International Journal of Advances in Pharmaceutics
E-ISSN: 2320-4923; P-ISSN: 2320-4931
Journal DOI: https://doi.org/10.7439/ijap

Research Article

Design, development, and evaluation of enteric coated tablets of Ciprofloxacin using different polymers

Abu Rafey*, Shweta Shukla and Om Prakash Agrawal

Bhabha Pharmacy Research Institute, Bhabha University, Jathkhedi, Narmadapuram Road-462026, Bhopal, M.P., India

***Correspondence Info:**
Mr. Abu Rafey,
Bhabha Pharmacy Research Institute,
Bhabha University, Jathkhedi,
Narmadapuram Road-462026,
Bhopal, M.P., India

***Article History:**
Received: 01/12/2025
Revised: 26/12/2025
Accepted: 26/12/2025
DOI: https://doi.org/10.7439/ijap.v14i2.5894

Abstract

Ciprofloxacin is a broad-spectrum fluoroquinolone antibiotic widely used for the treatment of bacterial infections; however, its conventional oral dosage forms are often associated with gastric irritation and non-targeted drug release in the stomach. The present study aimed to design, develop, and evaluate enteric coated tablet formulations of Ciprofloxacin to achieve gastric protection and targeted intestinal drug release. Core tablets were prepared by the wet granulation method and subsequently coated with different pH-dependent enteric polymers. Preformulation studies confirmed the identity, purity, and compatibility of Ciprofloxacin with selected excipients. Core tablets were evaluated for micromeritic and post-compression parameters, while enteric coated tablets were assessed for acid resistance, disintegration behavior, and in-vitro dissolution. All enteric coated formulations exhibited complete resistance in acidic medium and rapid drug release in phosphate buffer pH 6.8. Among the tested polymers, methacrylic acid copolymer–based coatings showed superior performance with faster intestinal disintegration and higher drug release. Accelerated stability studies demonstrated good stability of the optimized formulation. The study concludes that enteric coating is an effective strategy to improve the oral delivery of Ciprofloxacin by minimizing gastric exposure and ensuring targeted intestinal release.

Keywords: Ciprofloxacin, Enteric Coating, Ph-Dependent Polymers, Delayed-Release Tablets, Dissolution Studies.

1. Introduction

Oral solid dosage forms remain the most widely accepted route of drug administration due to their **ease of use, patient compliance, cost-effectiveness, and manufacturing feasibility**. Among oral dosage forms, tablets are particularly preferred because of their **dose accuracy, stability, and convenience of administration [1-3]**. However, conventional immediate-release tablets may not always be suitable for drugs that are **unstable in acidic conditions, cause gastric irritation, or require site-specific release within the gastrointestinal tract**. To overcome these limitations, modified oral drug delivery systems such as **enteric coated tablets** have been developed [4-5].

Enteric coated tablets are designed to **resist disintegration and drug release in the acidic environment of the stomach** and to release the drug selectively in the **intestinal pH** [6]. This approach is especially beneficial for drugs that cause gastric discomfort, undergo degradation in gastric fluid, or exhibit improved absorption in the intestine [7]. The effectiveness of enteric coating depends primarily on the **use of pH-dependent polymers**, which remain intact at low pH and dissolve at higher pH values encountered in the intestine [8-9].

Ciprofloxacin is a widely used **fluoroquinolone antibiotic** with broad-spectrum antibacterial activity against both Gram-positive and Gram-negative microorganisms [10]. It is commonly prescribed for the treatment of urinary tract infections, gastrointestinal infections, respiratory tract infections, and skin infections [11]. Despite its therapeutic efficacy, conventional oral formulations of Ciprofloxacin are often associated with **gastric irritation, nausea, and discomfort**, particularly during prolonged therapy. In addition, premature drug release in the stomach may reduce patient tolerability and compliance [12-13].

Enteric coating of Ciprofloxacin tablets offers a promising strategy to **minimize gastric exposure**, protect the drug from acidic degradation, and ensure **targeted release in the intestinal environment**, where absorption is

more favorable [14-15]. Various **enteric polymers**, including cellulose-based polymers and methacrylic acid copolymers, have been extensively studied for their ability to provide effective gastric resistance and controlled intestinal drug release. However, the performance of enteric coated tablets can vary significantly depending on **polymer type, polymer concentration, and coating parameters** [16-18].

Therefore, the present research work was undertaken to design, develop, and evaluate enteric coated tablet dosage forms of Ciprofloxacin using different pH-dependent polymers [19]. The study aims to compare the effect of various enteric polymers on acid resistance, disintegration behavior, and in-vitro drug release, with the objective of developing a stable, pharmacopeially compliant, and patient-friendly enteric coated Ciprofloxacin tablet formulation [20].

2. Materials and methods

2.1 Materials

Ciprofloxacin was used as the active pharmaceutical ingredient. Excipients such as microcrystalline cellulose, lactose monohydrate, polyvinylpyrrolidone (PVP K-30), croscarmellose sodium, magnesium stearate, and talc were employed for core tablet formulation. Enteric polymers including cellulose-based and methacrylic acid copolymers were used for coating. All chemicals and reagents were of analytical grade.

2.2 Preformulation Studies

Preformulation studies included:

- **UV–Visible spectroscopy** for identification and λmax determination
- **FTIR spectroscopy** for functional group analysis
- **Solubility studies** in different media
- **Melting point determination**
- **Drug–excipient compatibility studies** using FTIR and DSC

2.3 Preparation of Core Tablets

Core tablets were prepared by the wet granulation method. Ciprofloxacin and excipients were blended uniformly, granulated using a binder solution, dried, lubricated, and compressed into tablets. Multiple formulations were developed to optimize tablet properties.

Table 1: Composition of Ciprofloxacin Core Tablet Formulations (F1–F9)

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ciprofloxacin	250	250	250	250	250	250	250	250	250
Microcrystalline cellulose	80	90	100	85	95	105	90	100	110
Lactose monohydrate	40	30	20	35	25	15	30	20	10
PVP K-30	10	12	14	10	12	14	10	12	14
Croscarmellose sodium	10	10	10	15	15	15	20	20	20
Talc	5	5	5	5	5	5	5	5	5
Magnesium stearate	5	5	5	5	5	5	5	5	5
Total weight (mg)	**400**	**402**	**404**	**405**	**407**	**409**	**400**	**400**	**400**

2.4 Enteric Coating Process

Optimized core tablets were coated using different enteric polymers. Coating solutions were prepared by dissolving/dispersing polymers in suitable solvents along with plasticizers. Coating was performed in a pan coating apparatus under controlled conditions of pan speed, spray rate, and inlet air temperature.

2.5 Evaluation of Tablets

2.5.1 Core Tablets

Core tablets were evaluated for:

- Micromeritic properties (angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio)
- Post-compression parameters (weight variation, hardness, thickness, friability, drug content)

2.5.2 Enteric Coated Tablets

Enteric coated tablets were evaluated for:

- Appearance and coating uniformity
- Acid resistance in 0.1 N HCl
- Disintegration behavior in acid and buffer media
- In-vitro dissolution using USP Type II apparatus

2.6 Stability Studies

Accelerated stability studies were conducted as per ICH guidelines (40 ± 2 °C / 75 ± 5% RH) for three months. Tablets were evaluated for physical appearance, drug content, acid resistance, and dissolution behavior.

3. Results and Discussion

3.1 Preformulation Results

Preformulation studies were conducted to evaluate the physicochemical properties, identity, purity, solubility behavior, and compatibility of Ciprofloxacin with selected excipients. These studies form the scientific basis for formulation development and selection of an appropriate enteric coating strategy.

3.1.1 UV–Visible Spectroscopic Analysis

UV–Visible spectroscopy was performed to confirm the identity of Ciprofloxacin and to determine its characteristic absorption maximum (λmax), which was later used for quantitative analysis.

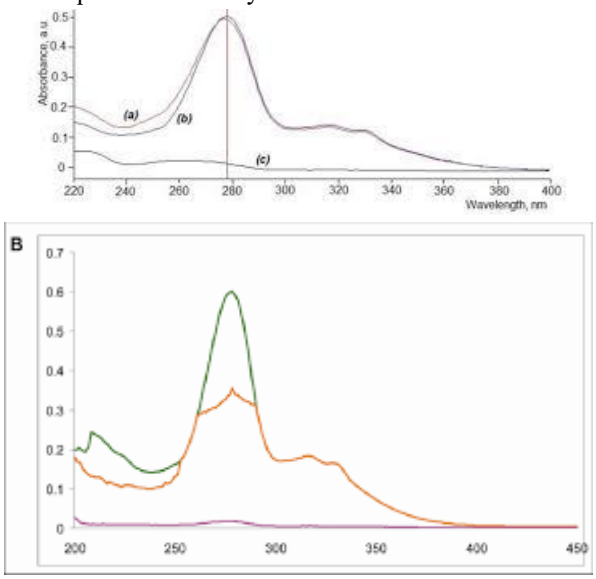

Figure 1: UV-VISIBLE SPECTRUM OF CIPROFLOXACIN

Table 2: UV–Visible Spectral Characteristics of Ciprofloxacin

Parameter	Observation
Solvent	0.1 N HCl / Phosphate buffer pH 6.8
Scanning range	200–400 nm
λmax	271 ± 1 nm
Peak nature	Sharp and well-defined

Discussion:

The observed λmax was in close agreement with reported values, confirming the identity and purity of Ciprofloxacin. The sharp absorption peak indicates suitability of the drug for UV-based quantitative estimation in further studies.

3.1.2 FTIR Spectral Analysis

FTIR spectroscopy was carried out to identify the functional groups present in Ciprofloxacin and to ensure its chemical integrity.

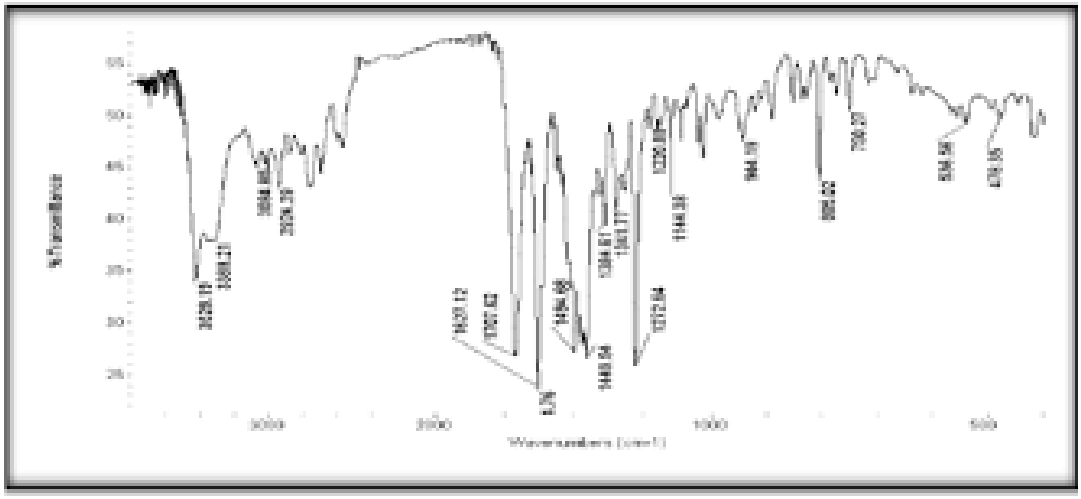

Figure 2: IR SPECTRUM OF CIPROFLOXACIN

Table 3: Characteristic FTIR Peaks of Ciprofloxacin

Wavenumber (cm^{-1})	Functional group
~3400	O–H / N–H stretching
~1715	C=O (carboxylic acid)
~1620	C=O (quinolone ring)
~1450	Aromatic C=C stretching
~1250	C–F stretching

Discussion:

All characteristic peaks of Ciprofloxacin were retained, indicating no chemical degradation or structural alteration of the drug.

3.1.3 Solubility Studies

Solubility studies were performed to evaluate the pH-dependent solubility profile of Ciprofloxacin, which is crucial for designing an enteric coated dosage form.

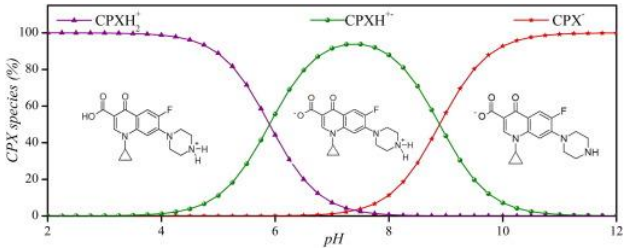

Figure 3: SOLUBILITY PROFILE OF CIPROFLOXACIN

Table 4: Solubility Profile of Ciprofloxacin

Medium	Solubility behavior
Distilled water	Slightly soluble
0.1 N HCl	Freely soluble
Phosphate buffer pH 6.8	Moderately soluble

Discussion: Ciprofloxacin showed higher solubility in acidic medium compared to intestinal pH. However, prolonged gastric exposure is associated with gastric irritation, supporting the need for enteric coating to delay release until the intestinal environment.

3.1.4 Melting Point Determination

The melting point of Ciprofloxacin was determined using the capillary method to assess its purity and crystalline nature.

Table 5: Melting Point of Ciprofloxacin

Parameter	Result
Observed melting point	318–320 °C
Reported melting point	318–320 °C

Discussion: The sharp melting point within the reported range confirms the high purity and crystalline nature of the drug sample used.

3.1.5 Drug–Excipient Compatibility Studies

(a) FTIR Compatibility Study

FTIR spectra of Ciprofloxacin–excipient physical mixtures were compared with that of pure drug.

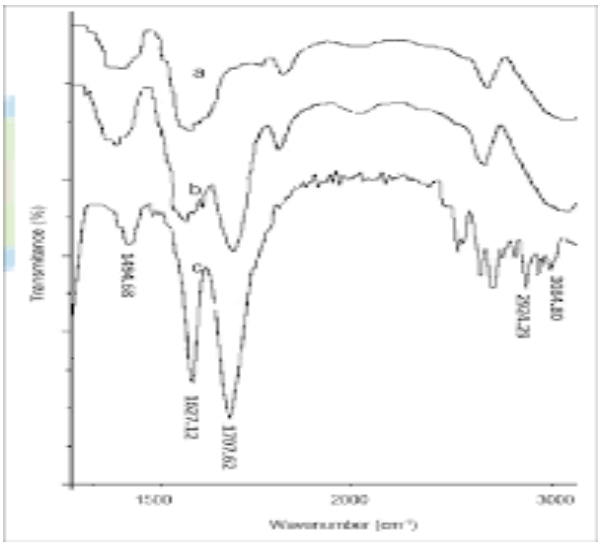

Figure 4: IR compatibility of ciprofloxacin

Observation:

No significant shifts, disappearance, or formation of new peaks were observed, indicating absence of chemical interaction between Ciprofloxacin and selected excipients.

(b) Differential Scanning Calorimetry (DSC)

DSC analysis was performed to evaluate thermal compatibility.

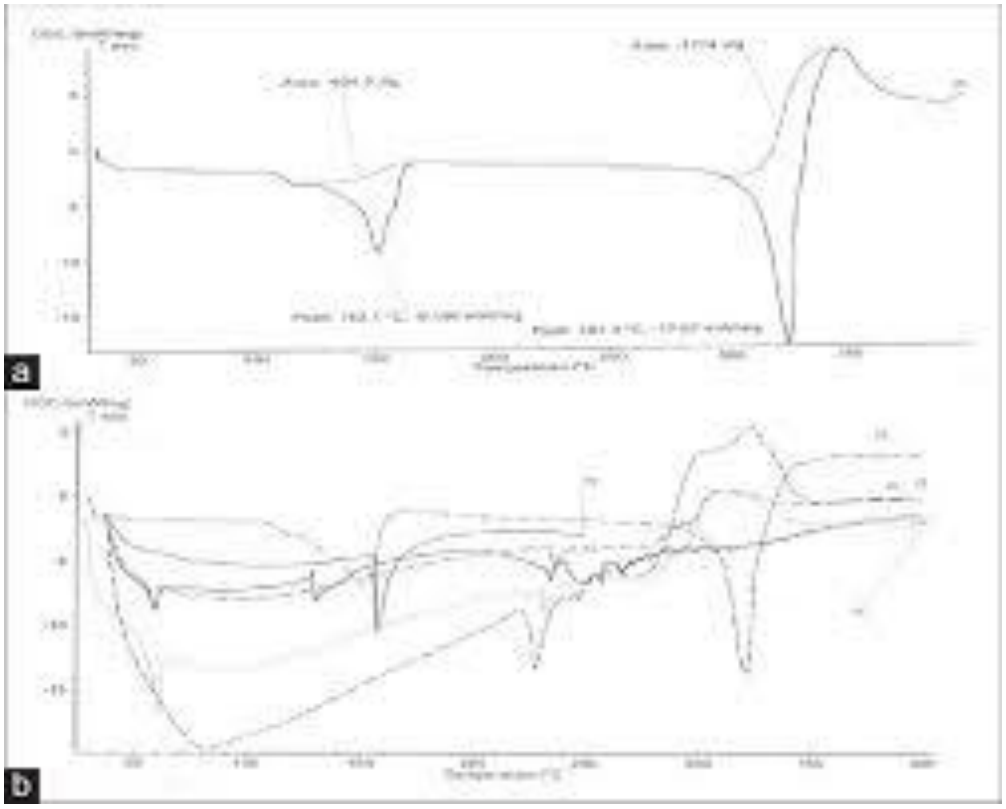

Figure 5: DSC SPECTRUM OF CIPROFLOXACIN

Observation: The characteristic endothermic peak of Ciprofloxacin was retained in the drug–excipient mixture, confirming thermal stability and compatibility.

3.1.6 Overall Interpretation of Preformulation Results

The preformulation results clearly demonstrated that:

- Ciprofloxacin possesses distinct UV and FTIR characteristics, confirming identity and purity
- The drug exhibits pH-dependent solubility, justifying the use of an enteric coating approach
- Melting point analysis confirmed high purity
- FTIR and DSC studies indicated excellent compatibility with selected excipients

These findings provided a strong scientific foundation for formulation of enteric coated Ciprofloxacin tablets and justified progression to formulation development and optimization studies.

3.2 Evaluation of Core Tablets

Evaluation of Ciprofloxacin core tablets was carried out to assess their flow properties, compressibility, mechanical strength, and content uniformity, which are critical for ensuring uniform enteric coating and reproducible performance. The results are discussed under micromeritic (pre-compression) properties and post-compression parameters.

3.2.1 Micromeritic Properties (Pre-Compression Results)

Micromeritic evaluation of granules prepared for core tablet formulations (F1–F9) was performed to determine flow ability and packing behavior.

Table 6: Micromeritic Properties of Ciprofloxacin Core Tablet Granules

Formulation	Angle of repose (°)	Bulk density (g/cm³)	Tapped density (g/cm³)	Carr's index (%)	Hausner's ratio
F1	27.4 ± 0.6	0.48 ± 0.02	0.56 ± 0.01	14.3 ± 0.5	1.17
F2	26.1 ± 0.4	0.50 ± 0.01	0.57 ± 0.02	12.3 ± 0.4	1.14
F3	28.6 ± 0.7	0.47 ± 0.02	0.55 ± 0.01	14.5 ± 0.6	1.17
F4	29.2 ± 0.5	0.46 ± 0.01	0.55 ± 0.02	16.4 ± 0.5	1.19
F5	27.9 ± 0.6	0.49 ± 0.02	0.57 ± 0.01	14.0 ± 0.4	1.16
F6	28.4 ± 0.5	0.48 ± 0.01	0.56 ± 0.02	14.3 ± 0.5	1.17
F7	30.1 ± 0.7	0.45 ± 0.02	0.55 ± 0.01	18.2 ± 0.6	1.22
F8	29.6 ± 0.6	0.46 ± 0.01	0.56 ± 0.02	17.9 ± 0.5	1.22
F9	30.4 ± 0.8	0.44 ± 0.02	0.55 ± 0.01	20.0 ± 0.7	1.25

(Values expressed as mean ± SD, n = 3)

Discussion: All formulations exhibited good to acceptable flow properties, with angle of repose values below 31°, Carr's index below 20%, and Hausner's ratio ≤ 1.25. Formulations F1–F6, particularly F2, showed superior flowability and compressibility, which is advantageous for uniform die filling and consistent tablet weight.

3.2.2 Post-Compression Evaluation Results

Post-compression evaluation was performed to ensure that the core tablets possessed adequate mechanical strength and uniform drug content to withstand the enteric coating process.

Table 7: Post-Compression Evaluation of Ciprofloxacin Core Tablets

Formulation	Avg. weight (mg)	Hardness (kg/cm²)	Thickness (mm)	Friability (%)	Drug content (%)
F1	399.6 ± 2.1	4.8 ± 0.3	4.12 ± 0.04	0.48	98.6 ± 1.2
F2	401.2 ± 1.9	5.1 ± 0.2	4.15 ± 0.05	0.42	99.4 ± 1.0
F3	398.8 ± 2.4	4.6 ± 0.3	4.10 ± 0.03	0.55	97.9 ± 1.3
F4	402.5 ± 2.0	5.3 ± 0.2	4.18 ± 0.04	0.46	98.2 ± 1.1
F5	400.3 ± 1.8	5.0 ± 0.3	4.14 ± 0.05	0.44	99.1 ± 0.9
F6	399.1 ± 2.2	4.7 ± 0.2	4.11 ± 0.04	0.52	98.7 ± 1.2
F7	401.8 ± 2.5	4.4 ± 0.3	4.16 ± 0.06	0.61	97.4 ± 1.4
F8	398.6 ± 2.3	4.5 ± 0.2	4.13 ± 0.05	0.58	96.9 ± 1.5
F9	402.1 ± 2.6	4.3 ± 0.3	4.17 ± 0.06	0.64	96.5 ± 1.6

(Values expressed as mean ± SD, n = 3)

Discussion: All formulations complied with pharmacopoeial limits for weight variation (±5%), friability (<1%), and drug content (90–110%). Tablet hardness ranged between 4–6 kg/cm², indicating sufficient mechanical strength. Among all batches, F2 and F5 exhibited the most favorable balance of hardness, low friability, and high drug content uniformity, making them ideal candidates for enteric coating.

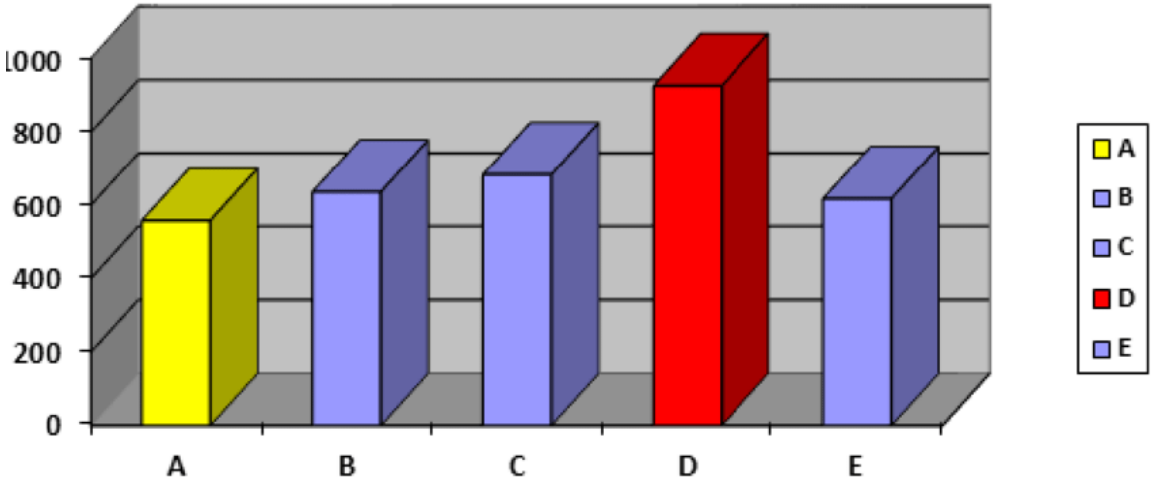

Figure 6: Comparative bar graphs showing hardness, friability, and drug content of Ciprofloxacin core tablet formulations (F1–F9)

3.2.4 Overall Interpretation

The micromeritic and post-compression evaluation results confirmed that the prepared Ciprofloxacin core tablets possessed:

- Good flowability and compressibility
- Adequate mechanical strength
- Uniform drug distribution

These properties are essential for achieving uniform and defect-free enteric coating. Based on the overall evaluation, Formulation F2 (with F5 as an alternative) was selected as the optimized core tablet for further enteric coating and performance evaluation.

3.3 Evaluation of Enteric Coated Tablets

The enteric coated Ciprofloxacin tablets prepared using different pH-dependent polymers were evaluated to confirm their delayed-release behavior, gastric resistance, and targeted intestinal drug release. The performance was assessed through acid resistance testing, disintegration behavior, and in-vitro dissolution studies and the results are discussed below.

3.3.1 Acid Resistance Test

Acid resistance testing was carried out to evaluate the integrity of the enteric coating in simulated gastric conditions.

Test conditions

- Medium: 0.1 N HCl (pH ≈ 1.2)
- Duration: 2 h
- Acceptance criterion: No disintegration, cracking, or drug release

Table 8: Acid Resistance Test Results

Formulation	Enteric polymer	Observation after 2 h in 0.1 N HCl	Result
EC-F1	HPMCP	Tablet intact, no drug release	Pass
EC-F2	Methacrylic acid copolymer (Type L)	Tablet intact, no drug release	Pass
EC-F3	CAP	Tablet intact	Pass
EC-F4	Methacrylic acid copolymer (Type S)	Tablet intact	Pass

Discussion:

All formulations successfully resisted acidic conditions for 2 hours, indicating that the selected polymers provided effective gastric protection. This confirms that the enteric coating was applied uniformly and at an adequate coating level.

3.3.2 Disintegration Behavior

Disintegration studies were conducted using a two-stage test to evaluate the delayed-release characteristics of the enteric coated tablets.

- Stage I (acid stage): 0.1 N HCl for 2 h
- Stage II (buffer stage): Phosphate buffer pH 6.8

Table 9: Disintegration Test Results of Enteric Coated Tablets

Formulation	Disintegration in acid stage	Disintegration time in pH 6.8 (min)
EC-F1	No disintegration	42 ± 2
EC-F2	No disintegration	38 ± 2
EC-F3	No disintegration	48 ± 3
EC-F4	No disintegration	55 ± 3

(Values expressed as mean ± SD, n = 3)

Discussion:

All formulations complied with pharmacopoeial requirements by remaining intact in acidic medium and disintegrating in intestinal pH. EC-F2 showed the fastest disintegration in pH 6.8, which can be attributed to the rapid ionization and dissolution characteristics of the methacrylic acid copolymer (Type L).

3.3.3 In-Vitro Dissolution Studies

In-vitro dissolution studies were carried out to evaluate the drug release behavior under simulated gastric and intestinal conditions.

Dissolution conditions

- Apparatus: USP Type II (paddle)
- Speed: 50 rpm
- Temperature: 37 ± 0.5 °C
- Media:
  - 0.1 N HCl (2 h)
  - Phosphate buffer pH 6.8 (subsequent stage)

Table 10: In-Vitro Dissolution Data of Enteric Coated Ciprofloxacin Tablets

Time (min)	EC-F1 (% release)	EC-F2 (% release)	EC-F3 (% release)	EC-F4 (% release)
Acid stage (0–120 min)	0	0	0	0
10	28 ± 2	32 ± 2	24 ± 2	20 ± 2
20	52 ± 3	58 ± 3	46 ± 3	40 ± 3
30	72 ± 2	78 ± 2	66 ± 2	58 ± 3
45	88 ± 2	92 ± 2	82 ± 2	75 ± 2
60	95 ± 2	98 ± 1	90 ± 2	85 ± 2

Discussion:

No drug release was observed during the acid stage for any formulation, confirming complete enteric protection. Upon exposure to intestinal pH, all formulations showed rapid drug release. EC-F2 exhibited the highest and fastest release, achieving nearly complete drug release within 60 minutes. The comparatively slower release observed with EC-F3 and EC-F4 may be attributed to slower polymer dissolution and higher trigger pH, respectively.

3.3.4 Overall Interpretation

The evaluation of enteric coated tablets demonstrated that:

- All formulations provided excellent gastric resistance
- Polymer type significantly influenced disintegration time and dissolution rate
- Methacrylic acid copolymer (Type L) offered the best balance between acid resistance and rapid intestinal release.

The enteric coated Ciprofloxacin tablets successfully exhibited delayed-release characteristics, with no drug release in acidic conditions and prompt release in intestinal pH. Among the evaluated formulations, EC-F2 showed superior performance in terms of disintegration behavior and dissolution profile, making it the optimized enteric coated formulation for further stability evaluation and potential clinical application.

3.4 Stability Study Results

Accelerated stability studies were performed on the optimized enteric coated Ciprofloxacin formulation (EC-F2) to evaluate the effect of temperature and humidity on its physical integrity, chemical stability, and functional performance. The study was conducted in accordance with ICH accelerated conditions (40 ± 2 °C / 75 ± 5% RH) for a period of 3 months.

3.4.1 Physical and Mechanical Stability

During the stability period, samples were periodically examined for appearance, weight variation, hardness, friability, and thickness.

Table 11: Physical and Mechanical Parameters During Accelerated Stability Study

Time (months)	Appearance	Avg. weight (mg)	Hardness (kg/cm²)	Friability (%)	Thickness (mm)
0 (Initial)	Smooth, uniform coating	401.2 ± 1.9	5.1 ± 0.2	0.42	4.15 ± 0.05
1	No visible change	400.6 ± 2.1	5.0 ± 0.2	0.44	4.15 ± 0.05
2	No visible change	399.8 ± 2.3	4.9 ± 0.3	0.46	4.14 ± 0.04
3	No visible change	399.4 ± 2.4	4.8 ± 0.3	0.48	4.14 ± 0.05

(Values expressed as mean ± SD, n = 3)

Discussion:

No discoloration, cracking, or peeling of the enteric coat was observed throughout the study. Minor variations in hardness and friability were within acceptable pharmacopoeial limits, indicating good mechanical stability of the formulation under accelerated conditions.

3.4.2 Drug Content and Acid Resistance

Drug content uniformity and acid resistance were evaluated to confirm chemical stability and retention of enteric functionality.

Table 12: Drug Content and Acid Resistance During Stability Study

Time (months)	Drug content (%)	Acid resistance in 0.1 N HCl (2 h)
0	99.4 ± 1.0	No disintegration – Pass
1	98.9 ± 1.1	No disintegration – Pass
2	98.3 ± 1.2	No disintegration – Pass
3	97.8 ± 1.3	No disintegration – Pass

Discussion:

Drug content remained within the acceptable range (90–110%), and all samples continued to exhibit complete resistance to acidic medium, confirming the chemical stability of Ciprofloxacin and integrity of the enteric coating.

3.4.3 In-Vitro Dissolution Stability

Dissolution profiles of EC-F2 were compared at initial (0 month) and after 3 months to evaluate any changes in release behavior.

Table 13: Comparative Dissolution Profile of EC-F2 During Stability Study

Time (min)	Initial (% release)	After 3 months (% release)
Acid stage (0–120 min)	0	0
10	32 ± 2	30 ± 2
20	58 ± 3	56 ± 3
30	78 ± 2	75 ± 2
45	92 ± 2	90 ± 2
60	98 ± 1	96 ± 2

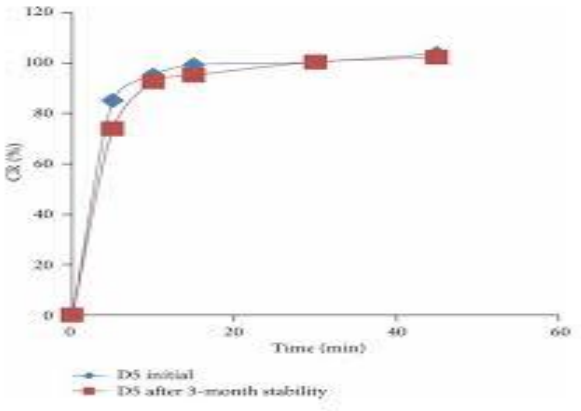

Figure 8: Comparative in-vitro dissolution profiles of optimized enteric coated Ciprofloxacin tablets (EC-F2) at initial and after 3 months under accelerated conditions.

Discussion:

The dissolution profiles before and after stability testing were highly comparable, indicating no significant change in drug release behavior. This suggests that the optimized formulation retained its functional performance during storage under accelerated conditions.

3.4.4 Overall Stability Interpretation

- No significant changes in appearance or mechanical properties were observed
- Drug content remained within acceptable limits
- Acid resistance was maintained throughout the study
- Dissolution profile showed minimal variation over time

The accelerated stability study confirmed that the optimized enteric coated Ciprofloxacin formulation (EC-F2) is physically, chemically, and functionally stable under ICH accelerated conditions. The formulation maintained effective gastric resistance and consistent intestinal drug release, demonstrating its suitability for further development and potential scale-up.

4. Conclusion

The present study successfully demonstrated the **design, development, and evaluation of enteric coated tablet dosage forms of Ciprofloxacin using different pH-dependent polymers** with the objective of achieving effective gastric protection and targeted intestinal drug release. Preformulation studies confirmed the **identity, purity, pH-dependent solubility, and compatibility** of Ciprofloxacin with selected excipients, providing a strong scientific basis for formulation development.

Ciprofloxacin core tablets prepared by the wet granulation method exhibited acceptable micromeritic properties, mechanical strength, and uniform drug content, ensuring their suitability for the enteric coating process. Application of enteric coatings using various polymers resulted in tablets with excellent acid resistance, as no disintegration or drug release was observed in simulated gastric conditions.

Comparative evaluation of enteric coated formulations revealed that polymer type significantly influenced disintegration behavior and dissolution profiles in intestinal pH. Among the polymers investigated, methacrylic acid copolymer–based enteric coating demonstrated superior performance by providing rapid disintegration and nearly complete drug release in phosphate buffer pH 6.8, while maintaining complete resistance in acidic medium.

Accelerated stability studies conducted according to ICH guidelines confirmed that the optimized formulation remained physically, chemically, and functionally stable, with no significant changes in appearance, drug content,

acid resistance, or dissolution behavior during the study period.

In conclusion, the developed enteric coated Ciprofloxacin tablets represent a stable, effective, and pharmacopeially compliant oral dosage form capable of minimizing gastric exposure and ensuring targeted intestinal delivery. This formulation approach has the potential to improve patient tolerability, therapeutic efficacy, and compliance, and may serve as a promising alternative to conventional immediate-release Ciprofloxacin tablets.

References

[1] Aulton ME, Taylor K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. Elsevier; 2018.

[2] Lachman L, Lieberman HA, Kanig JL. *The Theory and Practice of Industrial Pharmacy*. 4th ed. CBS Publishers; 2013.

[3] Remington JP. *Remington: The Science and Practice of Pharmacy*. 23rd ed. Pharmaceutical Press; 2021.

[4] Indian Pharmacopoeia Commission. *Indian Pharmacopoeia*. Ghaziabad, India; 2022.

[5] United States Pharmacopeial Convention. *USP–NF*. Rockville, MD; 2023.

[6] ICH Q1A(R2). *Stability Testing of New Drug Substances and Products*. International Council for Harmonisation; 2003.

[7] Sweetman SC. *Martindale: The Complete Drug Reference*. 41st ed. Pharmaceutical Press; 2020.

[8] Katzung BG, Trevor AJ. *Basic and Clinical Pharmacology*. 15th ed. McGraw Hill; 2021.

[9] Felton LA. Film coating of oral solid dosage forms. *AAPS PharmSciTech*. 2013;14(2):634–641.

[10] Porter SC, Sackett GL, Liu L. Development of enteric coated dosage forms. *Pharm Technol*. 2002;26(2):22–38.

[11] Thoma K, Bechtold K. Influence of polymer type on enteric coatings. *Eur J Pharm Biopharm*. 1999;47:39–45.

[12] Lecomte F, Siepmann J, Walther M, MacRae RJ, Bodmeier R. Polymer blends for controlled release coatings. *J Control Release*. 2004;99:1–13.

[13] Peppas NA. Analysis of Fickian and non-Fickian drug release. *J Control Release*. 1985;1:23–36.

[14] Higuchi T. Mechanism of sustained-action medication. *J Pharm Sci*. 1963;52:1145–1149.

[15] Korsmeyer RW, Gurny R, Doelker E, Buri P, Peppas NA. Mechanisms of solute release from porous hydrophilic polymers. *Int J Pharm*. 1983;15:25–35.

[16] Costa P, Sousa Lobo JM. Modeling and comparison of dissolution profiles. *Eur J Pharm Sci*. 2001;13:123–133.

[17] Shah VP, Tsong Y, Sathe P, Liu JP. In vitro dissolution profile comparison—statistics and analysis. *Pharm Res*. 1998;15:889–896.

[18] Cole ET, Scott RA, Connor AL, Wilding IR, Cade D. Enteric coated dosage forms. *Int J Pharm*. 2002;231:83–95.

[19] Gibson M. *Pharmaceutical Preformulation and Formulation*. CRC Press; 2016.

[20] Singh R, Poddar SS. Development of enteric coated tablets. *Indian J Pharm Sci*. 2005;67:726–730.