International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

Hydrotropic UV-Spectrophotometric Method for Diclofenac Sodium Using 5% Urea as Hydrotropic Agent: A Green Chemistry Approach

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Received: 2025-04-20 Revised: 2025-05-02 Accepted: 2025-05-07

ABSTRACT: -

A novel, safe, and sensitive ultraviolet spectrophotometric method has been developed for the quantitative estimation of diclofenac sodium in tablet dosage form using a 5% urea solution as a hydrotropic solubilizing agent. Diclofenac sodium, which is poorly soluble in water, showed significantly enhanced aqueous solubility in the presence of 5% urea solution—over 2 times greater than in distilled water. Beer's law was found to be obeyed in the concentration range of 10–60 µg/ml. The urea solution exhibited no absorbance interference above 260 nm. Common tablet excipients and urea did not interfere with the spectrophotometric analysis. The method was validated through statistical evaluation and recovery studies, and the results were found to be comparable to those obtained using the standard Indian Pharmacopeial method.

Keywords: - Hydrotropy, Diclofenac sodium, 5% urea solution, Spectrophotometry

INTRODUCTION: -

It is well established that concentrated aqueous solutions of various hydrotropic agents—such as sodium gluconate, niacinamide, urea, sodium benzoate, sodium salicylate, sodium ascorbate, and sodium glycinate can significantly enhance the aqueous solubility of poorly water-soluble drugs. The primary aim of this investigation was to utilize a hydrotropic solution, specifically a 5% urea solution, to extract diclofenac sodium from finely powdered tablet samples, thereby avoiding the need for expensive and environmentally hazardous organic solvents often used in spectrophotometric analysis. Organic solvents, while commonly used to dissolve poorly soluble drugs, present drawbacks such as volatility, toxicity, and environmental pollution. To improve aqueous solubility, several techniques are employed, among which hydrotropic solubilization is a promising approach. Hydrotropes are compounds that significantly increase the solubility of sparingly soluble substances under standard conditions. In the present study, a 5% urea solution was employed as a hydrotropic solubilizing agent for the spectrophotometric estimation of diclofenac sodium, a non-steroidal anti-inflammatory drug (NSAID), in tablet dosage form. The method demonstrated more than an 2-fold enhancement in the drug's solubility in the urea solution compared to distilled water. Given these findings, the use of hydrotropy was considered a valuable alternative to conventional solvent-based extraction methods for the analysis of diclofenac sodium. Chemically, diclofenac is known as 2-(2, 6-dichloranilino) phenylacetic acid.

MATERIALS AND METHODS: -

Diclofenac sodium tablets were procured from the local market. All other chemicals and solvents used were of analytical grade. Bulk drug (diclofenac sodium) was obtained from Krishna medical, Satara. A spectrophotometer (Model AU-2701) with 1 cm matched silica cells was used for spectrophotometric analysis.

Preliminary solubility study of diclofenac sodium: - Solubility of diclofenac sodium was determined in distilled water and 5% urea solution at 27 ± 1°C. Solubility was found to be increased by more than 2-fold in 5% urea solution as compared with the solubility in distilled water.

Analysis Of Diclofenac Sodium in Tablet Formulations Using the IP (2007) Method: -

Twenty tablets of diclofenac sodium (Formulation I) were accurately weighed and finely powdered. A portion of this powder, equivalent to 50 mg of diclofenac sodium, was transferred into a 200 ml volumetric flask. To this, 60 ml of methanol was added,

and the mixture was shaken thoroughly for approximately 10 minutes to ensure complete dissolution of the drug. The volume was then made up to the mark with methanol. From this stock solution, 5 ml was taken and further diluted to 100 ml using methanol. The absorbance of the final solution was measured at 285 nm using a UV spectrophotometer. The drug content in the tablet formulation was calculated accordingly. The same procedure was repeated for Formulation II, and results are presented in Table 1.

Analysis Of Diclofenac Sodium In Tablet Formulations Using The Proposed Method:-

Twenty tablets of diclofenac sodium (Formulation I) were weighed and crushed into a fine powder. A quantity of the powder equivalent to approximately 100 mg of diclofenac sodium was accurately weighed and transferred into a 100 ml volumetric flask containing 10 ml of 5% urea solution. The mixture was shaken thoroughly for about 10 minutes to ensure complete solubilization of the drug. The volume was then adjusted to 100 ml with distilled water. The resulting solution was filtered using Whatman filter paper No. 41. An appropriate volume of the clear filtrate was further diluted with distilled water, and its absorbance was measured at 277 nm against a reagent blank. The diclofenac sodium content in the tablet formulation was calculated accordingly. The same analytical procedure was applied to Formulation II, and the results are presented in Table 1.

RESULTS AND DISCUSSION: -

Results of solubility studies of diclofenac sodium revealed that enhancement in solubility in 5% urea solution was more than 2-fold as compared to its solubility in distilled water. It is evident from Table 1 that the values of mean percent drug (diclofenac sodium) estimated by IP and the proposed method are 99.26 and 100.31, respectively, for formulations. The results of the analysis by the proposed method are comparable to the results obtained from the IP method. The amounts of drug estimated by the IP and the proposed methods [Table 1] are very close to each other and are very close to 100.0, indicating the accuracy of the proposed method of analysis. Low values of standard deviation, percent coefficient of variation and standard error [Table 1] further validated the proposed method.

TABLE: -1

Analysis data of drug sample with statistical evaluation (n=3)

Formulation	Amount of drug taken (mg)	Method of analysis	Percent drug estimated (mean ± SD)	Coefficient of variation (%)	Standard error
I.	100	P.M	100±0.261	0.261	0.151
II.	50	I.P.M	99±0.100	0.101	0.057

CONCLUSION: -

The present study introduces a novel, simple, eco-friendly, accurate, and reproducible analytical method for the estimation of diclofenac sodium in tablet formulations. This method eliminates the use of harmful organic solvents without compromising accuracy, making it suitable for routine quality control. Furthermore, the approach shows promising potential for the analysis of other poorly water-soluble drugs by employing appropriate hydrotropic agents, thereby offering a safer and more cost-effective alternative to traditional solvent-based methods.

AKNOWLEDGEMENT: -

We are thankful to the staff of the YSPM, YTC, Satara for their valuable time and support. We also thankful to my mentor Dr. A. M. Bhagwat, HOD. OF Pharmaceutical chemistry, YSPM, YTC, SATARA. Special thanks to Mr. Prasad Patil sir (Assistant of chemistry laboratory). And my all FRIENDS.

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How to cite this article:
Manish. M. Pujari et al. Ijppr.Human, 2025; Vol. 31 (5): 14-16.

Conflict of Interest Statement: All authors have nothing else to disclose.