Uv Visible Spectroscopic Method Development and Validation of Etodolac in Bulk and Tablet Dosage Form

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***Abstract*—This study focused on the development and validation of a UV spectrophotometric method for the quantification of Etodolac in its bulk form and tablet dosage. Etodolac, classified as a BCS Class II drug, had been widely prescribed for its anti-inflammatory and analgesic properties. The developed method employed methanol as the solvent and identified the maximum absorbance (λmax) at 276 nm. Validation was conducted in accordance with ICH guidelines, covering linearity, accuracy, precision, quantitation and detection limits. Calibration curves demonstrated strong linearity within the 2–10 µg/mL range (R^2 > 0.998). Recovery studies affirmed the method's accuracy, with values ranging between 96% and 98%. The method was found to be simple, reliable, and cost-effective, making it suitable for routine quality control of Etodolac formulations.**

***Index Terms*—Etodolac, UV-visible spectrophotometry, pharmaceutical analysis, Analytical method validation.**

I. INTRODUCTION

Etodolac is a non-steroidal anti-inflammatory drug (NSAID) that has been widely used for its anti-inflammatory, analgesic, and antipyretic properties. It belongs to the pyranoindole group of NSAIDs and is primarily prescribed for the management of conditions such as osteoarthritis, rheumatoid arthritis, and other musculoskeletal disorders. By selectively inhibiting the cyclooxygenase-2 (COX-2) enzyme, Etodolac reduces the production of prostaglandins, which are chemical mediators responsible for pain, inflammation, and fever. This selective action minimizes gastrointestinal side effects compared to non-selective NSAIDs, making it a preferred choice for long-term therapy in certain patients. [1, 2]

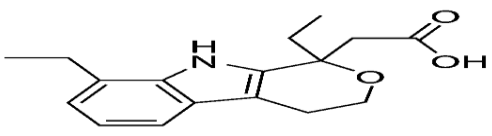

Fig No: 1. Structure of Etodolac

The IUPAC name of Etodolac is (RS)-2-(1,8-diethyl-4,9-dihydro-3H-pyrano[3,4-b]indol-1-yl)acetic acid.[3] Its molecular weight is 287.35 g/mol.[4] Etodolac belongs to BCS Class II, indicating it has low solubility but high permeability.[5] The drug works by selectively inhibiting the cyclooxygenase-2 (COX-2) enzyme, reducing the production of prostaglandins, which are responsible for pain, inflammation, and fever. This mechanism makes it effective for managing conditions like osteoarthritis and rheumatoid arthritis. [6, 7]

II. MATERIALS

Chemical and Reagents

Etodolac was obtained as gift sample from the IPCA Laboratories Ltd. Mumbai. Methanol (analytical grade).Distilled water required for any glassware cleaning and rinse.

Instrumentation

UV-visible spectrophotometer of systronics 2202, analytical balance, sonicator for sonication purpose, and these all instruments were utilized during the analytical study.

1. Preparation of Standard Stock Solution

10 mg of Etodolac was accurately weighed and transferred into a 100 mL volumetric flask. Approximately 50 mL of methanol (HPLC grade) was added, and the solution was sonicated for 5 minutes to ensure complete dissolution of the drug. The volume was then made up to 100 mL with methanol, resulting in a stock solution of 100 µg/mL. From this stock solution, 1 mL was pipetted out and diluted to 10 mL to prepare a solution with a concentration of 10 µg/mL.

2. Selection of Wavelength

The standard stock solution of 10 µg/mL was scanned in the UV-visible range (200–400 nm) using a UV-visible spectrophotometer. The wavelength of

maximum absorbance (λmax) for Etodolac was identified during the scan.

3. Preparation of Calibration Curve Solutions

A series of dilutions was prepared from the stock solution to obtain concentrations in the range of 2–8 µg/mL, using methanol as the solvent for all dilutions.

4. Analysis of Tablet Dosage Form

Twenty tablets of Etodolac were weighed and finely powdered. A quantity equivalent to 10 mg of Etodolac was accurately weighed and transferred into a 100 mL volumetric flask. Methanol was added to the flask, the solution was sonicated for 10 minutes, and then filtered. The filtrate was diluted to obtain a 10 µg/mL concentration and the absorbance was measured at the λmax.

5. Validation Parameters

- Linearity: Evaluated the linearity by preparing solutions of different concentrations and plotting the calibration curve.
- Accuracy: Performed recovery studies by spiking known amounts of Etodolac into the matrix and calculate the percentage recovery.
- Precision: Assessed the repeatability precision by analyzing sample of single concentrations at multiple times.
- Specificity: Confirmed the method is specific by ensuring no interference from excipients or other components.
- Limit of Detection (LOD) and Limit of Quantification (LOQ): Calculated LOD and LOQ based on the standard deviation of the response and the slope of the calibration curve.
- Robustness: Evaluated the robustness by making small deliberate changes in parameters like wavelength, solvent composition, etc.

III. RESULTS

Selection of Wavelength

The standard stock solution of 10 µg/mL was scanned and that shows 276 nm wavelength of maximum absorbance (λmax) for Etodolac.

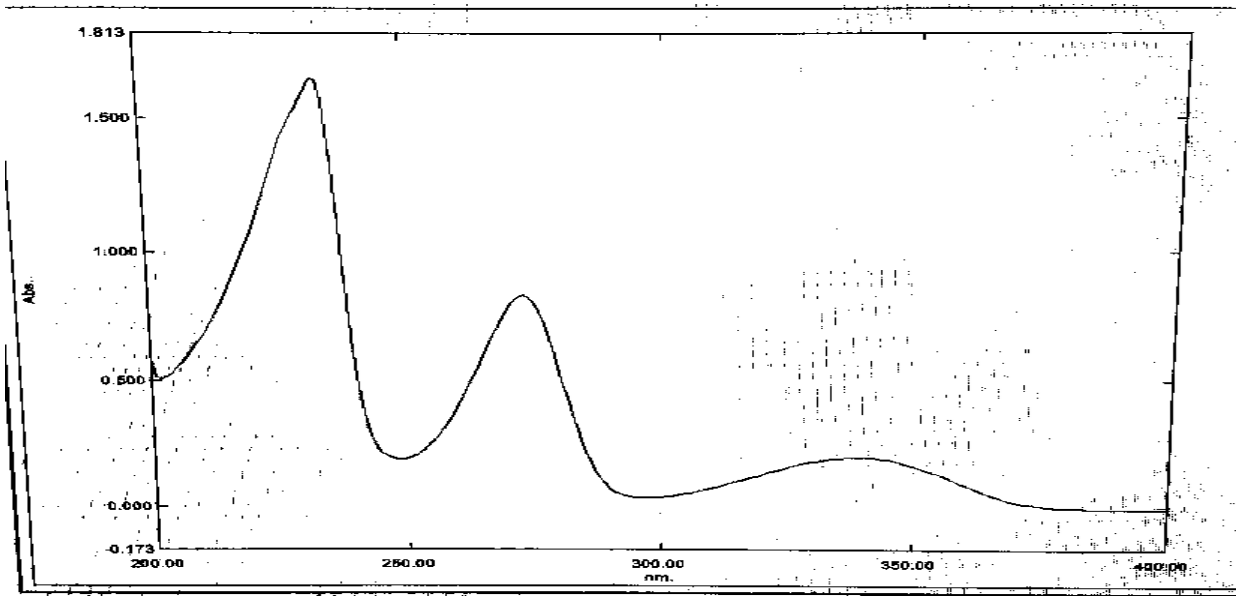

Fig No: 2. UV Spectrum of Etodolac.

Linearity

Calibration curve solutions were prepared and scanned at a wavelength of 276 nm. The absorbance for each solution was recorded, and a graph of absorbance versus concentration was plotted to evaluate the linearity of the method.

Concentration (µg/mL)	Absorbance
2	0.121
4	0.216
6	0.324
8	0.417
10	0.532

Table 1: Calibration Curve Data

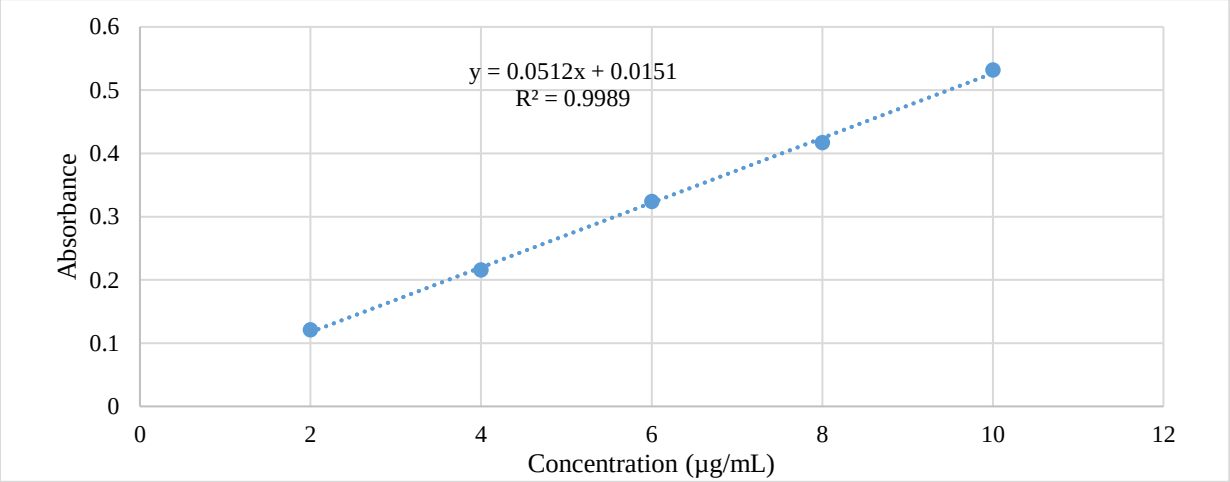

Fig No: 3. Graph of absorbance versus concentration

Accuracy (Recovery Studies)

A standard API solution and a tablet powder solution were prepared, each with a concentration of 50 µg/mL. Precise volumes of the standard API solution were added to the tablet powder solution of 50 µg/mL at different levels: 80%, 100%, and 120% of the expected concentration. The absorbance was measured, and the amount of API found in each solution was calculated.

Recovery Level (%)	Tablet Powder Sol. (mL)	Std. API Sol. (mL)	Conc.	Amount found (µg/mL)	Recovery (%)
0	1	0	4.35351563		
80	1	0.8	8.20117188	3.847656	96
100	1	1	9.25585938	4.902344	98
120	1	1.2	10.2714844	5.917969	98

Table 2: Accuracy (Recovery Studies)

The recovery percentages (96%, 98%, 98%) are within acceptable limits for pharmaceutical analysis (typically 95-105% for most analytical methods). The closeness of values at different levels demonstrates the method's reliability and accuracy.

Precision

The absorbance of the prepared solutions was measured at 8 µg/mL six times, and the data was analyzed to determine the precision of the method.

Concentration (µg/mL)	Precision (%RSD)
8	0.417
8	0.416
8	0.418
8	0.416
8	0.415
8	0.415
Mean	0.4162
Standard Deviation	0.00117
%RSD	0.281%

Table 3: Precision Data

LOD and LOQ

These values indicate the minimum concentration detectable (LOD) and the minimum concentration quantifiable (LOQ) with acceptable precision and accuracy.

LOD=3.3×SD/slope

=3.3×0.149/0.0512

≈9.61 µg/mL

LOQ=10×SD/slope

=10×0.149/0.0512

≈29.1 µg/mL

Parameters	Value
Mean	0.322
Standard deviation	0.149
LOD	9.61 µg/mL
LOQ	29.1 µg/mL

Table 4: Results of LOD and LOQ

Evaluation shows the regression equation offers good precision with a strong linear relationship (based on

consistent absorbance values). The LOD and LOQ suggest the method is suitable for detecting and quantifying concentrations above these limits.

Assay of Etodolac tablet

Absorbance of tablet powder solution shown 0.482 at 276nm.

%Assay=(Absorbance of sample/Absorbance of stan dard) ×100

= (0.513/0.532) ×100

= 96%

The assay percentage found to be of 96% complies with the IP specification for Etodolac tablets.

IV. CONCLUSION

The UV spectrophotometric method developed and validated in this study provided a robust analytical tool for the estimation of Etodolac in bulk and tablet dosage forms. The method adhered to ICH validation parameters, ensuring reliability, precision, and accuracy. Its simplicity, combined with high sensitivity and reproducibility, underscored its applicability for routine pharmaceutical analysis.

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