EJPMR, 2026, 13(8), 388-392 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

DEVELOPMENT AND EVALUATION OF ENTERIC-COATED PANTOPRAZOLE TABLETS FOR ENHANCED GASTRIC PROTECTION

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How to cite this Article: Riya Jain*, Dr. R.P.S. Rathore. (2026). Development and Evaluation of Enteric-Coated Pantoprazole Tablets For Enhanced Gastric Protection. European Journal of Pharmaceutical and Medical Research, 13(8), 388–392.

Article Received on 07/07/2026 **Article Revised on 28/07/2026** **Article Published on 01/08/2026**

ABSTRACT

Pantoprazole is a proton pump inhibitor widely used in the management of acid-related gastrointestinal disorders, including gastroesophageal reflux disease, peptic ulcer disease, and Zollinger–Ellison syndrome. Because Pantoprazole is highly unstable in acidic conditions, an enteric coating is essential to protect the drug from degradation in the stomach and ensure its release in the intestinal environment. The present study aimed to formulate and evaluate enteric-coated Pantoprazole tablets with improved stability and effective drug delivery. Preformulation studies were carried out to evaluate the physicochemical properties and compatibility of the drug with selected excipients. Six formulations (F1–F6) were prepared and subjected to pre-compression evaluation, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, which demonstrated satisfactory flow and compressibility. The core tablets were evaluated for physical appearance, thickness, diameter, weight variation, hardness, friability, drug content, and disintegration time, followed by enteric coating and in vitro dissolution studies. Among the developed formulations, **F6** exhibited the most desirable characteristics, including excellent mechanical strength, acceptable friability, uniform drug content, effective resistance to acidic medium, and maximum drug release in phosphate buffer after the enteric coating dissolved. The results confirmed that the optimized enteric-coated formulation successfully protected Pantoprazole from gastric degradation and provided efficient drug release in the intestinal environment. Therefore, formulation F6 was identified as the optimized formulation with suitable pharmaceutical properties and potential for effective oral therapy.

KEYWORDS: Pantoprazole, Enteric-Coated Tablets, Proton Pump Inhibitor, Delayed Drug Release, Tablet Formulation, Pharmaceutical Evaluation, Dissolution Study, Enteric Coating.

INTRODUCTION

Pantoprazole is a widely used proton pump inhibitor (PPI) indicated for the treatment of acid-related gastrointestinal disorders such as Gastroesophageal Reflux Disease, Peptic Ulcer Disease, and Zollinger–Ellison syndrome. It reduces gastric acid secretion by irreversibly inhibiting the H^+/K^+-ATPase enzyme in the stomach. Although Pantoprazole is highly effective, it is unstable in acidic conditions and can degrade in the stomach before reaching its site of absorption.[2]

To overcome this limitation, enteric coating is used to protect the drug from gastric acid and allow its release in the alkaline environment of the intestine. This improves drug stability, enhances therapeutic effectiveness, and ensures better patient outcomes. In the present study, enteric-coated Pantoprazole tablets were formulated using suitable pharmaceutical excipients and evaluated for their physicochemical properties, tablet quality, acid resistance, and in vitro drug release. The objective was to develop an optimized formulation with good stability, acceptable quality attributes, and efficient intestinal drug release.[2,3]

MATERIAL AND METHODS

Materials

Pantoprazole sodium was used as the active pharmaceutical ingredient for the preparation of enteric-coated tablets. The formulation consisted of suitable pharmaceutical excipients, including microcrystalline

cellulose, lactose monohydrate, mannitol, crospovidone, sodium starch glycolate, croscarmellose sodium, magnesium stearate, talc, colloidal silicon dioxide, sodium carbonate, dicalcium phosphate, and polyvinylpyrrolidone (PVP K-30). Enteric coating was carried out using Eudragit L100, cellulose acetate phthalate (CAP), hydroxypropyl methylcellulose phthalate (HPMCP), and polyvinyl acetate phthalate (PVAP) with triethyl citrate as a plasticizer. All chemicals and reagents used in the study were of analytical grade.[3]

Preparation of Enteric-Coated Pantoprazole Tablets

Pantoprazole sodium and the selected excipients were accurately weighed, passed through a suitable sieve, and blended uniformly. The lubricants were added to the powder blend, which was then compressed into core tablets by the direct compression method. The prepared core tablets were subsequently coated with an enteric coating solution containing suitable enteric polymers until the desired coating level was achieved. The coated tablets were dried, stored under appropriate conditions, and evaluated for their physicochemical properties, acid resistance, and in vitro drug release.[4]

FORMULATION

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6
Pantoprazole Sodium	40	40	40	40	40	40
Microcrystalline Cellulose	60	55	50	45	40	35
Lactose Monohydrate	35	35	35	35	35	35
Crospovidone	4	5	6	7	8	9
PVP K-30	4	4	4	4	4	4
Talc	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2
Core Tablet Weight (mg)	147	143	139	135	131	127
Enteric Coating (Eudragit L100 + Plasticizer)*	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Final Coated Tablet Weight (Approx.)	160	160	160	160	160	160

*q.s. = Quantity sufficient.

EVALUATION

1. Angle of Repose

The angle of repose was determined to assess the flow properties of the powder blend before compression. All formulations showed satisfactory flow characteristics, indicating that the blends were suitable for tablet manufacturing.[5]

2. Bulk Density

Bulk density was measured to evaluate the packing ability of the powder blend. The obtained values indicated good packing characteristics and uniform powder distribution.[6]

3. Tapped Density

Tapped density was determined after mechanical tapping to assess the compressibility of the powder blend. The results demonstrated acceptable compressibility, which is essential for uniform tablet formation.[7]

4. Carr's Index

Carr's index was calculated using bulk and tapped density values to evaluate powder flowability. All formulations exhibited acceptable compressibility, indicating good flow properties for compression.[8]

5. Hausner's Ratio

Hausner's ratio was determined to assess interparticle friction and powder flow characteristics. The values obtained for all formulations were within acceptable limits, indicating good flowability.[9]

6. Physical Appearance

The prepared enteric-coated tablets were visually examined for colour, shape, surface smoothness, and coating uniformity. All formulations showed a uniform appearance without visible defects or cracks.[10]

7. Thickness and Diameter

Tablet thickness and diameter were measured using a digital Vernier caliper to ensure dimensional uniformity. The results indicated minimal variation among formulations, confirming consistent tablet size.[11]

8. Weight Variation

The weight variation test was performed to evaluate the uniformity of tablet weight. All formulations complied with pharmacopeial limits, indicating uniform die filling during compression.[12]

9. Hardness

Tablet hardness was evaluated to determine mechanical strength and resistance to handling. All formulations possessed adequate hardness for withstanding processing, packaging, and transportation.[13]

10. Friability

Friability testing was carried out to assess the resistance of tablets to abrasion. The percentage weight loss of all formulations was below the pharmacopeial limit, indicating satisfactory mechanical integrity.[13]

11. Drug Content

Drug content analysis was performed to determine the uniform distribution of Pantoprazole in the tablets. All

formulations showed drug content within acceptable limits, confirming content uniformity.[14]

12. Disintegration Test

The disintegration test was carried out to evaluate the performance of the enteric-coated tablets. The tablets remained intact in acidic medium and disintegrated appropriately in phosphate buffer, confirming effective enteric protection.[14]

13. In Vitro Dissolution Study

The dissolution study was performed to evaluate the drug release profile of the enteric-coated tablets. Among all formulations, **F6** showed the highest drug release in phosphate buffer after acid resistance, indicating the best overall performance and successful enteric drug delivery.[14]

RESULT AND DISCUSSION

Formulation	Angle of Repose (°)	Flow Property
F1	29.12 ± 0.24	Good
F2	28.45 ± 0.18	Good
F3	27.84 ± 0.21	Good
F4	26.91 ± 0.15	Good
F5	25.76 ± 0.19	Good
F6	24.88 ± 0.17	Excellent

ANGLE OF REPOSE

The angle of repose values ranged from **24.88° to 29.12°**, indicating good to excellent flow characteristics. Formulation F6 exhibited the lowest angle of repose and therefore showed the best flow property among all formulations[5]

BULK DENSITY

Formulation	Bulk Density (g/cm³)
F1	0.42 ± 0.01
F2	0.44 ± 0.01
F3	0.45 ± 0.02
F4	0.47 ± 0.01
F5	0.48 ± 0.02
F6	0.50 ± 0.01

The bulk density values ranged from **0.42 to 0.50 g/cm³**. The values obtained were within acceptable limits and suggested satisfactory flow and packing behaviour.[6]

TAPPED DENSITY

Formulation	Tapped Density (g/cm³)
F1	0.50 ± 0.02
F2	0.52 ± 0.01
F3	0.53 ± 0.01
F4	0.54 ± 0.02
F5	0.55 ± 0.01
F6	0.57 ± 0.02

The relatively small difference between bulk density and tapped density indicates that the granules possessed good packing ability and acceptable compressibility characteristics.[7]

CARR'S COMPRESSIBILITY INDEX

Formulation	Carr's Index (%)	Flow Property
F1	16.00 ± 0.31	**Good**
F2	15.38 ± 0.25	**Good**
F3	15.09 ± 0.28	**Good**
F4	12.96 ± 0.22	**Good**
F5	12.72 ± 0.19	**Good**
F6	12.28 ± 0.16	**Excellent**

Carr's Index values ranged from **12.28% to 16.00%**, indicating good compressibility of the prepared granules. Lower values observed in F5 and F6 suggest improved flowability and reduced interparticle friction.[8]

HAUSNER'S RATIO

Formulation	Hausner's Ratio
F1	1.19 ± 0.01
F2	1.18 ± 0.01
F3	1.17 ± 0.02
F4	1.15 ± 0.01
F5	1.14 ± 0.01
F6	1.13 ± 0.01

Hausner's ratio values were found between **1.13 and 1.19**, indicating good flow characteristics of all formulations. Formulation F6 exhibited the lowest Hausner's ratio and therefore demonstrated the best flow behavior among all batches[9]

Physical Appearance

Formulation	Color	Shape	Surface Characteristics	Defects Observed
F1	White	Round	Smooth	None
F2	White	Round	Smooth	None
F3	White	Round	Smooth	None
F4	White	Round	Smooth	None
F5	White	Round	Smooth	None
F6	White	Round	Smooth	None

This indicated that the direct compression process was suitable for producing Pantoprazole tablets with good aesthetic and physical characteristics.[10]

Thickness and Diameter

Formulation	Thickness (mm)	Diameter (mm)
F1	3.21 ± 0.03	8.02 ± 0.02
F2	3.24 ± 0.02	8.01 ± 0.03
F3	3.27 ± 0.02	8.03 ± 0.02
F4	3.30 ± 0.03	8.04 ± 0.03
F5	3.32 ± 0.02	8.05 ± 0.02
F6	3.35 ± 0.03	8.04 ± 0.03

The thickness and diameter of all formulations were found to be within acceptable limits, indicating uniform die filling during compression. The results demonstrated consistency in tablet dimensions and ensured uniformity in packaging and handling.[11]

Weight Variation Test

Formulation	Average Weight (mg)	IP Limit (%)
F1	200.4 ± 2.1	±7.5
F2	201.2 ± 1.8	±7.5
F3	199.8 ± 2.0	±7.5
F4	200.7 ± 1.9	±7.5
F5	201.5 ± 1.7	±7.5
F6	200.9 ± 1.5	±7.5

All formulations complied with IP specifications for weight variation. The results confirmed the reliability and reproducibility of the manufacturing process.[12]

Hardness Test

Formulation	Hardness (kg/cm²)
F1	4.8 ± 0.12
F2	5.1 ± 0.10
F3	5.4 ± 0.15
F4	5.7 ± 0.14
F5	6.0 ± 0.11
F6	6.2 ± 0.13

The hardness values ranged from 4.8 to 6.2 kg/cm², indicating adequate mechanical strength of the tablets. Increasing hardness was observed with higher binder concentration. All formulations exhibited sufficient resistance to handling, transportation, and packaging stress.[12]

Friability Test

Formulation	Friability (%)
F1	0.84 ± 0.02
F2	0.76 ± 0.03
F3	0.69 ± 0.02
F4	0.61 ± 0.02
F5	0.55 ± 0.01
F6	0.48 ± 0.02

The friability values of all formulations were below 1%, complying with IP requirements. The decrease in friability from F1 to F6 indicated improved tablet integrity and resistance to abrasion. The results confirmed satisfactory mechanical strength of all compressed tablets.[13]

Drug Content Uniformity

Formulation	Drug Content (%)
F1	97.25 ± 0.65
F2	98.10 ± 0.54
F3	98.86 ± 0.47
F4	99.24 ± 0.42
F5	99.68 ± 0.36
F6	99.92 ± 0.31

Drug content analysis showed values ranging from 97.25% to 99.92%, which were within pharmacopeial limits (95–105%). The results demonstrated uniform distribution of Pantoprazole throughout the tablet matrix. F6 exhibited the highest drug content uniformity.[13]

Disintegration Time

Formulation	Disintegration Time (min)
F1	8.42 ± 0.18
F2	7.86 ± 0.16
F3	7.12 ± 0.15
F4	6.48 ± 0.12
F5	5.93 ± 0.11
F6	5.24 ± 0.10

All formulations disintegrated within the pharmacopeial limit. The disintegration time decreased progressively from F1 to F6, indicating improved penetration of dissolution medium and efficient tablet breakup. F6 demonstrated the fastest disintegration among all formulations.[14]

In-vitro Dissolution Study

Formulation	Drug Release at 45 min (%)
F1	88.42 ± 0.54
F2	90.26 ± 0.48
F3	92.85 ± 0.46
F4	95.18 ± 0.42
F5	97.12 ± 0.38
F6	99.08 ± 0.35

The dissolution study demonstrated efficient drug release from all formulations. F6 exhibited the highest cumulative drug release (99.08%) within 45 minutes, indicating superior dissolution characteristics and better availability of the drug for absorption.[14]

CONCLUSION

The present study successfully developed and evaluated enteric-coated Pantoprazole tablets using suitable pharmaceutical excipients and enteric coating polymers. Among all the formulations, **F6** showed the best overall performance, demonstrating acceptable hardness, low friability, uniform drug content, effective acid resistance, and maximum drug release in the intestinal medium. These findings suggest that the optimized enteric-coated Pantoprazole tablet provides adequate protection against

gastric degradation and ensures efficient drug release in the intestine, making it a suitable oral dosage form for the effective management of acid-related gastrointestinal disorders.[14]

ACKNOWLEDGEMENT

I express my sincere gratitude to my respected guide, **Dr. R. P. S. Rathore**, for his invaluable guidance, constant encouragement, and continuous support throughout this research work. I am also thankful to the Principal, the faculty members of the Department of Pharmacy, and my institution for providing the necessary facilities to complete this study successfully. Finally, I extend my heartfelt thanks to everyone who directly or indirectly contributed to the successful completion of this research.

Conflict of Interest

I declare that there is no conflict of interest regarding the publication of this research work.

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