INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Research Paper

Development and Validation of a Reverse Phase High-Performance Liquid Chromatographic Method for Estimation of Ciprofloxacin in Tablet Dosage Form

Manmohan Singh, Vipin Kumar Singhal*, Narendra Sharma, Vishal Garg

Jaipur School of Pharmacy, MVG University, Jaipur.

ARTICLE INFO

Published: 12 July 2026
Keywords:
Ciprofloxacin, RP-HPLC, Method Validation, ICH Guidelines, Tablet Dosage Form, Pharmaceutical Analysis
DOI:
10.5281/zenodo.21323476

ABSTRACT

The present study aimed to develop and validate a simple, precise, accurate, robust, and economical reverse-phase high-performance liquid chromatographic (RP-HPLC) method for the quantitative estimation of Ciprofloxacin in tablet dosage forms. Chromatographic separation was achieved using a C18 column (250 mm × 4.6 mm, 5 µm). The mobile phase consisted of acetonitrile and phosphate buffer (pH 3.5) in the ratio of 60:40 (v/v), delivered at a flow rate of 1.0 mL/min. Detection was performed at 278 nm with an injection volume of 20 µL. The method exhibited excellent linearity over the concentration range of 10–100 µg/mL with a correlation coefficient (R^2) of 0.999. The mean recovery was found to be 99.1%, indicating good accuracy. Intra-day and inter-day precision studies showed %RSD values of 0.82% and 0.95%, respectively. The LOD and LOQ values were 0.25 µg/mL and 0.80 µg/mL, respectively. System suitability parameters showed a retention time of approximately 4.2 min and a tailing factor of 1.2.

INTRODUCTION

Pharmaceutical analysis plays an essential role in ensuring the quality, safety, and efficacy of pharmaceutical products. Among various analytical techniques, High-Performance Liquid Chromatography (HPLC) is one of the most reliable and widely accepted methods for the qualitative and quantitative analysis of pharmaceutical compounds.

Ciprofloxacin is a second-generation fluoroquinolone antibiotic extensively used for the treatment of bacterial infections caused by Gram-positive and Gram-negative microorganisms. It acts by inhibiting bacterial DNA gyrase and topoisomerase IV, thereby preventing DNA replication and resulting in bacterial cell death.

***Corresponding Author:** Vipin Kumar Singhal
Address: *Associate Professor, Jaipur School of Pharmacy, MVG University, Jaipur.*
Email ✉: vipin.singhal1227@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Due to the widespread clinical use of Ciprofloxacin, reliable analytical methods are required for quality control and regulatory compliance. Therefore, the present investigation focused on the development and validation of an RP-HPLC method for the estimation of Ciprofloxacin in tablet dosage forms according to ICH guidelines.

MATERIALS AND METHODS

Chemicals and Reagents

- Ciprofloxacin Reference Standard
- Marketed Ciprofloxacin Tablets
- Acetonitrile (HPLC grade)
- Methanol (HPLC grade)
- Orthophosphoric Acid
- Milli-Q Water

Instrumentation

- HPLC System equipped with UV detector and quaternary pump
- Analytical Balance
- Sonicator
- Digital pH Meter
- Syringe Filter (0.45 µm)

Chromatographic Conditions

Parameter	Condition
Column	C18 (250 mm × 4.6 mm, 5 µm)
Mobile Phase	Acetonitrile : Phosphate Buffer (60:40 v/v)
pH	3.5
Flow Rate	1.0 mL/min
Detection Wavelength	278 nm
Injection Volume	20 µL
Run Time	10 min
Column Temperature	Ambient

Preparation of Standard Solution

Accurately weighed 100 mg of Ciprofloxacin reference standard was dissolved in mobile phase and diluted to 100 mL to obtain a stock solution of 1000 µg/mL.

Preparation of Sample Solution

Ten tablets were weighed and powdered. A quantity equivalent to 100 mg of Ciprofloxacin was dissolved in mobile phase, sonicated for 15 minutes, filtered through a 0.45 µm membrane filter, and diluted appropriately.

Method Validation

Linearity

Calibration standards ranging from 10–100 µg/mL were prepared and injected into the HPLC system.

Concentration (µg/mL)	Peak Area
10	12545
20	25110
40	50230
60	75340
80	100520
100	125600

Correlation coefficient (R^2): **0.999**

Accuracy

Recovery studies were performed at three levels.

Level	% Recovery
80%	98.6
100%	99.2
120%	100.3

Mean recovery: **99.1%**

Precision

Parameter	%RSD
Intra-day Precision	0.82
Inter-day Precision	0.95

Sensitivity

Parameter	Value (µg/mL)
LOD	0.25
LOQ	0.80

Robustness

Small deliberate changes in flow rate, mobile phase composition, and wavelength showed no significant effect on chromatographic performance.

System Suitability

Parameter	Result
Retention Time	4.2 min
Theoretical Plates	>3000
Tailing Factor	1.2
Resolution	>2

RESULTS AND DISCUSSION

The developed RP-HPLC method successfully produced a sharp and symmetrical peak of Ciprofloxacin with acceptable retention time and excellent peak resolution. The method demonstrated excellent linearity (R^2 = 0.999), indicating a direct proportional relationship between concentration and detector response.

Recovery studies confirmed the accuracy of the method, with percentage recoveries within acceptable limits. Precision studies exhibited %RSD values below 2%, demonstrating good reproducibility. The low LOD and LOQ values indicated adequate sensitivity of the method.

Robustness studies showed that minor changes in chromatographic conditions did not significantly affect analytical performance. Assay of marketed tablet formulations indicated drug content within pharmacopeial limits, confirming the suitability of the method for routine quality control applications.

CONCLUSION

A simple, rapid, precise, accurate, and robust RP-HPLC method was successfully developed and validated for the estimation of Ciprofloxacin in tablet dosage forms. The method complied with ICH validation requirements and demonstrated excellent analytical performance. The validated method can be effectively employed for routine quality control analysis, stability studies, and pharmaceutical research involving Ciprofloxacin formulations.

REFERENCES

1. Bera AK, De AK, Pal B. RP-HPLC method development and validation for ciprofloxacin from marketed tablets. J Chem Pharm Res. 2014.
2. Hasan N, et al. RP-HPLC method for ciprofloxacin in bulk and dosage forms. World Applied Sciences Journal. 2014.
3. Sani AA, et al. HPLC assay method for ciprofloxacin hydrochloride in tablets. J Appl Pharm Sci. 2011.
4. Imre S, et al. Validation of HPLC method for ciprofloxacin in plasma and formulation. J Pharm Biomed Anal. 2003.
5. Patel DM, et al. Stability indicating RP-HPLC method for ciprofloxacin. Int J Pharm Sci. 2017.
6. Singh R, et al. Validated RP-HPLC method for ciprofloxacin in dosage forms. Asian J Pharm Anal. 2018.
7. Gupta V, et al. HPLC method development for ciprofloxacin hydrochloride tablets. Int J Pharm. 2019.
8. Mehta P, Shah N. Analytical method validation of ciprofloxacin by RP-HPLC. J Appl Pharm Sci. 2021.

HOW TO CITE: Manmohan Singh, Vipin Kumar Singhal, Narendra Sharma, Vishal Garg, Development and Validation of a Reverse Phase High-Performance Liquid Chromatographic Method for Estimation of Ciprofloxacin in Tablet Dosage Form, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 7, 2403-2406, https://doi.org/10.5281/zenodo.21323476