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Original Article

Formulation, Compatibility, *In vitro*, and Stability Studies on Pantoprazole Sodium Enteric Coated Tablets with Super Disintegrants

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ABSTRACT

Background: Pantoprazole sodium is a highly effective proton pump inhibitor that has continued to languish in the therapeutic armory against the acid in the gastrointestinal tract. However, its pharmacokinetic properties are seriously affected by great instability at acidic pH, which requires the use of a strong enteric cover to allow its entry into the small intestine, where its absorption is possible. This study aimed at optimizing an enteric-coated tablet formulation of pantoprazole sodium by using a range of superdisintegrants to produce a rapid release profile in the intestinal environment after appropriate gastrointestinal shielding. **Materials and Methods:** The core tablet by wet granulation with various concentrations of superdisintegrants, Explotab, Kollidone, and HPMC: 50, 75, and 100%. Optimal core formulation referred to as PF_8 was then coated using three types of enteric polymers viz., Eudragit L 100, Polyvinyl Acetate Phthalate (PVAP), and Eudragit RS 100 at concentrations of 4, 6, and 8 (w/w). Resulting formulations were gauged under stringent assessment comprising pre-compression flow, post-compression properties, acid-resistance analysis, and *in vitro* dissolution analysis. **Results:** PF_8, which included 10% Kollidone, exhibited an exemplary disintegration kinetic, taking 10 sec to disintegrate, and near 100.1% of the active component was released in a 45-min range, which were the best results of the formulations evaluated. **Conclusion:** Among the enteric-coated tablets, the batch EC-PF_8 order, which is coated with 6% Eudragit RS 100, lasts 2 hr of acid resistance in 0.1N HCl until rapid release of the drug (100.10% in 45 min) is achieved in a pH 6.8 phosphate buffer.

Keywords: Compatibility, Enteric Coating, Formulation, *In vitro*, Pantoprazole, Stability.

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INTRODUCTION

Pantoprazole sodium is a benzimidazole derivative and a Potent Proton-Pump Inhibitor (PPI) used to treat Gastroesophageal Reflux Disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome (Gang *et al.*, 2004). By irreversibly inhibiting the H^+ / K^+ -ATPase enzyme activity in gastric parietal cells, the drug shows its therapeutic action, thereby reducing gastric acid secretion (Mei-Juan *et al.*, 2005). Despite its high therapeutic efficacy, Pantoprazole sodium is highly unstable in acidic conditions and undergoes rapid degradation in the stomach, which can significantly reduce its bioavailability.

To overcome this limitation to protect the drug from the acidic gastric environment, enteric coating is employed to ensure its release in the alkaline pH of the intestine, where absorption occurs. Enteric polymers are designed to remain intact at low pH but dissolve at higher intestinal pH levels, thereby enhancing drug stability and therapeutic effectiveness. Among the commonly used enteric polymers, Eudragit is used in the duodenum (pH>5.5), preventing drug hydrolysis by acid and delivering the drug to the main site of absorption in the small intestine (Naikwade *et al.*, 2008). Recent technologies in enteric coating have focused on pH-sensitive methacrylic acid copolymers like Eudragit L100 and RS100, which provide much finer trigger-release profiles and mechanical stability than traditional phthalate-based polymers (Neha *et al.*, 2021; Arun *et al.*, 2009; Nitesh *et al.*, 2009).

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In addition to enteric protection, fast offset of action is a very important quality attribute of PPIs. This has been done by attaching super disintegrants to the core of the pills. Kollidon ® AP (Crospovidone) and sodium starch glycolate (Explotab) are substances that speed up the breakup process of pills through swelling, wicking, and structural deformation mechanisms (Salunkhe *et al.*, 2009). Where Sulphur-coated systems are employed, the super disintegrant has to cause immediate disintegration when the enteric shell is dissolved in the intestinal fluid, thus ensuring the timely dissolution and absorption (Mohamed *et al.*, 2009). However, even with an extensive application of PPIs, there is still an obvious increase in disparities between the dissemination of super disintegration classes in the framework of enteric-coated core maximization. A high number of formulations are unsuitable due to a lack of acid resistance or slow release in the intestine, which affects bioavailability. In modern literature, it is emphasized that there is a need to achieve an optimal polymer 9 disintegrant ratio, which contributes to gastric stability and rapid intestinal intake (Aswar *et al.*, 2009; Vikas, 2010).

The main purpose of the research is to develop and test Pantoprazole sodium enteric- coated tablets by maximizing the core using different super disintegrants and using the best enteric polymer system. This research aimed to reach a solid formulation (EC-PF_8) with an Eudragit RS100 analyzed acid resistance and a rapid, complete release of the drug into the intestinal space to promote the overall stability and treatment of the drug.

MATERIALS AND METHODS

Pantoprazole sodium was obtained as a gift sample from Dhamtec Pharm, Mumbai. The super disintegrants used were Kollidone-CL (crospovidone), Explotab (sodium starch glycolate), and HPMC (Hydroxypropyl Methylcellulose). The enteric coating polymers that were used were Eudragit 100 (methacrylic copolymer type A), Eudragit 100(B), ammonia methacrylate, and Polyvinyl Acetate Phthalate (PVAP). Other analytical-grade excipients included mannitol (diluent), PVP K30 (binder), Aerosil (glidant), and magnesium stearate (lubricant) as shown in Table 1. The objective of using Eudragit RS 100 in these formulations to modulate drug release kinetics which enhance residence time and increase therapeutic performance simultaneously.

Pre-Formulation Studies

API Characterization for Pantoprazole Sodium was performed.

Spectrophotometric Method

An analytical method for Pantoprazole Sodium was developed using UV-visible spectrophotometry. The maximum absorption wavelength (λ_{max}) of the drug was determined by scanning a 10 µg/mL solution in methanol over a wavelength range of 200-400 nm.

Calibration Curve of Pantoprazole 0.1N HCl

In 10 mL volumetric flasks, aliquots of standard stock solution (1000 µg/mL) were diluted with 0.1N HCl to obtain concentrations of 4, 8, 12, 16, and 20 µg/mL. The absorbance of each solution was measured in triplicate at 285 nm using a UV-visible spectrophotometer Table 2, Figures 1 and 2.

Calibration Curve in a Phosphate Buffer of 6.8 pH

In 10 mL volumetric flasks, aliquots of the standard stock solution (1000 µg/mL) were diluted with phosphate buffer (pH 6.8) to obtain concentrations of 4, 8, 12, 16, and 20 µg/mL. Absorbance values were recorded in triplicate for the solutions at 285 nm.

Development of Formulation and its Compatibility Studies

Solubility Analysis

The solubility of the drug in other solvents such as water, ethanol, methanol, chloroform, and acetone was also looked at to determine the hydrophilic-lipophilic balance of the drug and thus offer an insight into which solvent was best to use in coating.

Drug-Excipient Compatibility (FT-IR)

To determine the chemical stability of the formulation, Fourier Transform Infrared spectroscopy was used based on the 2 mg KBr pellet technique. The pure drug and the optimized formulation (EC-PF_8) were obtained as spectra in the range of 400-4000 cm^{-1}, which allowed revealing possible interactions between the drug and the polymer.

Cores Zwalla (Wet Granulation) Wet Preparation

Wet granulation was used to manufacture core tablets and guarantee homogeneous distribution of the drug, and increase the flow properties. It was sifted using a 30-mesh screen with 1 Pantoprazole sodium, PVP K30, and the selected super disintegrant, which is Explotab, Kollidone, and HPMC. The solution was mixed with 2M mannitol as a diluent. The resulting mixture was granulated with the help of an appropriate binder solution, dried, and sieved. Aerosil and magnesium stearate were used to lubricate 4 g of granules before compression. The compression was done using a rotary tablet machine using an 8mm round, deep-concave tooling, aiming at a target weight of 200 mg. Wet granulation was considered a better method than direct compression to enhance the compressibility of the mannitol-pantoprazole mixture and maintain the structure of the mixture upon which coating would follow.

Enteric Coating Process

Entry of the core formulation (PF_8) into the enteric coating was due to optimized disintegration and dissolution characteristics. The solvent-evaporation method was used with the help of a coating pan. The coating solutions Eudragit L 100, PVAP,

Table 1: Types of Formulation.

Formulation	PF_1	PF_2	PF_3	PF_4	PF_5	PF_6	PF_7	PF_8	PF_9
Pantoprazole	40 (mg)								
Explotab (mg/1 g)	5			7.5			10		
Kollidone (mg/1 g)		5			7.5			10	
HPMC (mg/1 g)			5			7.5			10
PVPK 30	4 (mg/1 g)								
Mannitol	Sufficient Quantity								
Aerosil	2.5 (mg/1 g)								
Magnesium stearate	2 (mg/1 g)								
Total weight	200 (in mg)								

*" All values in % w/w" *

Table 2: UV concentration and Absorbance values of Pantoprazole.

Concentration (w/w)	Absorbance at 285 (nm)
0	0
2	0.202
4	0.395
6	0.558
8	0.745
10	0.912

*" Mean of three readings (*n*=3). Regression equation: y=0.0907x+0.0015R^2= 0.9988"*

and Eudragit 100 RS were dissolved in acetone at 4, 6, and 8 w/w, respectively. For plasticization, PEG 400 (1.5% w/w) was incorporated to enhance the flexibility of films and to reduce cracking. The solution was applied to pre-warmed pills of core at a rate of 3 RMP, until the desired weight increase was achieved as shown in Table 3 (Suresh Kumar *et al.*, 2024; Singh *et al.*, 2025; Song Huang *et al.*, 2026).

Evaluation tests for Tablets

Pre-compression Parameters

Attributes of a given granule (Angle of Repose, Bulk density, tapped density, Carr index, as well as Hauser's ratio) were also evaluated to monitor the best flowability and compressibility according to USP standards (Muhamed *et al.*, 2010; Thiruganesh *et al.*, 2010).

Post-compression Parameters

Compressed tablets (core and coated) were subjected to standard quality-control tests. Weight variation was determined by individually weighing 20 tablets to confirm compliance with USP specifications (Chetan *et al.*, 2010; Ghule Prashant *et al.*, 2010). For tablets weighing more than 200 mg, the permitted deviation is within ±7.5%.

Tablet hardness and friability tests were performed to ensure adequate mechanical strength during handling and transportation. Hardness was measured using a Monsanto hardness tester with a target range of 3.5-5.5 kg/cm^2. Friability testing was conducted using a Roche friabilator, and % age weight loss was maintained below 1%, as per pharmacopeial limits (Rasika *et al.*, 2010; Shibu, 2014).

Disintegration time was evaluated using a USP disintegration apparatus to assess the efficiency of different superdisintegrants incorporated in the formulations. Acid stage testing was also conducted to evaluate tablet behavior under simulated gastric conditions prior to further dissolution assessment (Vivek *et al.*, 2011; Joshikk *et al.*, 2022).

In vitro Dissolution Investigations

To maintain a homogeneous exposure of the enteric film to the dissolution media, dissolution testing was done using USP Apparatus I (basket) at 50 RPM. To determine the acid stage, the resistance of academia was tested after 2 hr of incubation with 0.9 L of 0.1 Normality of Hydrochloric acid (pH 1.2) in the presence of tablets were conducted at 37°C. The acid stage was followed by the buffer stage, a step during which the phosphate buffer with a pH of 6.8 was added, and 15, 30, 45, 60, and 120-min periods were used to sample. Then the samples were analyzed using UV 285 nm using UV-visible spectroscopy (Sharma *et al.*, 2016).

Stability Studies

Stability studies of the optimized formulation (EC-PF_8) were conducted in accordance with ICH guideline Q1A (R^2) to evaluate the stability of the tablets under different storage conditions (Abdul Samad *et al.*, 2020; Singh, 2024).

The tablets were packed in suitable containers and stored under the following conditions:

- **Long-term storage conditions:** 25°C ± 2°C/60% RH ± 5% RH.
- **Accelerated storage condition:** 40°C +/ -2°C/75% RH +/ -5% RH.

Samples were evaluated at predetermined intervals of 1 and 3 months for 1 and 3 months were studied with physical appearance, drug content (assay), and *in vitro* dissolution characteristics to assess formulation stability.

RESULTS

Pantoprazole sodium is a white to half-white crystalline powder exhibiting weakly basic characteristics. It is freely soluble in water and ethanol, slightly soluble in an acidic buffer with pH 7.4, and is insoluble in n-hexane. The melting point of pantoprazole sodium ranges between 137.5°C -145.5°C. The sample of the drug had the highest wavelength of absorption (λ_{max}), which was 285 nm. The absorption bands correspond to the major functional group shown in Table 4, the pure drug, and the optimized EC-PF_8 formulation. The FT-IR spectra of pantoprazole pure drug and enteric coated formulation, EC-PF_8 were shown in Figures 3A-3B.

Evaluation of parameters of Pantoprazole Tablets

Tables 5 and 6 show that the angle of repose from batches PF_1 to PF_9 had an angle of repose within the 25-30 range, which was within acceptable limits of flow behaviour. The formulated blend had a bulk density of between 0.4 and 0.5 g/mL, and a tapped density of between 0.5 and 0.6 g/mL. It was established that the % age compressibility of the batches PF_1-PF_9 was between 17% and was termed as excellent. Batches PF_1 through PF_9 exhibited a Hausner ratio of between 1.11 and 1.21; hence, indicating good flow attributes. The hardness of prepared batches PF_1-PF_9 was held within the range of 3.4 -3.6 kg/cm^2. The % age friability of PF_1 to PF_9 batches was less than 1% w/w. The range of assay values of batches PF_1-PF_8 was acceptable, ranging between 90 and 110% w/w. Formulation PF_8 contained optimal concentration levels of Kollidon and produced desirable flow properties and released 100.1% of the drug in 45 min which was exhibited in Table 7. The normal plot of Pantoprazole showed that it was very linear with an R^2 of 0.9988 in 0.1N HCl, which was sufficient to obey the law of Beer-Lambert. The typical plot of Pantoprazole was very satisfactory, and the R^2 was 0.9986, which also justifies the Beer-Lambert law.

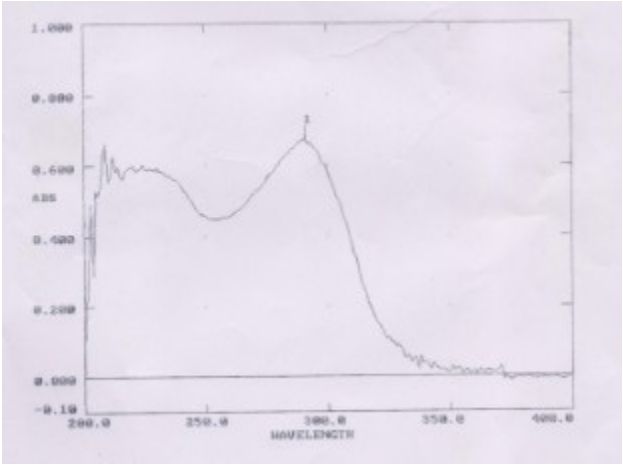

Figure 1: Pantoprazole standard graph (0.1 N HCl).

In vitro Drug Release tests

All formulations were dissolved under USP apparatus I, and the dissolution media was 0.1⁻ phosphate buffer of 6.8 -pH with 5.3 hr followed by 2 hr of study. Findings of the *in vitro* dissolution of formulations EC-PF_1-EC-PF_9 are provided in Table . The releases of the drugs versus time cumulative % drug release versus time plots, which are represented by Figures 4A-4B, show the comparisons of the % CDR of the formulations EC-PF_1 to EC-PF_9.

Table 8 shows the evaluated parameters of enteric-coated pantoprazole sodium; the change in the weights across all batches EC-PF_1 through EC-PF_9 was within the 5-% acceptable difference. In the case of formulated batches EC-PF_1 to EC-PF_9, the disintegration time ranged between 168 sec and 70 sec with a change in the concentration of the super disintegrant. The formulation EC-PF_8 contained optimal concentrations of Kollidon, exhibited desirable flow properties Table 9 and released 100.16% of the drug in 45 min. The formulation EC-PF_8, which had the highest drug release, is shown in Table 10 exhibits the absorbance values of enteric-coated pantoprazole sodium.

Among all 9 enteric-coated formulations, Formulation EC-PF_8 was selected for stability studies based on release characteristics.

Table 3: Enteric Coating – formulation.

Ingredients	EC-PF_1	EC-PF_2	EC-PF_3	EC-PF_4	EC-PF_5	EC-PF_6	EC-PF_7	EC-PF_8	EC-PF_9
Eudragit L 100	40 mg/1 g	60 mg/1 g	80 mg/1 g	-	-	-	-	-	-
PVAP (%W/W)	-	-	-	40 mg/1 g	60 mg/1 g	80 mg/1 g	-	-	-
Eudragit RS100 (%W/W)	-	-	-	-	-	-	40 mg/1 g	60 mg/1 g	80 mg/1 g
PEG	15 mg/g								
Acetone	Sufficient Quantity								

*" All values in % w/w" *

Table 4: Interpretation of FTIR.

Sl. No.	Functional group	Observed Range (nm)	Pure drug (nm)	Optimized EC-PF8 (nm)
1.	NH (Secondary amine)	3420-3632	3632.55	3632.43
2.	C=O (Carbonyl group)	1640-1708	1758.77	1708.92
3.	C=N (Imine group)	1019-1411	1271.15	1265.67
4.	C-O (Alcohol group)	1062-1150	1062.95	1019.12
5.	C-F (Fluro group)	893-1411	1150.61	1112.86

Table 5: Pre-compression - Evaluation parameters of pantoprazole sodium.

Formulations	Angle of repose (θ)	Loose Bulk Density (g/mL)	Tapped Bulk Density (g/mL)	% Compressibility	Hausner's ratio
PF_1	26.54±0.14	0.44±0.04	0.51 ±0.05	11.83±0.04	1.01±0.04
PF_2	27.46±0.11	0.44±0.02	0.51 ±0.03	11.83±0.03	1.13±0.05
PF_3	27.37±0.16	0.44±0.02	0.53±0.02	11.98±0.02	1.03±0.05
PF_4	24.33±0.17	0.45±0.01	0.53±0.07	14.09±0.04	1.05±0.04
PF_5	25.11±0.10	0.44±0.04	0.52 ±0.06	14.34±0.08	1.10±0.07
PF_6	28.67±0.13	0.45±0.09	0.51 ±0.05	14.33±0.05	1.10±0.06
PF_7	27.34±0.12	0.51±0.07	0.61±0.04	15.46±0.04	1.10±0.08
PF_8	24.67±0.15	0.58±0.05	0.67±0.01	18.27±0.02	1.19±0.01
PF_9	27.55±0.11	0.50±0.04	0.57 ±0.04	18.48±0.06	1.24±0.02

Table 6: Post-Compression Parameters of Pantoprazole sodium Core Tablet.

Formulation	Weight variation	Hardness (kg/m^2)	Thickness (mm)	Friability (%)	Disintegration time (in Sec)	Assay% (w/w)
PF_1	201	3.12	2.4	0.41	104	99.7
PF_2	203	3.26	2.1	0.43	108	99.6
PF_3	203	3.31	2.4	0.49	67	100.1
PF_4	200	3.12	2.0	0.47	65	98.7
PF_5	203	3.36	2.2	0.28	64	98.6
PF_6	203	3.27	2.1	0.29	60	99.1
PF_7	202	3.31	2.4	0.17	48	99.0
PF_8	200	3.49	2.1	0.17	10	100.1
PF_9	203	3.49	1.9	0.25	104	99.1

The studies were carried out at long-term storage 25°C±2°C/60% RH and accelerated storage conditions at 40°C±2°C/75% RH, which is shown in Table 11.

DISCUSSION

The drug exhibits pH-dependent solubility and is unstable under acidic conditions, necessitating enteric coating in oral dosage forms to protect it from gastric degradation. In the present study, Eudragit RS 100 was intentionally selected not as a conventional enteric polymer but as a controlled-permeability coating material to regulate drug diffusion and achieve a sustained-release profile in the gastrointestinal environment. All basic parameters showed no significant changes were observed in physical characteristics and dissolution profiles during the storage period, indicating stability of the optimized formulation. The characteristic peaks with only minor shifts in their positions, shown by the optimized EC-PF_8 formulation, indicate the absence of any significant chemical interaction between the drug and excipients. Thus, confirming the compatibility of the drug with the formulation and preservation of its chemical structure.

In the evaluation parameter study on pantoprazole sodium core, the change in the weights across all batches PF_1 through PF_9 was within the 5-% acceptable difference. In the case of formulated batches PF_1-PF_9, the disintegration time ranged between 108 sec and 10 sec with a change in the concentration of the super disintegrant. The formulation PF_8, which had

Table 7: ***In vitro*** **Dissolution Studies.**

Time (in hr)	PF_1	PF_2	PF_3	PF_4	PF_5	PF_6	PF_7	PF_8	PF_9
	6.8 pH Phosphate Buffer								
0.25	21.9	37.9	14.1	32.9	57.9	49.1	32.9	53.9	51.2
0.50	44.9	51.8	37.9	51.9	75.1	75.9	77.7	91.9	79.9
0.75	62.4	71.9	58.7	67.9	89.9	91.8	90.9	100.1	89.9
1.0	75.1	84.9	71.1	80.1	98.1	99.8	97.9	100.7	100.1

Table 8: **Evaluation Parameters for Enteric Coated Tablets.**

Formulations	Weight variation	Hardness (kg/m^2)	Thickness (mm)	Friability (%)	Disintegration time (in Sec)	Acid resistance time (in hr)	Assay % (w/w)
EC-PF_1	207	3.38	2.6	0.41	164	2	101.9
EC-PF_2	210	3.54	2.3	0.40	168	2	101.4
EC-PF_3	215	3.51	3.1	0.58	117	2	103.1
EC-PF_4	209	3.44	2.2	0.56	85	2	92.9
EC-PF_5	211	3.40	2.4	0.41	104	2	98.9
EC-PF_6	215	3.41	2.1	0.41	90	2	98.4
EC-PF_7	207	3.39	2.4	0.49	70	2	101.6
EC-PF_8	214	3.51	2.5	0.47	78	2	101.2
EC-PF_9	215	3.48	2.4	0.47	166	2	99.3

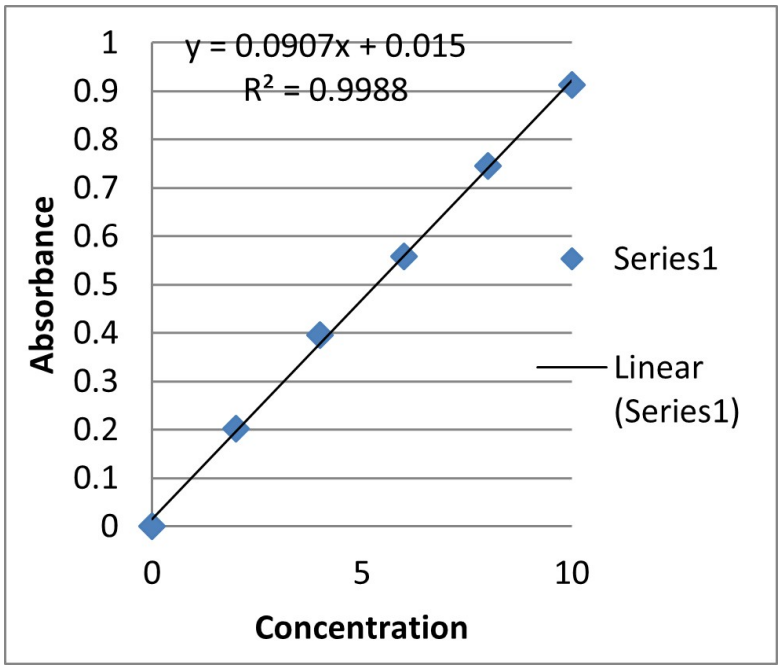

Figure 2: Pantoprazole - calibration curve in 0.1N HCl at 285 nm.

the highest drug release, had to be used in coating. The faster disintegration observed in PF8 may be attributed to the wicking and deformation mechanisms of Kollidone (crospovidone), which enable rapid water uptake and tablet rupture. In contrast, Explotab predominantly acts through swelling, resulting in comparatively slower disintegration. At different concentrations, three different coating polymers were used. 10 sec disintegration refers to the optimized core tablet (PF8). EC-PF formulations represent enteric-coated tablets that remain intact in acidic media and disintegrate only after the coating dissolves at intestinal pH. The formulation EC-PF_8, which had the highest drug release and exhibits the desirable flow properties. The stability study on formulation, EC-PF_8 shows that there were no significant changes in their physical appearance. It was observed that the

Table 9: Dissolution Study for Enteric Coated Tablets.

Time	EC-PF$_1$	EC-PF$_2$	EC-PF$_3$	EC-PF$_4$	EC-PF$_5$	EC-PF$_6$	EC-PF$_7$	EC-PF$_8$	EC-PF$_9$	Aciban
0.1N HCl Acidic Buffer										
1 hr	-	-	-	-	-	-	-	-	-	-
2 hr	-	-	-	-	-	-	-	-	-	-
6.8 pH phosphate buffer										
15 min	20.90	34.74	14.12	31.13	54.19	48.05	34.20	51.18	47.19	35.45
30 min	40.93	49.34	37.14	47.14	71.91	71.17	73.31	84.36	75.07	55.16
45 min	56.51	66.34	53.17	60.96	85.47	84.46	85.72	100.16	84.60	69.84
60 min	71.19	79.81	66.18	72.94	93.61	93.09	92.48	100.16	94.15	87.57
120 min	100.4	98.9	99.6	99.1	99.9	99.1	97.9	100.16	99.6	98.95

Table 10: Absorbance Values for Enteric Coated Tablet.

Time	EC-PF$_1$	EC-PF$_2$	EC-PF$_3$	EC-PF$_4$	EC-PF$_5$	EC-PF$_6$	EC-PF$_7$	EC-PF$_8$	EC-PF$_9$	Aciban
0.1N HCl Acidic Buffer										
1 hr	-	-	-	-	-	-	-	-	-	-
2 hr	-	-	-	-	-	-	-	-	-	-
6.8 pH phosphate buffer										
15 min	0.676	0.143	0.474	0.986	0.180	0.198	0.998	0.179	0.157	0.124
30 min	0.142	0.158	0.124	0.142	0.211	0.242	0.278	0.240	0.244	0.191
45 min	0.191	0.248	0.181	0.185	0.276	0.270	0.248	0.316	0.275	0.270
60 min	0.191	0.254	0.219	0.271	0.282	0.272	0.279	0.316	0.274	0.283
120 min	0.346	0.374	0.319	0.347	0.305	0.306	0.342	0.316	0.327	0.333

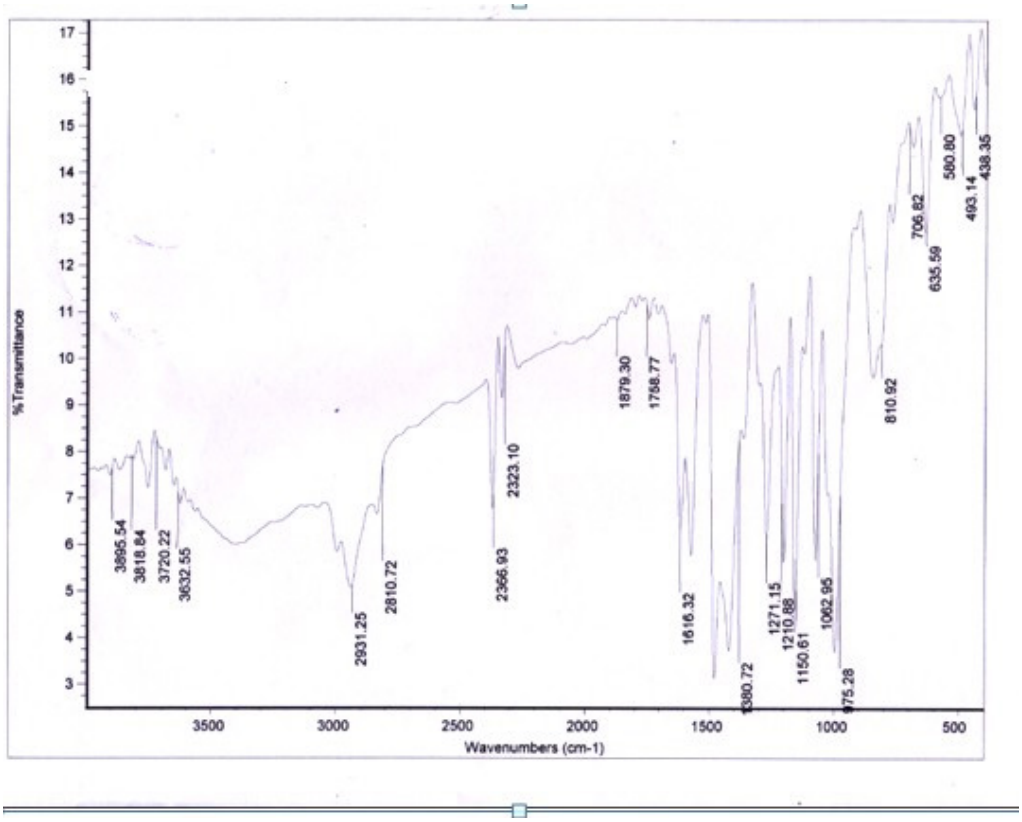

Figure 3A: FTIR Spectra - Pantoprazole Sodium.

Table 11: Optimized Enteric Coated Tablet (EC-PF$_8$) stability studies.

Sl. No.	Time points (hr)	Initial (±)	Cumulative % drug release			
			25°C ± 2°C /60 %RH		40°C ± 2°C /75% RH	
			1st month	3rd month	1st month	3rd month
1.	1 hr	0	0	0	0	0
2.	2 hr	0	0	0	0	0
3.	15 min	50.18	48.9	46.9	49.5	48.2
4.	30 min	84.96	84.0	81.3	81.6	81.3
5.	45 min	100.10	97.9	95.3	95.7	93.0
6.	60 min	100.46	97.9	95.4	98.7	98.8
7.	Assay	100.1	97.8	97.9	99.6	99.9

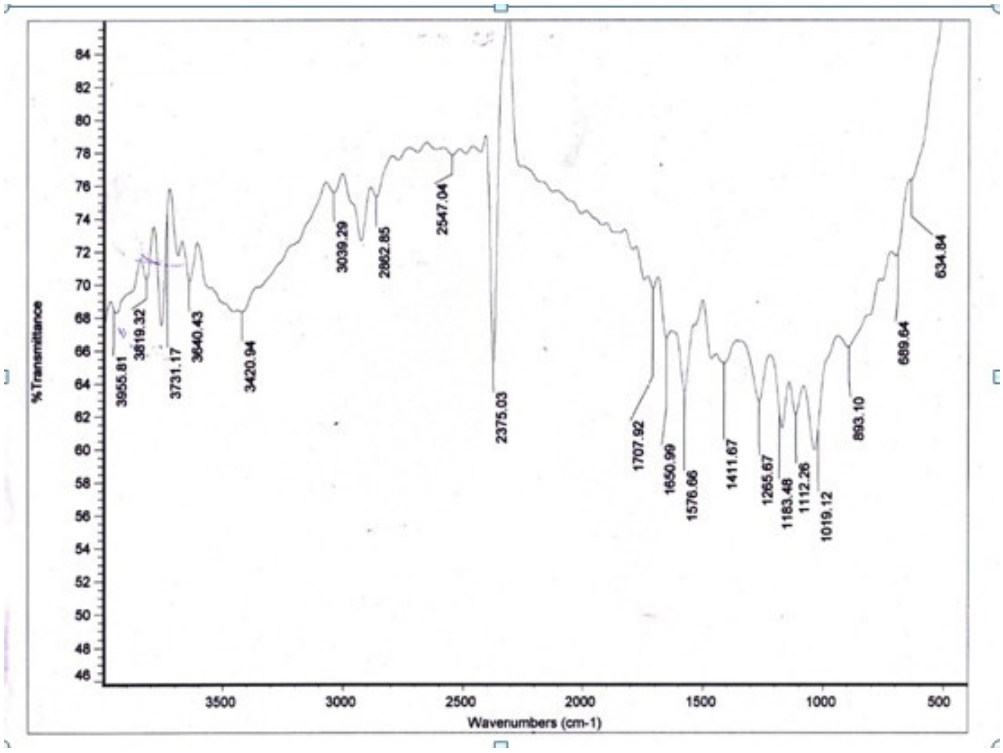

Figure 3B: FTIR Spectra - Pantoprazole Optimized Formulation EC-PF8.

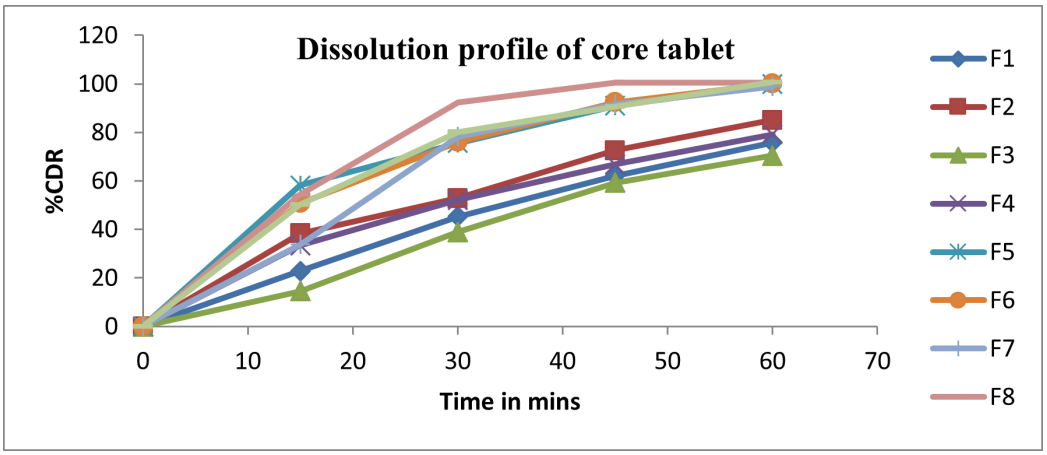

Figure 4A: Comparative *in vitro* Drug Dissolution Studies for Best Formulation.

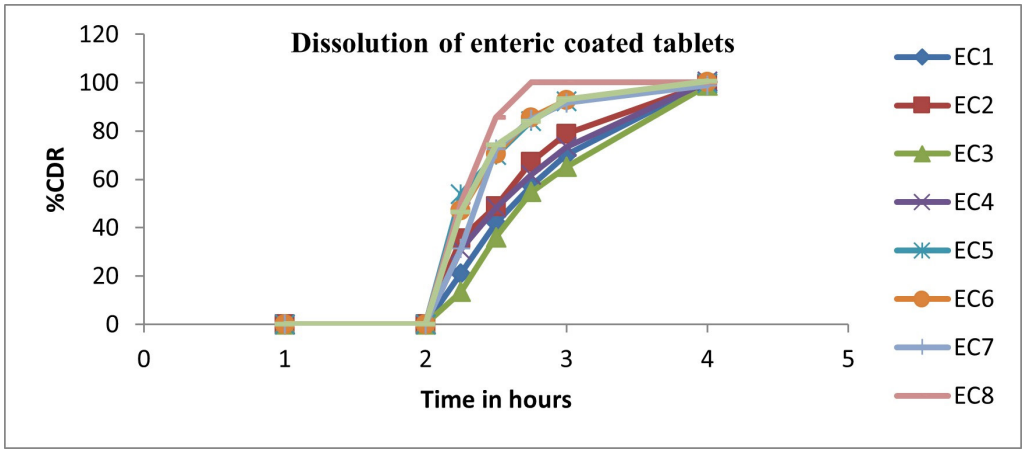

Figure 4B: Cummulative % Drug Release Graph for Formulation EC-PF1-EC-PF9.

initial drug content of the sample was analyzed after 1 and 3rd month of storage. Hence, it can be concluded that the strength of EC-PF_8 with 98.8% release and 99.9% assay after 3 months at 40°C±2°C/75% RH.

Stability studies of the optimized formulation EC-PF8 were conducted under long-term (25°C±2°C/60% RH ± 5% RH) and accelerated conditions (40°C±2°C/75% RH ± 5% RH) for up to 3 months. During this period, the formulation was evaluated for physical appearance, drug content, and *in vitro* dissolution performance. The results showed no significant changes in assay values or dissolution characteristics, indicating that the enteric coating effectively protected the acid-labile drug from degradation. Within the scope of the present study, no observable evidence of degradation or impurity formation was detected based on the evaluated parameters, suggesting that the optimized enteric coating system maintained the stability of pantoprazole during storage.

CONCLUSION

This research study found a stable, high-quality enteric-coated Pantoprazole tablet that has high acid resistance and fast drug release in intestinal environments. The compatibility of drugs and excipients was verified using FT-IR spectroscopy, and no interactions were observed. Core tablet powder exhibits favourable micromeritic properties as follows: angle of repose <30°C, and the Carr's index 12-18%. Nine formulations (PF_1-PF_9) were tested that were prepared by wet granulation, where mannitol was used as a diluent and super disintegrants; PF_8 (10% of Kollidone) was optimised due to its outstanding disintegration time (10 sec), friability (0.16 %), and highest release (100.6%) in pH 6.8 phosphate buffer. Enteric-Coated (EC-PF_8) cores were then enteric-coated at 4, 6, or 8% levels with Eudragit RS 100, L, or PVAP and optimised with results in acid resistance (EC-PF_8 required 2 hr to release in 0.1N HCl, 69.85% at 45 min at pH 6.8 (better than marketed Aciban 69.85% at 45 min at pH 6.8). Stability tests verified the strength of EC-PF_8, with 94% or more release and 98.5% assay remaining after 3 months at 40°C/75% relative humidity. Therefore, EC-PF_8 is an enhanced formulation that exceeds commercial standards of release kinetics and stability. The enteric-coated formulation, EC-PF_8, showed the highest release of 100.16% in 45 min at 6.8 pH phosphate buffer, following the resistance of acids, and across all formulations, EC-PF_8 recorded the highest release of the drug in 45 min compared to the rest. The optimized formulation demonstrated adequate gastric protection and rapid drug release under intestinal pH conditions, ensuring improved stability of the acid-labile drug. From a clinical perspective, this approach supports enhanced therapeutic effectiveness by delivering the drug at the intended absorption site. From an industrial standpoint, the formulation strategy using conventional wet granulation and enteric coating techniques provides a reproducible and scalable platform for manufacturing gastro-resistant proton pump inhibitor tablets, highlighting its potential applicability in pharmaceutical production.

ABBREVIATIONS

PF: Pantoprazole Formulation; **EC-PF:** Enteric-Coated Pantoprazole Formulation; **PVAP:** Polyvinyl Acetate Phthalate; **GERD:** Gastroesophageal Reflux Disease; **PPI:** Proton-Pump Inhibitor; **pH:** Potential of Hydrogen; **HPMC:** Hydroxypropyl Methylcellulose; **µg/mL:** Microgram per Milliliter; **FT-IR:** Fourier Transform Infrared Spectroscopy; **USP:** United States Pharmacopeia; **ICH:** International Council for Harmonisation; **Q1A (R^2):** Stability Testing of New Drug Substances and Products - Revision 2; **UV:** Ultraviolet; **HCl:** Hydrochloric Acid.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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AUTHORS CONTRIBUTION

Dr. V.S. Chandrasekaran - Manuscript review. Dr. Muthukumaran Mylasalam - Proofreading of Manuscript for final approval. Mr. Pughazendhi Ravi - Manuscript editing. Ms. Manimegalai Karnan- Manuscript research progress. Mr. Gowrishankar Jayabalan - Manuscript drafting.

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