FORMULATION AND EVALUATION OF ESOMEPRAZOLE TABLETS BY USING DIFFERENT POLYMERS

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Abstract

The present study describes the formulation and evaluation of esomeprazole using different polymers. This study describes a drug formulated as a delayed-release tablet to provide the desired effect at a certain time in a maintained concentration without producing any unwanted effects on patient compliance and to improve bioavailability by decreasing its exposure to the gastrointestinal tract. The delayed-release dosage form was designed to release the drug from the dosage form immediately after administration. This was estimated using UV spectroscopy. The esomeprazole tablets were prepared using pre-compression parameters such as the angle of repose, bulk density, and tapped density. The drugs were subjected to FTIR spectroscopy followed by direct compression. Bioavailability studies were performed using dissolution studies. The coated tablets were compared with the marketed sample for optimization, and the dissolution results of the enteric coated tablets showed the release of esomeprazole at simulated gastric pH 1.2. This study describes a formulation prepared by passing the degradation of esomeprazole through an enteric coating for the treatment of acid release disease.

Keywords: Esomeprazole, Enteric coating, Delayed release, Bioavailability.

1. Introduction

Esomeprazole, which is the S-isomer of omeprazole, is a proton pump inhibitor (PPI) very commonly prescribed for the treatment of gastro esophageal reflux disease (GERD), peptic and duodenal ulcers, Zollinger-Ellison syndrome and other gastric acid related gastrointestinal disorders. It inhibits the secretion of gastric acid by blocking the H+/K+ ATPase proton pump, by selectively found in the secretory surface of gastric parietal cells. By inhibiting the last stage of the acid formation, esomeprazole causes a decrease in gastric acidity and contributes to the recovery of the ulcer and symptoms in hypersecretory conditions. Despite the therapeutic benefits of esomeprazole, its chemical structure is acid-labile and its degradation in the acidic environment occurs quickly. Its chemical stability is highly pH dependent, the molecule degrades rapidly in the gastric fluid and is stable in alkaline conditions (1). This instability is a significant pharmaceutical problem in the formulation of oral solid dosage forms.

In order to overcome the acid degradation, and increase the systemic availability, esomeprazole is often manufactured as delayed release, enteric coated preparation. Enteric coatings are bio-compatible and are made in such a way that they can resist the acidic gastric environment and dissolve only at the higher pH of the intestinal environment. Methacrylic acid copolymers and pH-sensitive polymers are widely used for this purpose. However, the use of polymer coating may not always be enough to completely safeguard the tablets, as gastric fluid can still penetrate the tablet core and cause degradation. Therefore, the blending of alkalizing excipients in the core formulation has been attracting and requires more attention (2,3). These agents form a localized alkaline microenvironment around the drug making them chemically stabile, soluble and better dissolution performing, once reached intestinal conditions.

Calcium carbonate is a pharmaceutically accepted alkalizing agent that can act as buffer in the acidic environment and increase the dissolution of weak basic compounds. For esomeprazole formulations, the calcium carbonate aids in the maintenance of an elevated microenvironmental pH (which prevents the premature degradation of the formulation and aids in the rapid release of the drug after breakage of the enteric coat). Combining the alkalizer based stabilization with optimized enteric coating systems may therefore provide a robust dosage form that has improved intestinal release characteristics and that provides therapeutic reliability (4,5).

The present study was conducted in order to prepare and test enteric-coated esomeprazole tablet using calcium carbonate as an alkalizing agent. Core tablets were prepared by direct compression

and assessed for the pre and post compression properties of tablets. Different concentrations of calcium carbonate were studied to ensure the best dissolution performance. The best formulation was then coated with a methacrylic acid based enteric polymer to avoid gastric release (6,7). The final formulation was characterized for physicochemical attributes, acid resistance, disintegration behavior and in-vitro drug release using the release of a marketed reference product. Stability studies were also carried out according to the conditions recommended by ICH.

This work contributes to the continuous development of acid stable, delayed released PPI dosage forms by demonstrating the importance of alkalizing excipients in driving the increase in micro environmental pH and promoting efficient intestinal absorption. A scientifically optimized enteric coated formulation of esomeprazole may enhancing the compliance, response and long term management of acid related gastrointestinal disorders in patients.

2. Materials and Methods

2.1. Active Pharmaceutical Ingredient

Esomeprazole was obtained from Metro Chem API Pvt. Ltd., Hyderabad, India.

2.2 Excipients

The excipients used were mannitol anhydrous and microcrystalline cellulose PH-112 (diluent), calcium carbonate (alkalizing agent), povidone K-30 (binder), croscarmellose sodium (super-disintegrant), Colloidal silicon dioxide (glidant), and magnesium stearate (lubricant). These materials were obtained from reputed suppliers from India and China. Coating materials were Instacoat Moist Shield, Protectab Enteric M1, Isopropyl alcohol, methylene dichloride, iron oxide red; and Insta Coat Glow. A full list of materials and their manufacturers is given in the materials list in the thesis. All chemicals and excipients used were of pharmaceutical grade and used as received.

2.3 Equipment

Tablet Compression, coating, and analytical evaluation were performed on standard pharmaceutical equipment as indicated in the instrument schedule (Ultraviolet and Visible spectrophotometer, tablet compression press, USP Dissolution apparatus II (Paddle Method), tablet hardness tester, tablet friability tester, analytical balance, pH meter, Fourier transform infrared spectrophotometer and coating pan systems).

2.4 Preformulation Studies

Preformulation testing was done to characterize the physicochemical properties of the API and determine compatibility with excipients (8).

2.4.1 Organoleptic Characteristics

The color, odor, and taste of esomeprazole were assessed visually and organoleptically. The drug was in the form of white odorless bitter tasting powder consistent to pharmacopeial reference standards (9).

2.4.2 Solubility Profile

The solubility of esomeprazole was determined qualitatively in various solvents. The API was very soluble in dimethyl sulfoxide, soluble in methanol, ethanol, and slightly soluble in water. These characteristics were taken into account during formulation to provide sufficient dissolution performance when the package is broken by the gastric region (10).

2.4.3 Drug - Excipient Compatibility Study

Compatibility between the API and selected excipients was carried out by physical observation for 30 days. Binary mixtures were prepared and kept under ambient conditions and checked periodically for changes in color, odor or physical properties of the mixture. No characteristic change (NCC) was observed for the combination over the whole study period suggesting the absence of macroscopic interaction. In addition, FTIR spectroscopy was also used to assess potential chemical interactions (11). The characteristic absorption peaks of esomeprazole did not change in the presence of excipients, which confirms that compatibility was found.

2.5 Formulation Development of Core Tablets

2.5.1 Formulation Strategy

Esomeprazole is an extremely acid-labile proton pump inhibitor, and fast degradable in gastric pH. Therefore, the formulation strategy was developed, which protects the drug in the stomach and induces fast release in the intestine (12,13). Two complementary stabilization approaches were made, microenvironmental pH control within the tablet core, and use of an external enteric coating to avoid gastric exposure.

Table.1 Formulation Strategy of Esomeprazole Tablets

Ingredients	Quantity per tablet (mg)						
	FORMULATION CODE						
	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII
Esomeprazole (mg)	20.00	20.00	20.00	20.00	20.00	20.00	20.00
Mannitol anhydrous (mg)	50.00	45.00	45.00	45.00	40.00	40.00	40.00
Microcrystalline Cellulose (mg)	45.00	45.00	40.00	35.00	35.00	35.00	35.00
Calcium Carbonate (mg)	-	5.00	10.00	15.00	20.00	25.00	25.00
Povidone K30 (mg)	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Croscarmellose sodium (mg)	16.00	16.00	16.00	16.00	16.00	16.00	16.00
Colloidal Silicon di oxide (mg)	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Magnesium stearate	3.00	3.00	3.00	3.00	3.00	3.00	3.00
Avg wt of each uncoated tablet (mg)	145.00	145.00	145.00	145.00	145.00	145.00	145.00
Seal coating							
Insta Coating shield (gm)	3.00	3.00	3.00	3.00	3.00	3.00	3.00
Isopropyl alcohol(ml)	200	200	200	200	200	200	200
Methylene(ml)	100	100	100	100	100	100	100
Enteric Coating							
Protectab Enteric (mg)	5.80	5.80	5.80	5.80	6.00	8.00	11.80
Isopropyl Alcohol (mg)	300	300	300	400	500	600	600
Methylene(ml)	300	300	300	400	500	600	600
Iron oxide red(gm)	0.20	0.20	0.20	0.20	0.20	0.20	0.20

2.5.2 Method of preparation (Direct compression)

2.5.2.1 Blending

Each component was put through an appropriate mesh sieve to remove agglomerates. The API, diluents, alkalizing agent, binder and disintegrant were weighed accurately, and mixed well to give

uniformity (14). Colloidal silicon dioxide and magnesium stearate were added in order, in the final blend to obtain better flow and lubrication.

2.5.2.2 Direct Compression

The blended powder was compressed to form tablets using a tablet compression machine with suitable tools. The compression force was varied so as to achieve tablets with acceptable mechanical strength without sacrificing disintegration performance (15).

2.6 Pre-Compression Evaluation of Powder Blend.

The powder blend formulated for the various esomeprazole tablet formulations were tested for their micromeritic properties to determine their suitability for direct compression. Flow behavior was found by determining the angle of repose using the fixed funnel method and the bulk and tapped densities were recorded for the determination of the Carr's compressibility index and Hausner's ratio (16). These parameters gave some insight into packing characteristics and flow dynamics for the blends.

All formulations showed angle of repose values suggestive of good to acceptable flow, whereas the compressibility index and Hausner's ratio were in the pharmaceutically acceptable range, assuring good flowability and compressibility for the manufacture of tablets. The addition of colloidal silicon dioxide was responsible for the enhanced glidant properties and there appeared to be no evidence of segregation or poor mixing of the blends. Overall, the micromeritic results allowed the powder blends to be classified as suitable for direct compression without the need for granulation, and this was confirmed for the consistent die filling process and the uniform tablet production.

2.7 Post Compression Evaluation of Core Tablets

The compressed core tablets were assessed for critical quality parameters such as general appearance, average weight, thickness, hardness, friability and uniformity of drug content. All batches met pharmacopoeial requirements for satisfactory mechanical integrity and batch uniformity for further processing.

Invitro performance was measured by the disintegration and dissolution tests in pH 6.8 buffer. Drug content across the formulations was within acceptable limits, hence proving uniform distribution of esomeprazole in the matrix (17). The results showed that the optimized formulations with an appropriate strength without impairing rapid dispersion after exposure to the intestinal

conditions supporting further investigation for enteric coating and delayed release development processes.

2.8 Invitro Dissolution studies of Core Tablets

Dissolution tests were done using USP Apparatus II (paddle method). Tablets were tried in the phosphate buffer pH 6.8 (900 mL, 37 ± 5° C, 100 rpm). Aliquots were removed after given intervals (e.g., 5, 10, 15 and 45 min), filtered, fresh medium was added, and analyzed at 289 nm with UV spectrophotometry. The results revealed progressive enhancement of the drug release with an increase in the concentration of the alkalizer. F-VI and F-VII showed 95.78 and 100.67% release in 45 minutes while F-I to F-V showed poor dissolution.

2.9 Enteric Coating of Tablets

2.9.1 Selection of Coating System

To avoid the degradation of esomeprazole in the acidic environment of the stomach, enteric polymers, methacrylic acid copolymers, were chosen for coating to stop the degradation. This class of polymers is soluble only in the gastrointestinal tract (at intestinal pH), therefore the drug is released as the polymer is absorbed only after completion of gastric transit.

2.9.2 Coating Procedure

The protective subcoat was painted to reduce the moisture ingress. Thereafter, enteric coating was taken in incremental weight gains (18). The method of coating was done in a perforated pan coater with controlled temperature and air flow. Uniformity and surface integrity was monitored visually.

2.10 Evaluation of Enteric Coated Tablets

The enteric coated esomeprazole tablets were investigated in terms of their physicochemical quality and respective functional performance. Routine tablet parameters, including appearance, weight variation, thickness, hardness, friability and assay, were determined according to pharmacopoeial procedures to ensure mechanical integrity and uniformity. An acid resistance test was performed in which the coated tablets were exposed to 0.1 N hydrochloric acid for 2 hours. The tablets were analyzed for the presence of swelling, cracking, softening, or disintegration, and the analysis of the medium was done to confirm the absence of drug release. Following exposure to acid, however, the tablets were moved to phosphate buffer pH 6.8 to ensure rupture of the enteric coat and subsequent drug release.

For the invitro dissolution studies, USP Apparatus II was used. After the initial 2 hrs. exposure to acidic medium, the dissolution was further continued in pH 6.8 buffer, and samples were withdrawn at known intervals of time and analyzed spectrophotometrically (19). The optimized formulation showed full resistance to gastric situations and fast release in intestinal pH, and the performance was similar or better than the marketed reference product. These results proved correct functionality of the enteric coating system and the successful protection of acid liable drug.

2.11 Stability Studies

To check the effect of storage conditions on product quality, stability testing of the optimized enteric coated formulation was carried out as per ICH guidelines. Tablets were packed in ALU-ALU blister packs and stored at 25 ± 2°C / 60 ± 5 %RH (long-term) and 40 ± 2°C / 75 ± 5%RH (accelerated) for a period of three months. Samples were withdrawn at predetermined intervals and determined for their appearance, hardness, friability, average weight, assay, disintegration time and dissolution characteristics.

The results showed that there was no significant change in the physicochemical properties and drug release behaviour of the tablets over the study period (20). The assay was within acceptable limits, and dissolution profiles showed little variation, proving that the optimized formulation had acceptable chemical and physical stability. These observations confirmed the effect of the combination of the alkalizing and the enteric coating strategy to give rise to a robust dosage form of esomeprazole that could maintain the performance over storage.

3. Results and Discussion

3.1 Preformulation Studies

The organoleptic analysis of esomeprazole has confirmed the fact that the drug was a white, odorless powder with a bitter taste, which corresponds to pharmacopoeial specifications. Solubility studies proved that esomeprazole showed a very soluble property in dimethyl sulfoxide, soluble in methanol and ethanol and less solubility in water which pointed out the necessity to find formulation strategies to improve dissolution. Drug - excipient compatibility studies performed by physical observation have revealed no characteristic time changes between 30 days. FTIR spectral analysis revealed no shifting or disappearance of characteristic peaks of esomeprazole in the presence of selected excipients, which is good evidence for the absence of any chemical interactions and suitability of excipients for formulation.

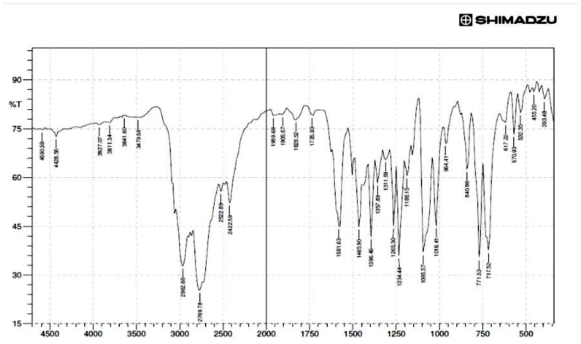

Figure.1 FTIR Spectrum of pure Esomeprazole

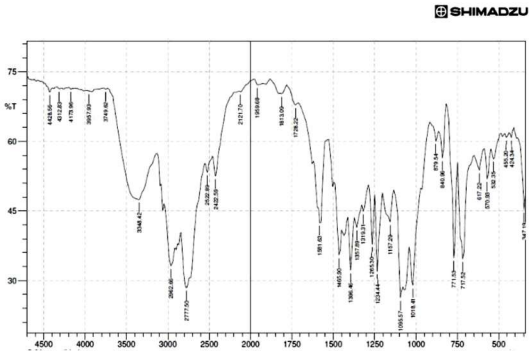

Figure.2 FTIR Spectrum of Esomeprazole + Croscarmellose sodium

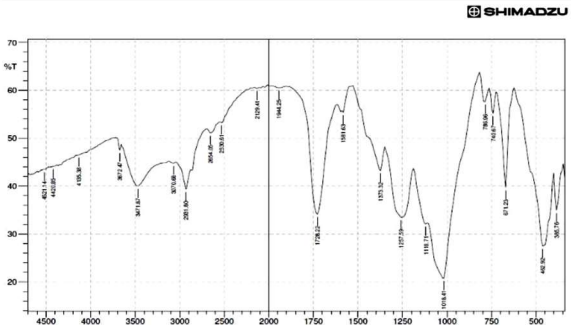

Figure.3 FT IR Spectral analysis of Protectab enteric M1

3.2 Pre Compression Evaluation of Powder Blends

All the powder mixtures prepared for formulations F-I to F-VII had acceptable micromeritic characteristics. The angle of repose values indicated good flow behavior but bulk density, tapped density, Carr's index and the Hausner's ratio were acceptable for direct compression. The addition of colloidal silicon dioxide provided good flow characteristics and prevented segregation during blending. Overall, the precompression parameters confirmed the use of the blends with sufficient flow ability and compressibility to ensure uniform distribution of the powder in the die while stamping the tablets to achieve consistent tablet weight during compression.

Table.2 Precompression Evaluation of Powder Blends

Formulation Code	Angle of Repose (θ)	Bulk Density (g/cm3)	Tapped Density (g/cm3)	Compressibility Index (%)	Hausner's Ratio F
F-I	28.56±0.3	0.562±0.2	0.690±0.5	18.55±0.7	1.15±0.7
F-II	30.09±0.7	0.640±0.1	0.745±0.3	14.09±0.2	1.16±0.6
F-III	25.46±0.2	0.305±0.3	0.351±0.5	13.11±0.1	1.15±0.2
F-IV	25.38±0.4	0.310±0.5	0.376±0.2	13.53±0.5	1.16±0.5
F-V	25.55±0.2	0.308±0.4	0.393±0.4	13.18±0.2	1.15±0.3
F-VI	24.98±0.6	0.317±0.7	0.367±0.1	13.63±0.6	1.15±0.5
F-VII	24.23±0.1	0.310±0.5	0.360±0.2	13.89±0.3	1.17±0.3

*All the values are expressed as mean ± SD, n=3.

3.3 Post Compression Evaluation of Core Tablets

The compressed core tablets of all the formulations had a uniform appearance, no visible defects were noticed in any of them. Tablet thickness and weight variation were within pharmacopoeial limits and hence uniform compression was indicated. Hardness values indicated acceptable mechanical strength values, while the friability value stood below the acceptance limit, which meant resistance to abrasion during handling. Drug content analysis showed uniform distribution of esomeprazole in all formulations, which was between 98.55% - 102.16% as assay results. These results proved that the prepared core tablets met essential quality requirements.

Table.3 Post Compression evaluation of core Tablets

Formulation code	Thickness (mm)	Hardness (kg /cm2)	Weight variation (mg)	Friability (%)	Disintegration (min)
F-I	3.22± 0.055	7.20± 0.32	145.50±1.55	0.14±0.007	8 min30 sec
F-II	3.35± 0.010	6.60± 0.29	144.50±1.20	0.12±0.004	8 min
F-III	3.30± 0.017	6.50± 0.23	144.25±1.02	0.11±0.005	7 min45 sec
F-IV	3.39± 0.018	6.40± 0.29	143.80±1.20	0.11±0.009	6 min35 sec
F-V	3.40± 0.017	7.00± 0.27	145.25±1.08	0.10±0.010	5 min45 sec
F-VI	3.36 ±0.016	7.50± 0.49	145.00±0.13	0.16±0.005	7 min30sec
F-VII	3.29 ±0.020	7.20± 0.24	146.03±0.12	0.12±0.003	9 min30 sec

*All the values are expressed as mean ± SD, n=3.

3.4 Invitro Dissolution Studies of Enteric Coated Tablets

The dissolution profile of the enteric coated tablets revealed that no drug was released in the early acidic phase, shows the gastric protection. Upon exposure to phosphate buffer pH 6.8, formulation F-VII showed excellent and rapid drug release. Comparative dissolution studies (figure.4) in formulation F-VII, showed similar drug release behaviour and some cases superior drug release to that of the marketed enteric coated esomeprazole tablet, indicating good protection from the enteric coating and rapid release in the intestine. The table.4 shows the invitro dissolution studies of enteric coated tablets.

Table.4 Invitro Dissolution Studies of Enteric Coated Tablets

Time (Min)	Percentage Drug release %						
	Formulation code						
	F-I	F-II	F-III	F-IV	F-V	F-VI	F-VII
5	4.35	6.70	8.78	9.74	7.57	12.10	12.57
10	21.78	24.78	24.98	25.32	27.97	28.01	28.96

15	32.42	34.97	36.98	37.87	45.78	46.18	46.60
20	45.25	47.89	48.93	52.11	53.29	54.75	55.89
25	51.35	57.81	58.93	62.11	61.29	62.00	63.89
30	60.71	66.98	74.87	78.98	87.16	90.17	95.78
45	89.12	91.29	92.11	93.84	94.56	96.13	100.67

*All the values are expressed as mean ± SD, n=3.

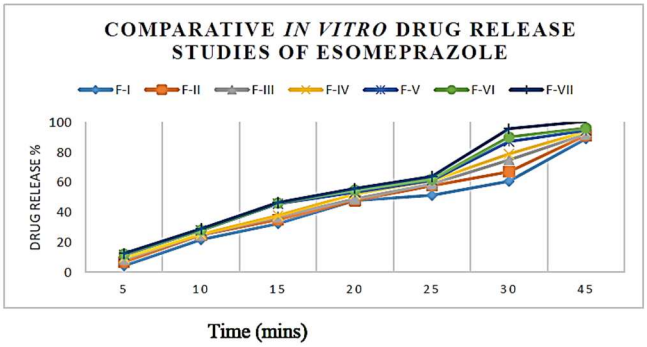

Figure.4 Comparative in vitro drug release studies of Esomeprazole

Table.5 Evaluation of Esomeprazole Enteric Coated Tablets

Formulation code	Thickness (mm)	Weight variation	Disintegration time (min)	
			0.1 N HCL	pH 6.8 Phosphte Buffer
F-I	3.45± 0.019	151.10±2.19	30 min	
F-II	3.39± 0.028	153.09±2.28	35 min	
F-III	3.38± 0.022	154.10±2.21	40 min	
F-IV	3.45± 0.017	156.12±2.22	45 min	
F-V	3.37± 0.023	157.00±2.25	50 min	
F-VI	3.41 ± 0.011	158.05±2.25	55 min	
F-VII	3.42± 0.026	160.50±1.90		15min 30 sec
Marketed Sample	2.90± 0.055	210.00±2.50		15 min 40 sec

*All the values are expressed as mean ± SD, n=3.

3.5 Stability Studies

Stability studies of optimized formulation F-VII conducted at 25 ± 2°C / 60 ± 5%RH and 40 ± 2°C/75 ± 5%RH for a period of 3 months demonstrated no significant changes in physical appearance, hardness, weight variation, assay, disintegration time, and dissolution profile. Drug content was within acceptable limits throughout the study time period and little variation in dissolution behavior occurred. These results confirmed that the optimized enteric coated esomeprazole tablets had satisfactory physical and chemical stability under the conditions of both long term and accelerated storage conditions.

Table.6 Stability Studies report

Test Interval	Specification Limit	1st Month	2nd Month	3rd Month
Test		Observation/Results		
Description	Red colored circular shaped enteric coated tablets	Red colored circular shaped enteric coated tablets	No Changes in the Appearance	No Changes in the Appearance
Average Weight	157.00±7.5% (145.22 – 168.77)	158.06 mg	157.90 mg	158.09 mg
Dissolution Test	0.1 N HCl			
	pH 6.8 Phosphate Buffer	15 mins 45sec	16 mins 30sec	16 mins 55sec
Assay	98.55% to 102.16%	100.58±0.12	100.55±0.11	100.51±0.09

4. Conclusion

The present study was effective to show formulation and evaluation of enteric coated tablets of esomeprazole using calcium carbonate as an alkalizing agent to overcome the acid liable nature of the drug and its formulation. Preformulation studies were possible, demonstrating the physicochemical suitability of esomeprazole and the compatibility of selected excipients, having been supported by micromeritic investigation to choose the manufacturing process (direct compression) as a reliable procedure. All core tablet formulations showed acceptable mechanical properties as well as uniform drug content, thus showing consistency and reproducibility of the formulation process. A systematic increase in calcium carbonate concentration showed a predominant role in the enhanced drug dissolution by the modulation of the micro-environment pH. Among the developed formulations, F-VI showed a significantly enhanced dissolution performance with complete drug release by F-VII. Enteric coating with a copolymer of methacrylic acids further ensured the effective protection of gastric. Formulation F-VII, coated with 8% enteric polymer successfully resisted acidic conditions for 2 hours and released the drug rapidly in intestinal pH and showed similar or better performance than the marketed product. Stability studies performed under conditions recommended by the International Council for Harmonization (ICH) ensured that the optimized formulation did not alter its physicochemical integrity and release of the drug over the period of the stability study. Overall, the use of a combination of alkalizing excipients and enteric coating is an effective strategy for the development of robust and delayed release esomeprazole tablets suitable for the treatment of acid related gastrointestinal disorders.

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