Research Article

SGVU Journal of Pharmaceutical Research & Education

ISSN: 2456-4508

JPRE

Journal homepage: http://www.gyanvihar.org/researchjournals

UV VISIBLE SPECTROSCOPIC METHOD DEVELOPMENT OF ETODOLAC FROM IT'S TABLET FORMULATION BY DIFFERENCE SPECTROSCOPY

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ABSTRACT:

Simple, sensitive and specific spectrophotometeric method were developed and validated for quantification of etodolac by difference spectroscopy.Etodalac exhibits a substantial difference in absorbance in the two solvents that is in 0.01 N HCL and 0.01 N NaoH at 225 nm. Beer's law was obeyed in the concentration range of 2 to 20 µg /ml for etodolac.The results indicated excellent recoveries ranging from 99.13 to 101.23% for ibuprofen with a mean of 99.62%.Recoveries obtained do not differ significantly from 100% showed that there was no interference from the common excipients used in the tablet formulation indicating accuracy and reliability of the method.

KEY WORDS: Etodolac, Difference Spectroscopy.

INTRODUCTION:

The analytical chemistry has challenge in developing various methods for analysis with the help of number of analytical techniques which are available for estimation of the drugs and their combination1. Analytical monitoring of pharmaceutical product or of specific ingredients within the product is necessary to ensure the safety and efficacy throughout the shelf life, including storage, distribution and use2. The selectivity and accuracy of spectrophotometric analysis of samples containing absorbing interferences may be markedly improved by the technique of difference spectrophotometry.

Etodolac (ETD), is chemically 1,8-Diethyl-1,3,4,9-tetrahydropyrano (3,4-b)indole-1-acetic acid. It is a member of non-steroidal anti-inflammatory drugs (NSAIDs). ETD is official in Indian

pharmacopoeia, British, European and United State pharmacopoeia. A 200mg of Etodolac is available commercially as tablet. The etodolac is used as analgesic treatment of Osteoarthritis.

MATERIALS AND METHOD:

Apparatus:

The instrument used for the present study was JASCO V530(UV spectrophotometry) with 1cm matched pair quartz cell and spectral band width of 1nm.

Selection of common solvents:

0.01N NaOH and 0.01N HCl was selected as a common solvents for developing spectral characteristics of drug. The selection was made after using different acids and bases and their different normalities.

Preparation of Standard Drug Solution

Standard stock solution containing etodolac was prepared by dissolving 10mg of ETD separately in 100ml of 0.01N HCl and 0.01N NaOH sonicated for 5min and then final volume of both the solutions was made upto 100ml with same solvents to get stock solution containing 100 µg/ml of ETD in 0.01N NaOH and 0.01 N HCl in two different 100ml volumetric flasks.

Determining of sampling Wavelength for Simultaneous Analysis

By appropriate dilution of two standard drug solutions with 0.01N HCL and 0.01N NaOH solutions containing 10µg/ml of ETD were scanned separately in the range of 200-400nm to determine the wavelength of maximum absorption for the drug. The difference spectrophotometric method developed for analysis of Etodolac and one wavelength was selected for estimation ETD from overlain spectra as shown in **Fig. No**.1The wavelength selected for the estimation of drug was 200-400nm.

Selection of Wavelength for simultaneous analysis

The wavelength was selected for estimation of ETD from the overlain spectra as shown in **Fig.No.1** ETD was estimated by recording the absorbance difference in 0.01NHCl and 0.01N NaOH at 225 nm and results shown in **Table No.1**

Procedure for Plotting Calibration Curve

From standard stock solution of drug six working standard solutions were prepared and scanned in the wavelength range of 200-400nm. The appropriate aliquots of drug pipetting out from standard stock solution of drug were pipetting out from standard stock solution of the drug in 0.01N NaOH and 0.01N HCl into series of 10 ml volumetric flask. The volume was made upto get solution of concentration 2,4,6,8,10 and 12 of ETD in both 0.01 N NaOH and 0.01N HCl separately. Calibration curve was constructed at wavelengths 225 nm by recording absorbance difference between two solvents against concentration of drug.ETD obeyed Beer's law in the concentration range of 2-20µg/ml. By using quantitative modes of instrument slope, intercept and correlation coefficient values for calibration curve was obtained. The concentration of ETD was calculated by using formula Abs= A+B*C where A= 0.057,B=0.025 ,C= concentration of ETD and correlation coefficient for ETD was 0.995 shown in **Table No.1**.

Analysis of Tablet Formulation

Marketed tablet formulations containing 200mg of ETD were analyzed by this method. Twenty tablets were triturated; an amount equivalent to 10mg of ETD was weighed and transferred to 100ml volumetric flask. The contents of the flask were dissolved in the 50 ml of 0.01N HCl and 0.01N NaOH separately with the aid of sonication for 10 min. The solution was filtered through Whatmann filter paper no.41 and then final volume of the solution was made upto 100ml with the same solvents to get a stock solution containing 100 µg/ml of ETD in 0.01N HCl and 0.01N NaOH. After appropriate dilutions, the absorbances were measured and concentration of each analyte was determined with the equations obtained from calibration curve. The results of tablet analysis after replicate determinations are shown in **table.no2**.

Method validation

The proposed method was validated according to ICH Q2B guidelines for analytical procedures in order to determine accuracy, precision, repeatability, robustness, linearity, limit of detection, limit of quantitation, robustness results are shown in **Table No.3**respectively.

Recovery studies

The accuracy of the proposed method was determined by recovery of the drug by standard addition technique. To the pre analysed formulation, a known amount of ETD raw material was added in different concentrations viz., 80%, 100%, and 120% in both reference and sample solutions. Result of recovery studies indicated that the method was rapid, accurate and reproducible. The recovery obtained after replicate determinations is shown in **Table No.2**

Detection limit (LOD)

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. The LOD of ETD by the proposed method was found to be **0.032µg/ml.**

Quantitation Limit (LOQ)

The quantitation limit of an individual analytical procedure is the lowest concentration of analyte in a sample, which can be quantitatively determined with a suitable level of precision and accuracy. The LOQ of ETD by the proposed method was found to be **0.098µg/ml**.

Linearity

The linearity of an analytical procedure is its ability to obtain test results which are proportional to the concentration of analyte in the sample. [4] The calibration curve of ETD was linear over the range of **2-12µg/ml.**

Robustness

Robustness study was determined by using 1N NaOH and 1N HCl solvents. The experimental results showed that the variation in composition of solvents was not affected on this method. So developed method was found to be robust. Results were shown in **Table No.3**

RESULT AND DISCUSSION:

Tables: Absorbances values of etodolac,calibration curve at 225nm

Table No.(1) Result of data characteristics of etodolac

Parameters	Values of Etodolac
Beer's limit(µg/ml)	2-20
Correlation co efficient(r^2)	0.995
Regression equationY*	0.057x+0.025
Slope	0.057
Intercept	0.025

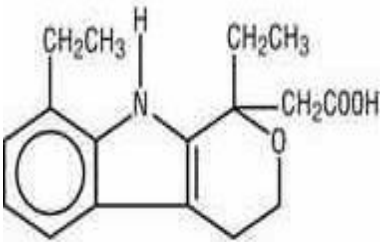
Table No.(2) Result of Sample Analysis

Analyte	Label claim (mg/tab)	% Label claim estimated (Mean ±S.D.)	%R.S.D.
Etodolac	200	100.06±0.00067	0.1924

Table no. (3) Result Of Validation Parameters:

Analyte	parameters	Interday	Intraday	Change in analyst
ETODOLAC	**%Recovered(mean)**	**100.01**	**99.75**	**100.37**
	SD	**± 0.0007**	**±0.0017**	**±0.00056**
	%RSD	**0.21**	**0.21**	**0.07**

FIGURES:



Structural formula of ETODOLAC

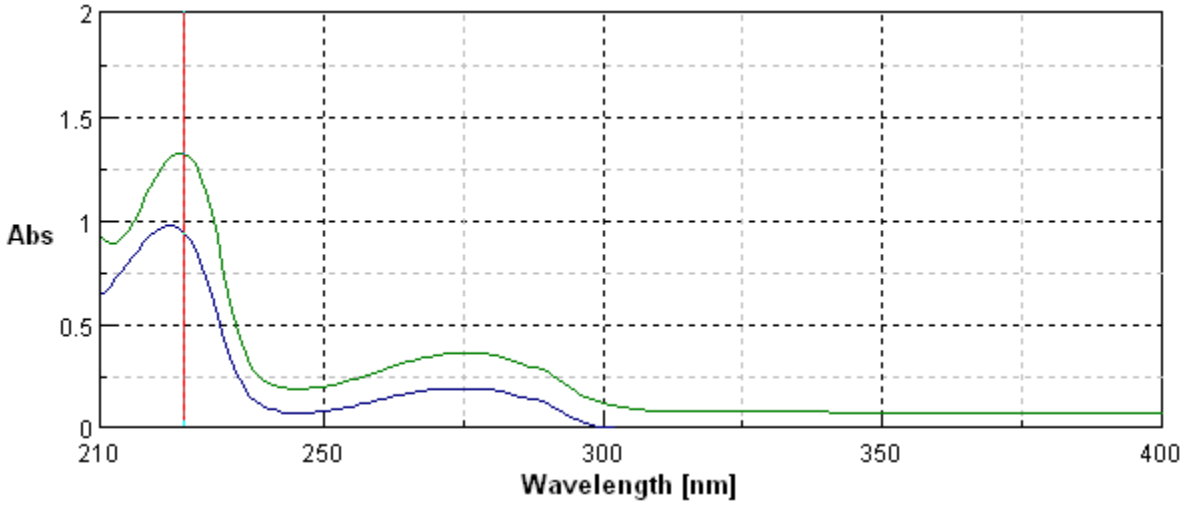


Fig.no.1Overlay of etodolac in 0.01N NaoH and 0.01NHcl

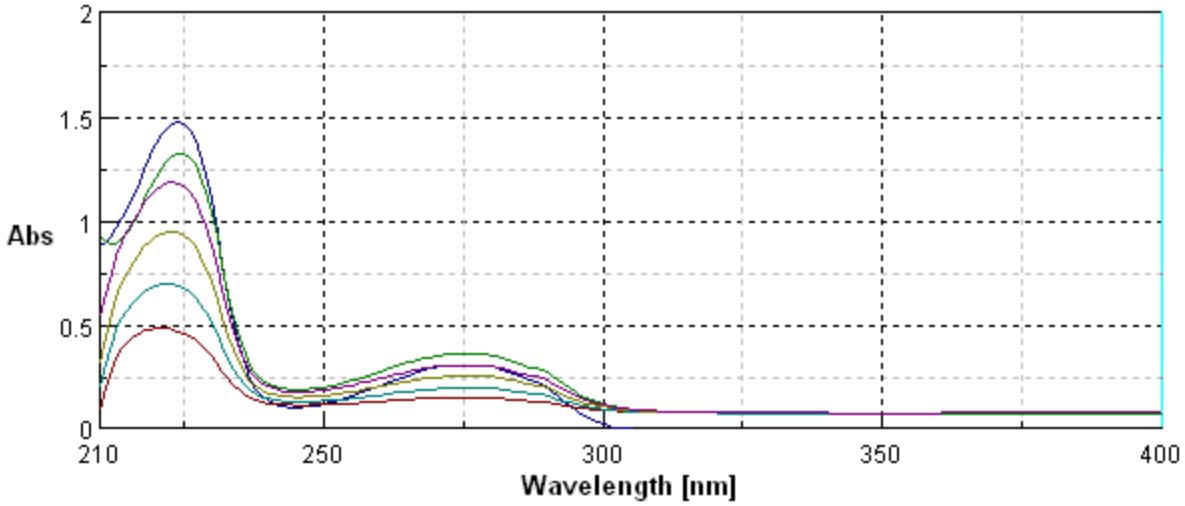


Fig no.2 Overlay of etodolac in 0.01N NaoH

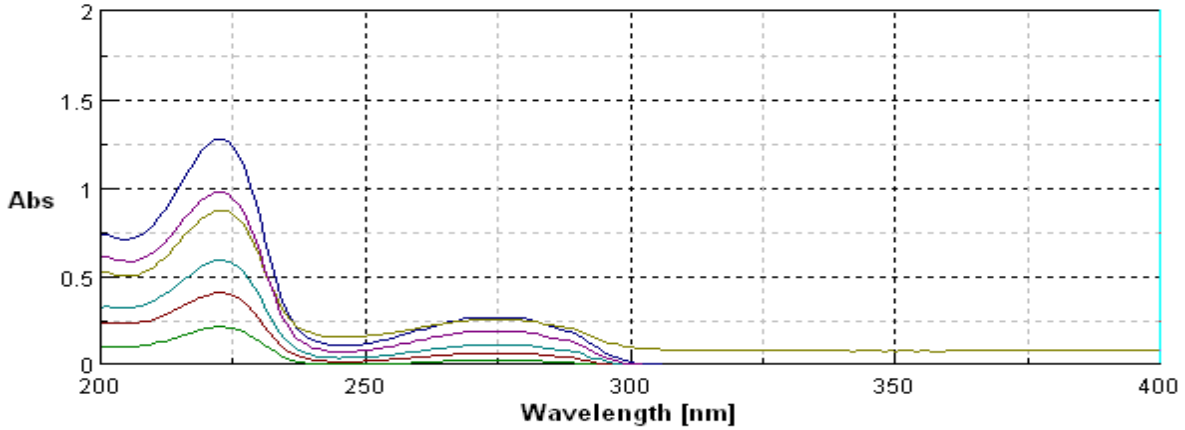


Fig.no.3 Overlay of etodolacin 0.01N HCl

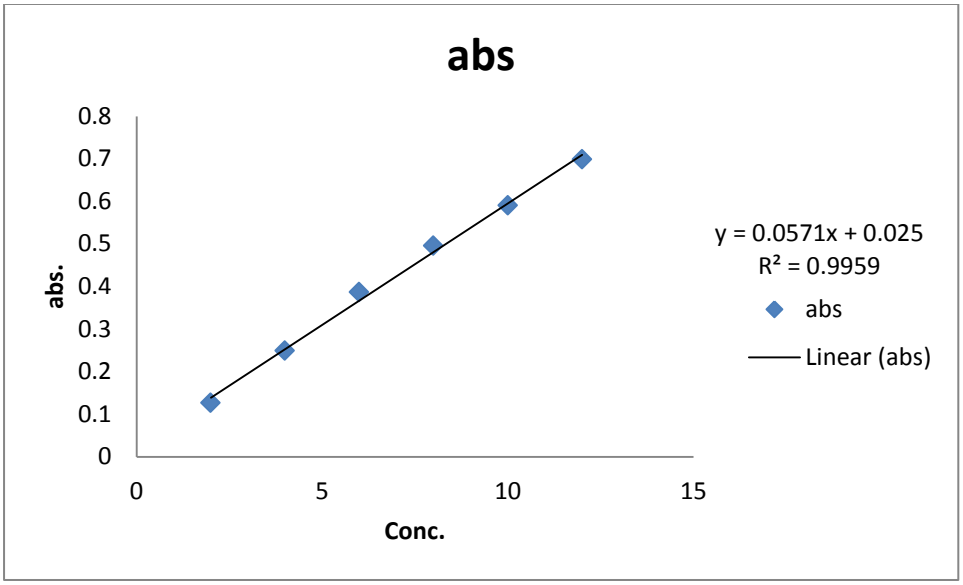


Fig.no.4 Calibration curve of etodolac of difference in absorbances.

The difference spectroscopy method was developed for etodolac using 0.01N NaOH and 0.01NHCl successfully. Thus standard calibration curve was the difference between the absorbances in alkali solvent and acidic solvent, which showed r^2 0.995 within the selected wavelength. The recovery data for etodolac at 80%, 100% and 120% was found to be 99.63%, that concluded the method developed to be accurate.

From the statistical data for precision was within limit and so method developed was found to be simple, accurate, precise and reproducibile.

CONCLUSION:

The accuracy of the method was determined by estimating the recovery of etodolac. Accuracy of analysis was determined by performing recovery studies by spiking different concentration of pure drug in the preanalyzed tablet samples. Results of recovery studies indicated that the method of precise, accurate and reproducible. The proposed method for different spectrophotometric estimation of etodolac was found to be simple, accurate and reproducible for routine estimation of etodolac in tablet formulation. The recoveries obtained from table no.3 for each drug do not differ significantly from 100 % and there were no interferences from common excipients used in the formulation indicating accuracy and reliability of the method.

ACKNOWLEDGEMENT:

The authors are greatly thankful to shree santkrupa college of Pharmacy, Ghogaon, India. For providing access to facilities and necessary infrastructure to carry out research work.

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