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Formulation and Evaluation of Enteric Coated Tablets of Pantoprazole Sodium Sesquihydrate Using Eudragit L-100 and Cellulose Acetate

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ABSTRACT

The current study object to formulate and evaluate enteric-coated tablets of pantoprazole sod. sesquihydrate using direct compression followed by enteric coating with polymers likeCAP and Eudragit L100. Pantoprazole, is a PPI, is highly sensitive to gastric acid and thus requires a formulation approach that ensures its release in the intestinal region. Nine core formulations (F1–F9) were prepared by using varying concentrations of excipients like microcrystalline cellulose, mannitol, and croscarmellose sodium. These were evaluated for pre- and post-compression parameters including bulk density, hardness, friability, and drug content. The optimized batches (F3 and F9) were coated using 6% and 8% solutions of CAP and Eudragit L100. In vitro dissolution evaluation confirmed that all enteric-coated formulations resisted acidic degradation for up to 90 minutes and exhibited targeted drug release in 6.8 pH phosphate buffer. Among these, batch C2F9 demonstrated the best release profile (97% in 180 min) with excellent physicochemical properties and stability over 3 months. The study confirms that the developed enteric-coated formulation offers a promising oral administration for acid-labile drugs like pantoprazole.

Keywords

Pantoprazole sodium sesquihydrate, enteric coating, Eudragit L100, CAP, direct compression, in vitro dissolution

1. INTRODUCTION

It is a widely prescribed PPI used in the medication of acid-related gastrointestinal disorders like gastroesophageal reflux disease,peptic ulcers and Zollinger-Ellison syndrome. It acts by irreversibly inhibiting the H^+/K^+ ATPase enzyme system in gastric parietal cells, thereby suppressing gastric acid secretion. However, its chemical structure renders it unstable in acidic conditions, necessitating an enteric-coated formulation to prevent chemical breakdown in the stomach and ensure therapeutic efficacy in the intestine.

Conventional oral delivery of pantoprazole without protective coating leads to premature drug degradation and poor bioavailability. To overcome

this challenge, enteric coating using pH-sensitive polymers like CAP and EL100 has been proposed. These polymers remain intact in low pH but dissolve in the more basic environment of the intestine, ensuring targeted drug release. presence of investigation, pantoprazole tablets formulated by direct compression and subsequently coated with enteric polymers by the dipping method. Preformulation studies,physicochemical characterization, FTIR compatibility analysis, and In-Vitro medicine release studies were carried out. A stability measurement also carried out to confirm the robustness of the optimized formulation. This study aims to provide a stable and efficacious formulation for oral administrationof pantoprazole using simple and scalable manufacturing techniques.

2. METHODSAND MATERIALS

Materials

It was obtained as a free sample. Croscarmellose sodium,dicalcium phosphate, mannitol, (MCC), talc, Eudragit L100,magnesium stearate, and (CAP) were purchased from commercial sourcesand used as received. Analytical grade reagents and solvents were employed throughout the study. The pH buffers (1.2 and 6.8) were prepared as per USP specifications. All aqueous preparations were made using double-distilled water.

Methods

Preformulation Studies

Method of Preparation of Standard Curve in 1.2pH Buffer

a. Determination of λmax:

A stock solution was prepared by dissolution in100 mg of drug in 100 mL of 1.2 pH buffer. From this, a working solution was obtained by diluting 2 mL to 100 mL. A 2 mL aliquot from the working solution was diluted to 10 mL and scanned in the UV-visible spectrophotometer (range 200–400 nm). The λmax was observed at 283 nm.

b. Calibration Curve:

Aliquots of 1–6 mL from the standard solution were diluted to 10 mL with pH 1.2 buffer to obtain concentrations from 2–12 µg/mL. Absorbance was recorded at 283 nm.

Preparation of Standard Curve in 6.8pH Phosphate Buffer

a. Explanation of λmax:

The same procedure was followed as in section 2.2.1, but using pH 6.8 phosphate buffer. λmax was obtained 288 nm.

b. Calibration Curve:

Aliquots of 1–6 mL working solution were diluted to 10 mL with phosphate buffer to achieve 2–12 µg/mL concentrations. Absorbance was measured at 288 nm.

FTIR Compatibility Study

Drug-excipient compatibility was evaluated by Fourier-transform infrared (FTIR) spectroscopy using a Bruker FTIR spectrophotometer. Physical mixtures containing pantoprazole sodium with excipients (MCC, mannitol, croscarmellose

sodium, and dicalcium phosphate) were analyzed. Samples (10 mg) were triturated with 400 mg of potassium bromide, pressed into pellets, and scanned between 4000–400 cm^{-1}. Spectral peaks were analyzed for potential chemical interactions.

Evaluation of Precompression Parameters

Bulk Density (BD)

Accurately weighed granules were 10 gmgently transferred to a graduated cylinder, and bulk volume was noted. Bulk density (g/mL) was calculated using:

BD = Mass / Bulk volume

Tapped Density (TD)

Granules in a graduated cylinder were tapped 50 times. Tapped volume was recorded, and tapped density was computed:

Dt = Weight / Tapped volume

Compressibility Index &Hausner's Ratio

Compressibility Index (%) = [(TD – BD) / TD] × 100

Hausner's Ratio = TD / BD

Static Angle of Repose (θ)

The granules flowed through a funnel positioned 2 cm above a level surface, producing a cone-shaped heap. The angle of repose was determined as follows:

$$\theta = \tan^{-1}(h / r)$$

Where, h = height of pile, r = radius of base

Formulation of Core Tablets

Preparation of Powder Blend

Pantoprazole tablets were manufactured by the direct compression technique. Accurately weighed amounts of pantoprazole sodium, MCC, mannitol, croscarmellose sodium, and dicalcium phosphate were mixed, passed through #80 mesh, and lubricated with talc &magnesium stearate.

Tablet Compression

The prepare blends compressed into tablets of 250 mg using an 8 mm concave punch at rotary tablet press (Rimek RDB4-10, India). Each tablet contained 50 mg of pantoprazole sodium.

Table 1. Composition of Pantoprazole Sod. Enteric Coated Tablets

Ingredient (mg/tab)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Pantoprazole Sodium 50	-	-	-	-	-	-	-	-	-
Croscarmellose Sodium	3	6	9	3	6	9	3	6	9
MCC	45	40	35	45	40	60	75	55	35
Mannitol	67	84	101	55	89	91	62	70	80
Dicalcium Phosphate	85	60	45	87	55	30	55	59	66
Talc	4	4	4	4	4	4	4	4	4
Magnesium Stearate	6	6	6	6	6	6	6	6	6
Total 250	-	-	-	-	-	-	-	-	-

Evaluate the Post-Compression Parameters

Hardness Test

Tablet hardness measured by the Monsanto hardness tester &expressed in kg/cm².

Friability

Twenty tablets weighed (W_initial), rotated in a Roche friabilator at 25 rpm for 100 revolutions, and reweighed (W_final). Friability (%) was calculated as:

F = [(W_initial – W_final) / W_initial] × Hundred

Weight Variation

Twenty tablets weighed individually. The avg weight and percentage deviation were calculated.

Tolerance: ±7.5% for tablets weighing 80–250 mg (IP).

Uniformityof Drug Content

Three tablets powdered, and an amount equivalent to 40 mg the drug Pantoprazole was dissolved in phosphate buffer (pH 6.8), filtered, diluted, and its concentration determined at 288 nm.

Disintegration Time

The tablets were tested for disintegration in phosphate buffer (pH 6.8) at 37 ± 0.5 °C using an Electrolab ED-2L apparatus..

Enteric Coated TabletsPreparation

Coating Solution Preparation

Enteric coating solutions prepared by 6% and 8% w/w of either CAP or Eudragit L100 in a solvent system of acetone and IPA, with PEG 400 (1.5% w/w) as plasticizer. The mixture stirred at 1000 rpm for 1 hour and then filtered by muslin cloth.

Coating by Dipping Method

The enteric coating was applied to the core tablets by dipping them in polymer solution until the specified weight gain was obtained.Coated tablets tested for weight uniformity, hardness, thickness, and drug content

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Evaluation of Coating Films

Using solvent casting, films were prepared on a glass plate and left to dry for 24 hours. Cut pieces (1 cm²) were assessed for:

- Thickness (digital micrometer)
- Solubility in pH 1.2 and 6.8 at 37 ± 1 °C

In Vitro Dissolution Study

Dissolution performed by USP Type II paddle apparatus (Electrolab TDT-08L). Tablets placed in 900 mL of 1.2 pHbuffer for 2 hours, followed by 6.8 pH phosphate buffer for 1 hour. Temperature: 37 ± 0.5 °C; Speed: 100 rpm. Samples were withdrawn periodically and analyzed at 283 nm (acid buffer) and 288 nm (phosphate buffer).

Testingof Stability

Accelerated testing ofstability performed on optimized batches (e.g., C2F9) as per ICH guidelines (40 ± 2 °C / 75 ± 5% RH) for 3 months. Tablets were evaluated at 0, 1, 2, and 3 months for:

- Physical appearance
- Hardness
- Drug content

3. RESULTS &DISCUSSION

Preformulationstudy

StandardgraphsPreparation

Separate standard curves for drug were plotted in 1.2pH and 6.8pH phosphate buffer. **Table 2 and 3**show the concentrations of pantoprazolesod. 1.2pH&6.8pHphosphatebuffersandtherespective absorbance.TheFig 4&5 show the pantoprazole sod. calibration graphs were generated in both 1.2 pH and 6.8pHphosphate buffer.

Table 2: Pantoprazole sod.calibration values in0.1 N hydrochloric acid(1.2pH)

Concentration (mg/mL)	Predicted Absorbance (nm)
0	0.001
0-2	0.075
2-4	0.15
4-6	0.224
6-8	0.298
8-10	0.372
10-12	0.447

Figure 1: Standard plot of pantoprazole sodium in 0.1 N Hydrochloric acid(1.2pH)

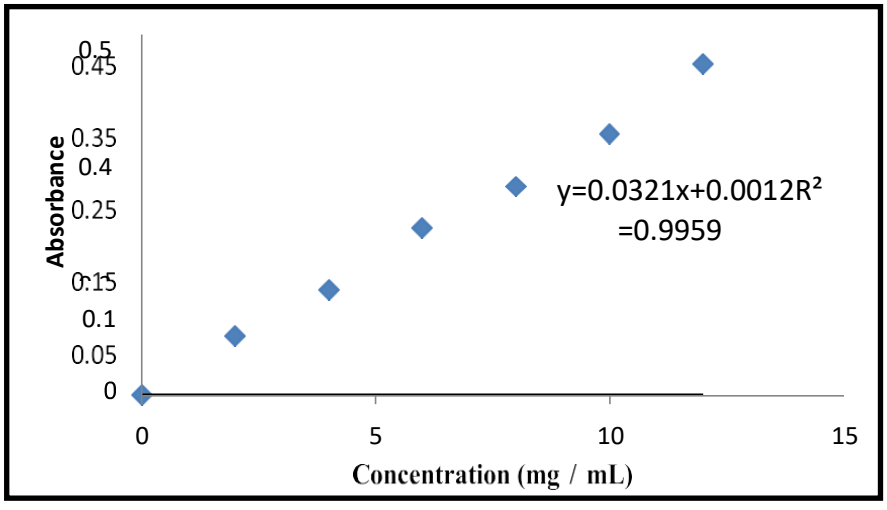
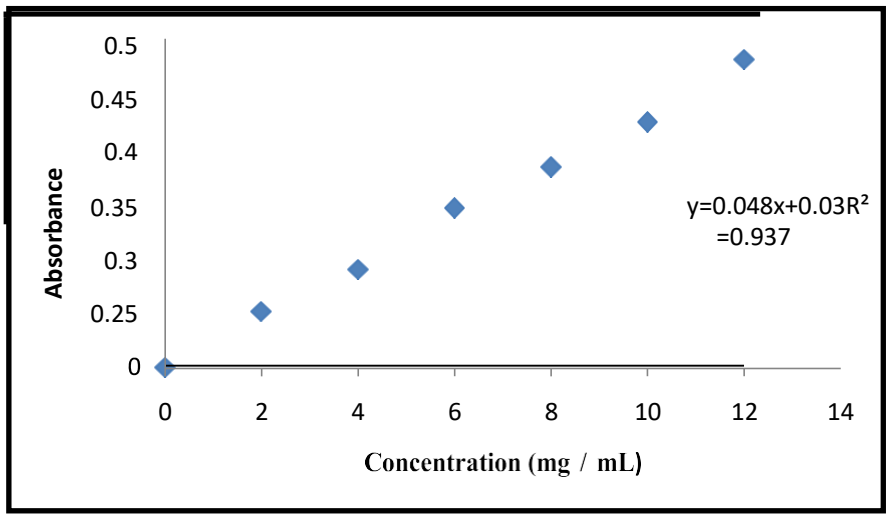


Table3.Calibration data of pantoprazole sodium in phosphate buffer (pH 6.8)

Concentration (mg/mL)	Absorbance*(nm)
-	-
2.0	0.084±0.0040
4.0	0.148±0.0036
6.0	0.248±0.0015
8.0	0.308±0.0075
10.00	0.378±0.0051
12.00	0.568±0.0020

*Mean±SD,*n*=3

Figure2.Standard calibration graph of pantoprazole sod.in phosphate buffer (6.8 pH)



FTIRspectralstudy

This study was conducted separately to findout the drug compatibility inbetween the microcrystallinecellulose and pantoprazole,mannitol,dicalciumphosphate,croscarmellose sodium. The FTIR performed for drug, polymer and the mixtureof the Drug-polymer.The spectralobtained from FTIR spectroscopy

The peaks in the spectra of the drug-polymer mixtures were consistent with one another.That indicatesthedrugwascompatiblewiththeformulationcomponents.IRstudiesindicatedno interaction in the drugandpolymers.

Figure 3: FTIR spectra of a physical combination of mannitol and pantoprazole sodium

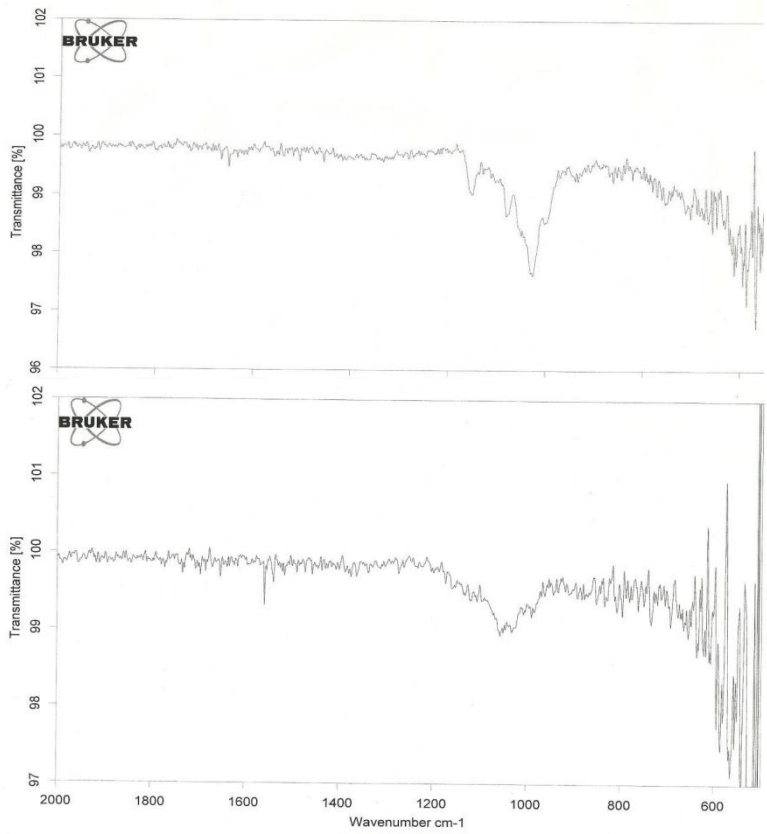
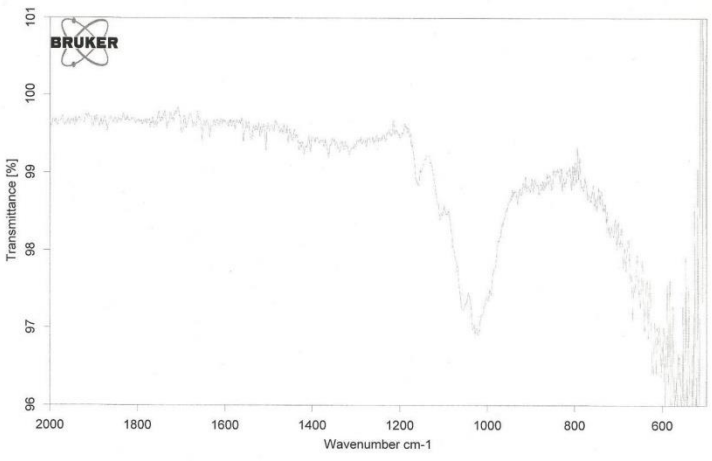


Figure 4: FTIR spectra of a physical combination of diethium phosphate and pantoprazole sodium

Figure 5. FTIR spectra of a physical combination of mannitol, dicalcium phosphate& pantoprazole sod.

Table 4. Pantoprazole Sod.Std Band Frequency

Wave numberincm^{-1}	Characteristic
1900	C=H
1650 -1580	N-Hbending
1600 -1400	AromaticC=Cstre tching
1400 -1000	C-Nbending



1373	C-F
1049	S=O

Thisgraph producedto the physical mixture show all the principle peaks ator around the requisite wave no. of pure drug. Hence, no chemical interaction occurred between the drug and polymer, with the drug maintaining its purity and integrity in the physical mixtures .

Evaluations

Pre-compression parameters

Pantoprazole powder blends were prepared for tableting by the direct compression technique.Thispantoprazolepowderblendevaluate dangleofreposetappeddensity,bulkdensity,Hausn er'sratioandcompressibilityindexasgivenon **Tableno. 8.**The bulk density of the granules ranged from 0.306 ± 0.03 to 0.384 ± 0.04 g/mL, whereas the tapped density ranged from 0.313 ± 0.04 to 0.429 ± 0.05 g/mL.Granule flow characteristics were assessed through determination of the angle of repose and Carr's index of compressibility. Compressibility values (5.74 ± 0.13–10.48 ± 0.20%) indicate that the granules possess good flow properties. The angle of repose, ranging from 25.79 ± 0.24° to 29.52 ± 0.14°, also supports the favorable flow behavior of all formulations.

Formulationstudies

Preparation of the pantoprazole sod. tablets

A total of nine formulations (F1–F9) of pantoprazole sodium sesquihydrate tablets prepared via direct compression on a rotary tablet press (8 mm diameter, Riddhi 10 STD, Rimek,Ahmedabad,India). Compositions of the pantoprazolesod.sesquihydrate tablets .

Table5pantoprazolesodiumpre-compressionparameters

Formulation Code	Bulk density (gm/mL)	Density after tapping(gm/mL)	Carrâs Index (%)	Hausnerâs ratio	Static angle of repose
F1	0.372	0.395	5.82	1.061	27.85
F2	0.319	0.342	6.73	1.072	27.05
F3	0.298	0.318	6.29	1.067	28.97
F4	0.305	0.327	6.73	1.072	25.95
F5	0.318	0.345	7.83	1.085	26.42
F6	0.39	0.441	11.56	1.13	25.31
F7	0.366	0.391	6.39	1.068	28.73
F8	0.294	0.325	9.54	1.105	27.22
F9	0.351	0.371	5.39	1.057	25.88

*****Mean±SDn=3

Post-compressionparametersof thepantoprazolesodiumcoretablet

Based on evaluation parameters of all 9 formulations (F1–F9), notable variations

observed in tablet friability, hardness,, disintegration timeanddrug content. The hardness ranged from 4.56 ± 0.24 kg/cm² (F2) to 6.83 ± 0.08 kg/cm² (F3), with F3 showing the highest mechanical strength. Friability values remains within acceptable limits (<1%), with F7 exhibiting the lowest friability ($0.24 \pm 0.027\%$), indicating superior mechanical resistance. Weight variation across formulations was consistent and within pharmacopeial limits, indicating uniform tablet size. Drug content was highest in F6 ($101.34 \pm 0.12\%$) and lowest in F9 ($95.08 \pm 0.36\%$), demonstrating efficient drug loading in most batches. The fastest disintegration was observed in F6 (8.13 ± 0.26 min), followed closely by F3 (8.38 ± 0.24 min), highlighting their potential for immediate effect. Among all formulations, F6 showed the most favorable combination of mechanical strength, rapid disintegration, and drug content.

Table6 Post- compressionparametersof pantoprazole sod.coretablets

Product Code	Parameter				
	Hardness(Kg/cm^2)*	Friability (%)*	Wt. variation (mg)*	content of drug(%) *	Time of Disintegration(min)*
F1	5.60± 0.12	0.79 ± 0.016	248± 0.12	97.28± 0.14	11.6±0.63
F2	4.56± 0.24	0.61± 0.016	256± 0.24	98.62± 0.28	9.26±0.57
F3	6.83± 0.08	0.58± 0.015	251± 0.17	98.51± 0.37	8.38±0.24
F4	4.92± 0.15	0.54± 0.016	258± 0.20	99.17± 0.17	10.48±0.16
F5	6.73± 0.25	0.61± 0.017	253± 0.16	96.92± 0.43	10.32±0.19
F6	6.12± 0.34	0.78± 0.027	256± 0.14	101.34± 0.12	8.13±0.26
F7	6.66± 0.17	0.24± 0.027	248 ± 0.22	99.50± 0.49	11.54±0.44
F8	5.20± 0.35	0.59± 0.026	254± 0.18	97.41± 0.32	10.12±0.72
F9	6.60± 0.24	0.52± 0.019	251± 0.15	95.08± 0.36	9.02±0.22

*Mean±SD,n=3

Physicochemicalcharacterizationof thecoatingfilms

The CAP and Eudragit L-100 coating films were subjected to physicochemical evaluation, including assessment of film thickness, weight, and solubility. CAP and Eudragit L-100, as enteric polymers, dissolved completely at 6.8pH while remaining insoluble at pH 1.2.

Evaluation of physicochemical properties of pantoprazole sodium enteric-coated tablets

Thiscoveredtablets of F3 and F9, selected based on their superior disintegration time and drug content, evaluated for key physicochemical parameters following dip coating. The weight variation ranged from $0.211 \pm 0.024\%$ to 214 ± 0.021 mg, indicating good uniformity in tablet mass post-coating. Drug content remained within acceptable pharmacopeial limits, varying from $93.47 \pm 0.23\%$ to $98.45 \pm 0.12\%$, suggesting minimal drug loss during the coating process. The hardness of coated

tablets ranged between 5.2 ± 0.11 and 6.5 ± 0.15 kg/cm², reflecting sufficient mechanical strength to withstand handling and packaging. Overall, the results confirm that dip coating did not compromise key tablet properties, and the coated formulations maintained satisfactory quality attributes.

Table7Physicochemical analysis of several coating films made of polymers

Polymers	Parameter		
	Filmsolubility		Thickness of film(mm)*
CAP Polymer	Insoluble in pH 1.2	Soluble in pH6.8	0.34±0.07
EudragitL100 polymer	Insoluble in pH1.2	Soluble in pH 6.8	0.29±0.09

*****Mean±SD,*n*=3

Table8.Physicochemical parameters used in the evaluation of enteric-coated tablets

Polymer	Batch Code	Weight Variation (mg)	Hardness (Kg/cm²)	Drug Content (%)
CAP	C1F3	249 ± 0.035	6.7 ± 0.15	97.82 ± 0.14
	C2F3	252 ± 0.016	6.1 ± 0.24	95.14 ± 0.35
	C1F9	250 ± 0.006	5.8 ± 0.09	95.68 ± 0.26
	C2F9	248 ± 0.024	6.5 ± 0.14	99.63 ± 0.12
Eudragit L100	E1F3	251 ± 0.021	5.9 ± 0.16	95.38 ± 0.23
	E2F3	250 ± 0.012	6.2 ± 0.06	96.42 ± 0.14
	E1F9	253 ± 0.015	6.8 ± 0.31	99.14 ± 0.45
	E2F9	249 ± 0.024	6.0 ± 0.20	97.43 ± 0.12

*****Mean±SD,*n*=3

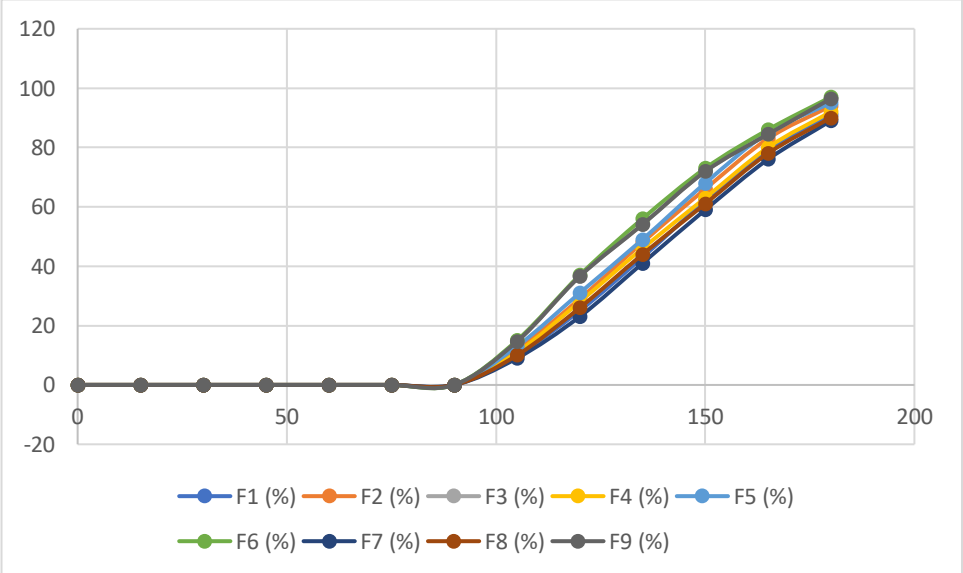
In vitro assessment of drug release from enteric-coated tablets

In-vitro dissolution analysis of formulations F1-F9 revealed a consistent enteric-coated drug release behavior, characterized by zero Drug Release during the 1st 90 minutes in acidic medium, thereby confirming the integrity of the enteric coating. Upon transition to the phosphate buffer (pH 6.8), drug release commenced at 105 minutes for all formulations. Among them, F6 demonstrated the highest and fastest release rate, reaching 97% at 180 minutes, followed closely by F3 and F9, both showing 96.42% release. F2 and F5 also exhibited robust performance, with over 94% cumulative release. Formulations F1, F4, F7, and F8 showed relatively lower but acceptable release profiles, ranging from 89% to 92% at 180 minutes. These results presents all compositions successfully delayed release in the acidic pH and liberatedthe drug effectively in intestinal pH, formulations F3, F6, and F9 were the most optimized in terms of controlled and complete drug delivery. The data suggest these could be promising candidates for targeted intestinal drug release.

Table9.*In-vitro*DrugReleaseofpantoprazolesod.

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)	F9 (%)
0	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
60	-	-	-	-	-	-	-	-	-
75	-	-	-	-	-	-	-	-	-
90	-	-	-	-	-	-	-	-	-
105	10	12	14.62	11	13	15	9	10	14.62
120	25	29	36.58	28	31	37	23	26	36.58
135	43	48	54.05	46	49	56	41	44	54.05
150	62	66	71.91	63	68	73	59	61	71.91
165	79	83	84.46	80	85	86	76	78	84.46
180	91	94	96.42	92	95	97	89	90	96.42

Figure6.*In-vitro*DrugReleaseofpantoprazolesod.TIME VS % CON



7.3.1.2 Stabilitystudies

The stability study of cellulose acetate phthalate-coated formulation C2F9 was conducted over a three-month period under standard storage conditions. The physical appearance of tablets remained unchanged throughout the study, with no signs of discoloration, cracking, or degradation, indicating good formulation stability. The hardness showed a gradual

increase from an initial 5.3 ± 0.14 kg/cm² to 7.3 ± 0.26 kg/cm² by the third month, possibly due to slight moisture loss or polymeric film tightening over time. Drug content remained within acceptable limits, though a minor dip

was observed in the second month ($92.16 \pm 0.36\%$), followed by a recovery to $97.07 \pm 0.28\%$ in the third month. These results suggest that the enteric-coated tablets maintained their physicochemical integrity over the testing period, affirming their suitability for long-term storage with minimal impact on efficacy and quality.

Table 10. Stability study of CAP coated tabletformulationC2F9

Parameters Evaluation	InmonthObservation			
	Initial Point	**1st(month)**	**2nd(month)**	**3rd(month)**
PhysicalChanges	Tablets whitecolor	-	-	-
Compactness(Kg/cm²)	5.3± 0.14	7.2± 0.56	7.2± 0.64	7.3± 0.26
DrugContent(%)	99.54± 0.13	97.36± 0.52	92.16± 0.36	97.07± 0.28

*****Mean±SD,n=3

4. Conclusion

This study successfully demonstrated the formulation & evaluation of the enteric-coated tablets of pantoprazole sodium sesquihydrate prepared by direct compression followed by polymeric film coating. Pantoprazole, being acid-labile, necessitates protection from the gastric environment to ensure therapeutic efficacy. In this regard, pH-dependent polymers for example CAP and Eudragit L100 were effectively utilized for enteric coating.

Among nine core tablet formulations (F1–F9), F6, F3, and F9 emerged as promising candidates based on pre- and post-compression evaluations, including superior drug content, acceptable friability, and rapid disintegration. FTIR studies confirmed the absence of drug–excipient incompatibility, validating the physical stability of formulation.

Enteric-coated tablets maintained integrity in acidic conditions for 90 minutes and exhibited efficient drug release in intestinal pH during in vitro studies; F9 (C2F9) with 8% CAP coating achieved the best performance (97% release at 180 minutes) and excellent mechanical properties. Additionally, accelerated stability study conducted by 3 months shows the optimized batch maintained its physical appearance, hardness & Drug Content within standard limits.

In conclusion, the developed enteric-coated formulation (C2F9) of pantoprazole sod. offers a reliable and efficient oral dosage form with acid resistance, targeted intestinal drug release, and good stability. This approach is ideal for improving bioavailability& therapeutic effectiveness of pantoprazole and other acid-labile drugs in the management of acid-related gastrointestinal disorders.

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