies included drug–excipient compatibility analysis via FTIR spectroscopy and pH compatibility testing by measuring the pH of 1:1 aqueous mixtures of drug and excipients.

Preparation of Oral Thin Films (OTFs):[9-10]

The solvent casting method was employed due to its simplicity and cost-effectiveness.Firstly the water-soluble polymers are dissolved in water at 1,000 rpm and they were heated up to 60°C. All the other excipients like colors, flavoring agent, sweetening agent, etc., are dissolved separately.

Then both the solutions obtained are mixed thoroughly stirring at 1,000 rpm. The obtained solution is incorporated with the API dissolved in suitable solvent. The entrapped air is removed by vacuum. The resulting solution is cast as a film and allowed to dry, which is then cut into pieces of the desired size.

Table 1: Formulation of Oral Thin Film

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1.	Famotidine	20	20	20	20	20	20	20	20	20	20
2.	Domperidone	10	10	10	10	10	10	10	10	10	10
3.	Hypromellose	10	15	5	20	--	--	20	10	--	15
4.	Carbomer 974	10	5	15	--	20	20	--	10	10	5
5.	Polyethylene Glycol	10	15	5	20	--	15	--	--	10	10
6.	Polyvinyl Alcohol	10	5	15	--	20	--	15	10	--	10
7.	Benzoic Acid	10	15	5	20	--	20	--	10	10	20
8.	Sodium Benzoate	10	5	15	--	20	--	20	--	10	--
9.	Citric Acid	2	1	1	2	2	1	2	2	2	1
10.	Sucrose	1	2	1	2	1	2	1	1	1	2
11.	Crosscarmellose Sodium	5	5	5	5	5	5	5	5	5	5
12.	Polyplasdone	3	3	3	3	3	3	3	3	3	3
13.	Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Total (mg)		100	100	100	100	100	100	100	100	100	100

Evaluation of Oral Thin Films (OTFs): [11-15]

- **Physical Appearance:** OTFs were visually and sensually evaluated for color, homogeneity, transparency, smell, texture, taste, and flavor.
- **Folding Endurance:** Films were folded repeatedly at the same spot until they broke, with the number of folds recorded as folding endurance.
- **Swelling Property:** Films were weighed and immersed in pH 6.8 buffer, and the increase in weight was measured at intervals until constant weight was achieved.
- **Drug Content:** HPLC was used to determine drug content under specified chromatographic conditions (detection at 284 nm, run time of 20 min).
- **In-vitro Disintegration Studies:** Disintegration time was measured in water or buffer, typically ranging from 5 to 30 seconds, depending on formulation content.
- **Dissolution Studies:** Dissolution rates were assessed in 900 ml pH 6.8 buffer at 37°C ± 1°C using a USP basket apparatus at 50 rpm, with samples analyzed at regular intervals.

Results and Discussion

Analytical Evaluation of Drug API

Appearance

The appearance of the drugs was consistent with their expected forms: Famotidine appeared as a white powder, while Domperidone was observed as a fine white powder, indicating the purity of the drugs.

Identification Tests

Identification of Famotidine and Domperidone was performed using Infrared (IR) Spectroscopy and UV absorbance spectra.

IR Spectroscopy: The IR spectrum of Famotidine (Figure 1.1) revealed characteristic peaks at 3445.22 cm^{-1} (O-H stretching), 1726 cm^{-1} (C=O stretching), and 1515.71 cm^{-1} (Aromatic C=C stretching), among others, confirming its identity.

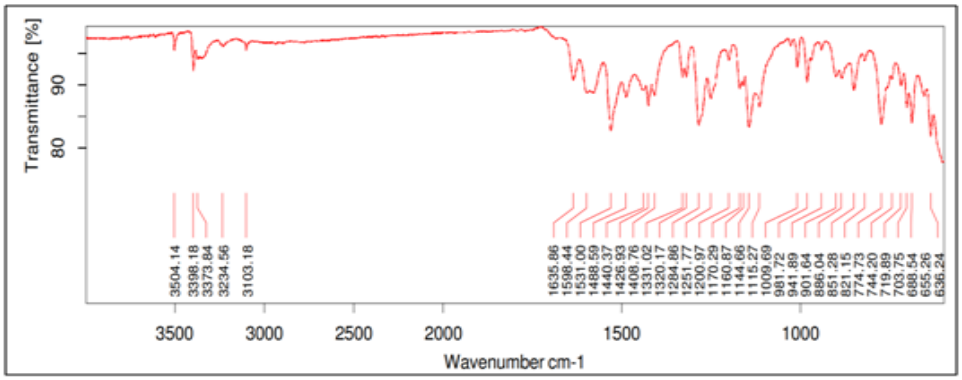

Figure 1: IR Spectra of Famotidine

For Domperidone (Figure 1.2), the prominent peaks at 2953 cm^{-1} (C-H stretching), 1662 cm^{-1} (C=O stretching), and 1557 cm^{-1} (Aromatic C=C stretching) were observed, supporting its structural identity.

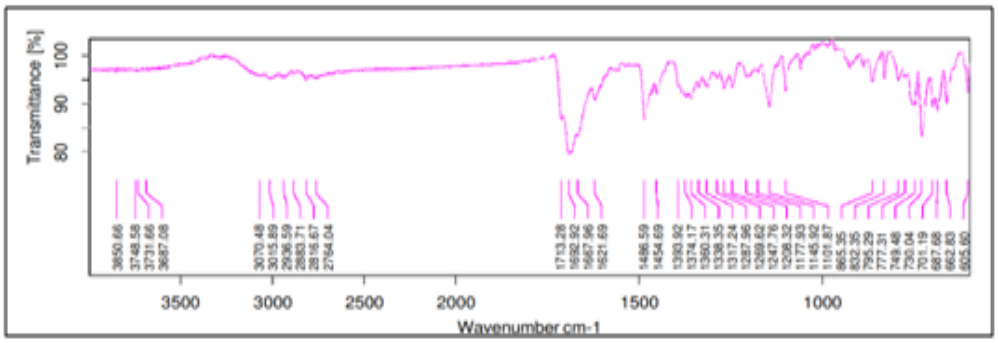

Figure 2: IR Spectra of Domperidone

UV Spectroscopy: Famotidine exhibited a λmax at 287 nm (Figure 1.3), which corresponds to its known absorbance, confirming its identity.

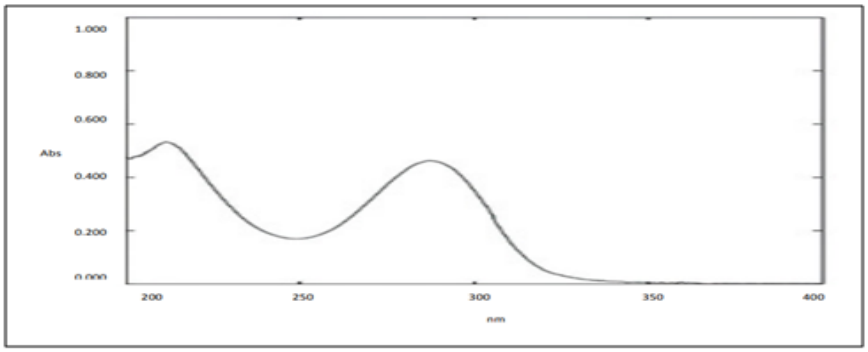

Figure 3: UV Spectra of Famotidine

Domperidone showed a λmax at 285 nm (Figure 1.4), which is characteristic of the drug and supports its identification. The UV spectra of both drugs displayed distinct absorption peaks, useful for quality control purposes.

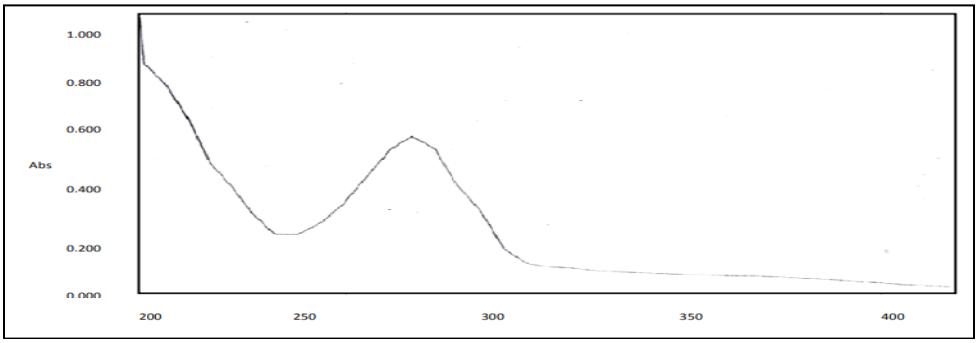

Figure 4: UV Spectra of Domperidone

Solubility

Famotidine and Domperidone were tested for solubility in various solvents.

- Famotidine was sparingly soluble in water, soluble in methanol and pH 1.2 buffer, and slightly soluble in pH 6.8 buffer.
- Domperidone, on the other hand, was practically insoluble in water, slightly soluble in methanol, and soluble in both pH 1.2 and pH 6.8 buffers.

Melting Point

The observed melting points for Famotidine (154.8°C) and Domperidone (241.9°C) matched the reported values, confirming the purity of both drugs.

HPLC Analysis

The purity of Famotidine (99.24%) and Domperidone (99.76%) was evaluated using High-Performance Liquid Chromatography (HPLC) (Figures 1.5 and 1.6). Both drugs were within the acceptable purity range, indicating minimal impurities and confirming their pharmaceutical-grade quality.

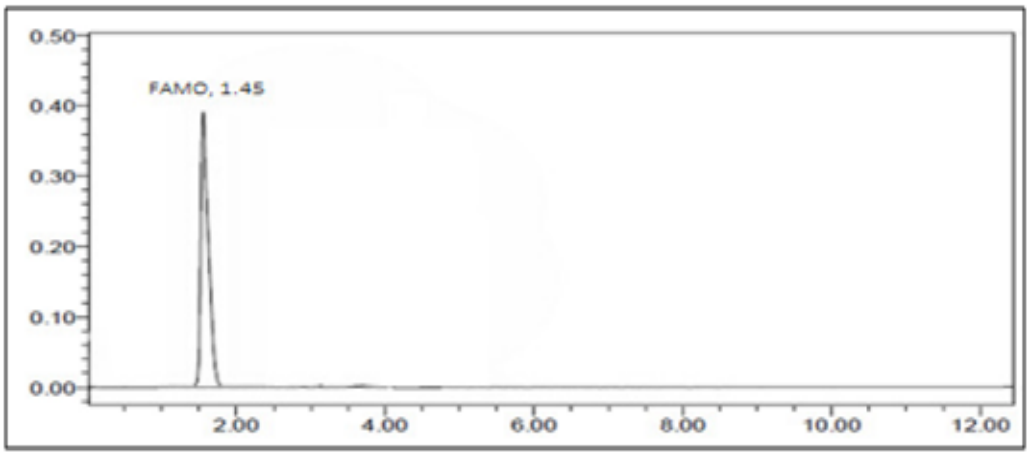

Figure 5: Chromatogram of Famotidine Pure drug

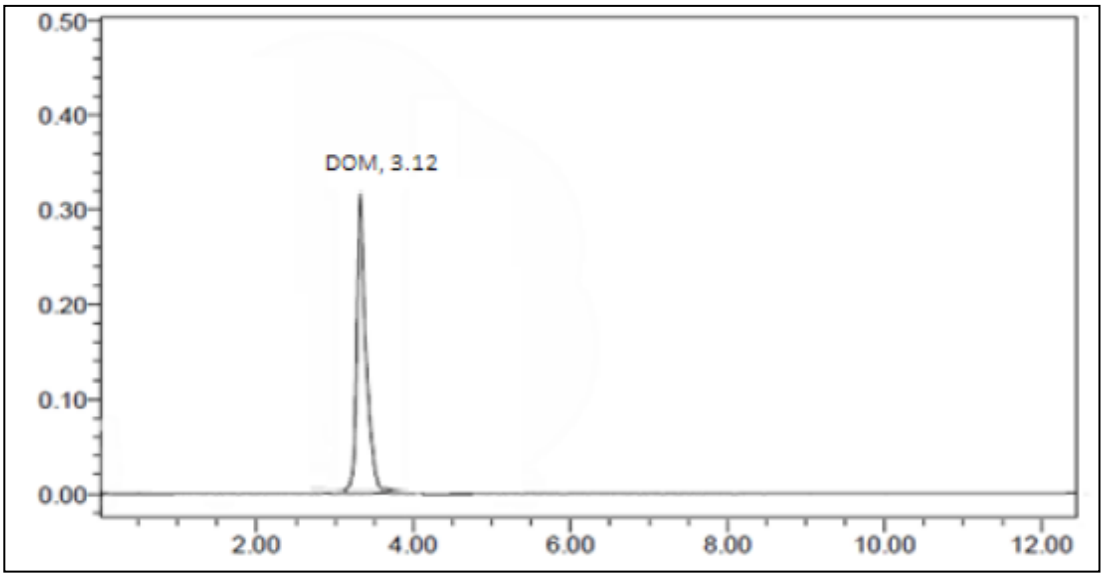

Figure 6: Chromatogram of Domperidone Pure drug

Drug-Excipients Compatibility Study: The pH values of various excipients in combination with Famotidine and Domperidone were evaluated (Table 1.2). Most excipients were compatible, with pH values ranging from 4.4 to 7.6, indicating suitability for formulation without significant pH-induced instability.

Table 2: pH of Drug and Excipients Datasheet

Sr. No.	Drug and Excipients	Ph
1.	FAM+DOM: Hypromellose	6.7
2.	FAM+DOM: Carbomer 974	7.2
3.	FAM+DOM: Polyethylene Glycol	6.1
4.	FAM+DOM: Glycerin	6.4
5.	FAM+DOM: Polyvinyl Alcohol	5.9
6.	FAM+DOM: Benzoic Acid	4.9
7.	FAM+DOM: Sodium Benzoate	4.6
8.	FAM+DOM: Citric Acid	2.4
9.	FAM+DOM: Sucralose	5.3
10.	FAM+DOM: Crosscarmellose Sodium	6.2
11.	FAM+DOM: Polyplasdone	5.7

Evaluation of OTF Batches: The evaluation of oral thin film (OTF) batches (F1 to F9) revealed varying characteristics in terms of appearance, folding endurance, swelling properties, and drug content. The drug content for Famotidine ranged from 93.54% to 99.12%, and for Domperidone, it ranged from 96.42% to 99.83%. The in-vitro disintegration times varied from 12 to 32 seconds, demonstrating the suitability of these films for rapid drug release (Table 1.3).

Table 3: Evaluation of OTF batches (F1 to F9)

Batch	Appearance Transparency	Folding Endurance	Swelling Properties (%)	Drug Content % (Famotidine)	Drug Content % (Domperidone)	In-vitro Disintegration Time (sec)
F1	White to colorless	135±2.497	59.64	97.46 %	96.30 %	21±1.496
F2	White to colorless	165±2.465	60.78	98.62 %	97.49 %	26±1.159
F3	White to colorless	174±1.764	61.68	96.11 %	96.67 %	20±1.648
F4	White	144±3.864	58.91	95.28 %	98.58 %	25±1.453
F5	White to colorless	196±1.156	60.37	96.30 %	97.48 %	19±1.184
F6	White to colorless	147±0.448	64.84	95.29 %	98.62 %	16±1.431
F7	White	185±2.154	62.52	96.67 %	96.11 %	29±1.520
F8	White	194±3.945	63.06	98.58 %	95.28 %	31±1.349
F9	White to colorless	161±3.652	69.98	97.48 %	96.30 %	27±1.765
F10	White to colorless	137±3.102	67.77	94.36 %	97.23 %	23±1.486

In-Vitro Drug Release

The in-vitro dissolution studies of Famotidine and Domperidone (Tables 1.4 and 1.5) showed that both drugs released gradually over time, with Famotidine achieving 97.53% cumulative release in 25 minutes and Domperidone reaching 98.87%. The dissolution profiles of both drugs indicated controlled release characteristics, with a good fit to various kinetic models (Figures 1.9, 1.10), suggesting potential for effective therapeutic delivery.

In conclusion, the analytical evaluation and formulation studies for Famotidine and Domperidone confirmed their high purity, stability, and suitability for oral thin film formulation, with efficient drug release profiles and minimal impurity levels.

Table 4: In-Vitro Drug Release of Famotidine

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	28.9±1.24	28.4±1.35	26.2±1.24	29.1±1.43	27.0±1.24	23.6±1.43	25.3±1.54	28.4±1.59	27.7±1.46	28.4±1.56
10	40.8±1.64	41.1±1.26	39.0±1.74	32.7±1.24	33.3±1.75	40.3±1.64	43.3±1.26	41.2±1.33	31.7±1.24	31.3±1.75
15	74.8±1.27	71.0±1.74	65.2±1.23	69.5±1.15	62.4±1.74	77.5±1.44	70.7±1.74	72.4±1.54	67.5±1.15	66.4±1.74
20	91.7±1.45	96.5±1.46	95.8±1.43	95.2±1.23	94.2±1.64	89.7±1.24	91.3±1.46	90.2±1.13	91.1±1.23	89.2±1.64
25	94.2±1.34	-	-	-	-	95.3±1.42	95.6±1.55	94.9±1.64	93.3±1.95	95.9±1.53

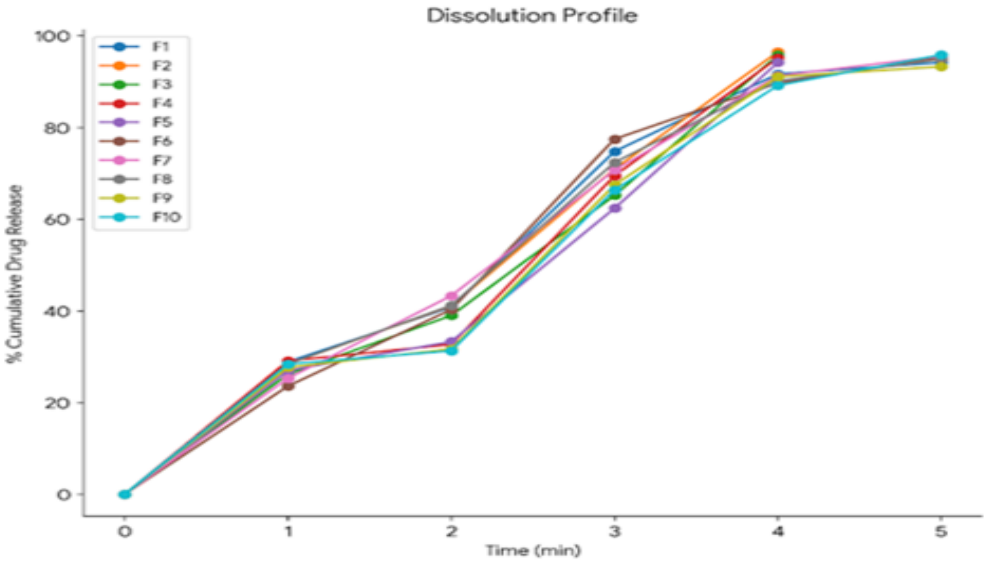

Figure 7: Dissolution Profile of Famotidine

Table 5: In-Vitro Drug Release of Domperidone

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	23.2	28.8	25.7	28.9	23.2	28.4	23.6	25.3	28.4	23.9
10	36.3	34.3	38.4	47.8	35.3	31.3	40.3	43.3	41.2	34.6
15	67.7	62.4	63.7	62.5	63.2	66.4	77.5	70.7	72.4	64.3
20	84.4	85.5	88.3	74.7	86.3	89.2	89.7	91.3	90.2	82.2
25	95.4	97.4	98.6	92.6	92.5	95.9	95.3	95.6	94.9	96.7

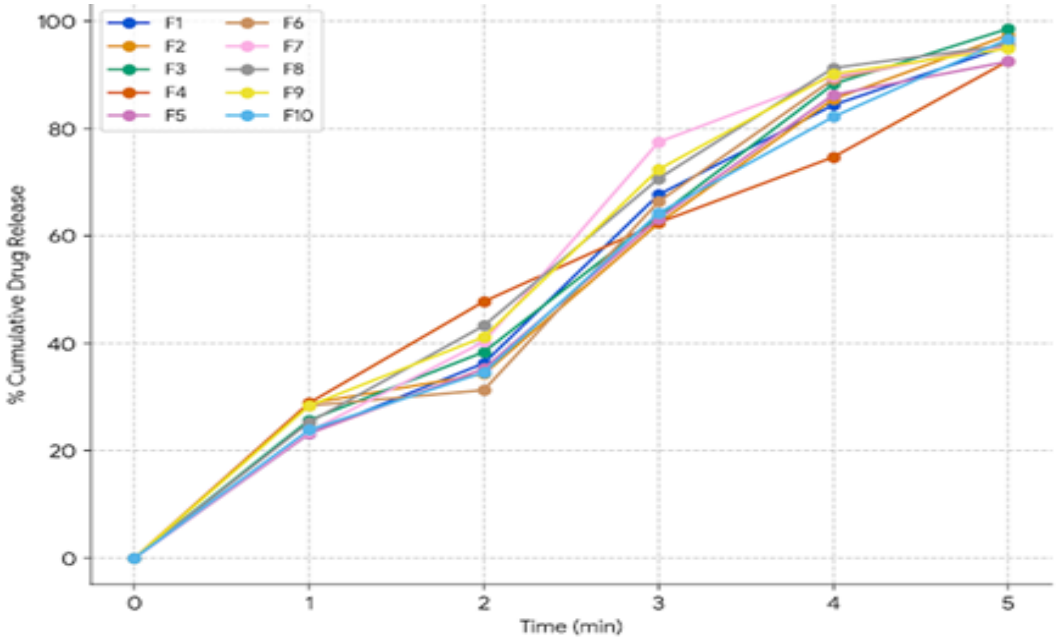

Figure 8: Dissolution Profile of Domperidone

Discussion

The analytical evaluations confirmed that Famotidine and Domperidone met pharmacopeial standards, with characteristic IR and UV spectra, melting points matching reported values, and HPLC purity above 99%. Solubility studies indicated suitability for rapid release in acidic conditions, supporting gastrointestinal absorption. Drug–excipient compatibility tests showed no significant pH-related instability, suggesting formulation stability.

Evaluation of oral thin film (OTF) batches demonstrated good mechanical strength, rapid disintegration (12–32 seconds), and high drug content uniformity. In-vitro dissolution studies showed over 97% release of both drugs within 25 minutes, with dissolution kinetics indicating efficient release profiles. These results validate the feasibility of developing stable, fast-dissolving OTFs for combined delivery of Famotidine and Domperidone.

Conclusion

The study successfully developed and evaluated fast-dissolving oral thin films containing Famotidine and Domperidone using a 3^2 factorial design. Analytical and preformulation studies confirmed drug purity, compatibility with excipients, and suitability for formulation. The optimized OTF batch demonstrated excellent mechanical strength, rapid disintegration, high drug content uniformity, and over 97% drug release within 25 minutes. These findings indicate that the formulated OTF offers a promising, patient-friendly dosage form for the rapid relief of gastroesophageal reflux and associated symptoms.

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