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Research Article

Area Under Curve Method Development for Etodolac in Bulk and Tablet dosage form

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ABSTRACT

A simple,precise, rapid and economical spectroscopic method has been developed for the determination of Etodolac in bulk and tablet dosage form. In methanol Etodolac shows absorbance maxima at 281nm. Method used was area under curve in which area incorporated in the wavelength range of 275nm-285nm.Etodolac obeys Beer's law in concentration range 0-60µg/ml. Calibration curves were plotted at selected wavelengths and it was found to be linear (r2=0.9997) Linearity for detector response was observed in the concentration range of 5-30µg/ml. The recovery studies established accuracy of the proposed method and results validated according to ICH guideline. Precision and Accuracy studies were carried out and results were satisfactory. Robustness of the given method was studied by using two wavelength, 279nm and 283nm respectively. Results were found satisfactory and reproducible. The developed method was successfully applied to estimate the amount of Etodolac in pharmaceutical formulation.

Keywords: Area under curve; accuracy, precision; spectroscopic method.

INTRODUCTION

Etodolac is non steroidalanti inflammatory drug which is belongs to pyranocarboxylic acid class developed in the 1970s. It blocks production of certain natural substances that causes inflammation [1]. Etodolac is chemically 1, 8-Diethyl-1, 3, 4, 9-tetrahydropyrone (3, 4-b) indole -1-acetic acid. Molecular formula of Etodolac is C17H21No3 [2].Cox present in two separate entities, one is Cox-1 and other is Cox-2[3, 4]. It inhibits synthesis of peripheral prostaglandins, by decreasing the activity of the Cox enzyme. Cox-1 protect the integrity of the stomach lining and sustain normal renal function in a kidney .Cox-2 plays a vital role in both control of cell growth and inflammation [5].Peak serum concentration achieved within 2 hours of oral administration of Etodolac 200mg and 400mg respectively [6] It is rapidly metabolized in the liver, followed by renal elimination as the primary route of excretion [7].

It is used for rheumatoid arthritis and osteoarthritis, postoperative pain and inflammation [8].It is used as anti-inflammatory agent, analgesic antipyretic and cyclooxygenase inhibitor. Etodolac is official in the United States Pharmacopoeia and British Pharmacopoeia [9].

Method development is the process of verifying that an analytical method is good enough for exercise to measure the concentration of an API in a particular compounded dosage form which allow basicmeasures to be employed to confirm that an analysis procedure, precisely and consistently will deliver a trustworthy measurement of an active ingredient in a compounded preparation [10].Primary purpose of method development to generate date regarding efficiency, safety, impurity, stability (that shows degradation of product), bioavailability and the effect of manufacturing parameter (that shows steadiness of the product) [11].

MATERIALS AND METHODS

The spectrophotometric analysis was carried out using a Labindia UV-3000 Uv/Vis spectrophotometer with 1 cm matched quartz cell. The spectra were obtained with the instrumental parameters as follows:Wavelength range (nm):

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200-400 nm; Scan speed: Fast; Sampling Interval: 1.00 nm; spectral bandwidth: 2.00 nm. All weights were taken on electronic balance, Model: Shimadzu AUX220.

Reagents

Etodolac was procured as gift sample from IPCA Laboratories, Mumbai. Analytical grade Methanol was used for the experiment. A tablet formulation containing 400mg of Etodolac was purchased from local market.

Standard Solutions

The standard solution was prepared by dissolving 10 mg of drug in Methanol and diluted to 100 ml with same solvent to obtain a final concentration of 100 ug/ml.Dilutions were done to get concentration of 5-30 ug/ml. The solution of Etodolac was analyzed in the wavelength range of 200-400 nm. The spectrum was recorded at 281 nm.

Preparation of Sample Solution

The sample solution was prepared by dissolving 10mg of tablet (Etova-400) formulation in methanol and diluted it with of same solvent to attaina final concentration of 100 µg/ml.

Area Under Curve

The AUC (Area Under Curve) method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength such as λ1 and λ2 representing start and end point of curve region [12]. The AUC (Area Under Curve) between λ1and λ2 was calculated using UV probe software. In this study area was integrated between wavelength ranges from 275 nm to 285 nm. The horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated observations so as to get the linearity between area under curve and concentration.

Validation

The method were validated with respect to linearity, accuracy, precision and robustness.

Linearity

Linearity was performed 3 times for validation. Fresh aliquots were prepared from the stock solution (100 µg/ml) ranging from 5-30 µg/ml. Higher concentration was scanned at 281nm and absorbance of all other dilutions were recorded. The calibration curve was constructed by plotting the response (y) versus the theoretical concentrations of standards(x), by using linear regression analysis.

Accuracy

Accuracy is the degree of agreement between the measured value and the true value. An absolute true value is seldom known. More realisticdefinition of the accuracy is the agreement between a measured value and the accepted value. This parameter was evaluated by the percent recovery studies. Solutions were prepared in triplicate at concentrations level of 80%, 100% and 120% with the help of Etodolac sample solution, and absorbance of each solution was taken. The recovery result showed that the proposed method has an acceptable level of accuracy for Etodolac

Precision

The reproducibility of the recommended method was estimated by performing intraday precision (on same day) and inter day precision (on three different days). Precision were performed by preparing nine determinations at specified range (15, 20 and 25 µg/ml). Low % RSD indicates that the method has good precision. The results of precision were expressed in% RSD.

Robustness

Robustness of the proposed method was carried out by analyzing aliquots at different wavelength (279 nm, 281 nm and 283 nm). The results are expressed in terms of percent relative standard deviation.

RESULT AND DISCUSSION

The molecular structure of the Etodolac. Methanol was selected as the solvent for Etodolac because it gives excellent solubility and other uniqueness for the AUC measurements. The absorbance and AUC spectrum of Etodolac in methanol for the method is represented.

The optical characteristics of Etodolac are given in Table 1.The AUC calibration curve exhibit good linear relationship at concentration range of 5-30 µg/ml for Etodolac. Linear regression equation was found to be y=0.299x-0.018 (r2=0.999). Percent amount found was between 91-97%. Precision was expressed in % relative standard deviation. The %RSD values found to be less than 2, therefore it specify that this method is precise for the drug Figure 1.

It can be concluded that this UV Spectrophotometric method is quite simple, rapid accurate, precise and economical for the determination of Etodolac in the bulk drug as well as tablet formulations. In this method the linearity was observed in the concentration range of 5-30 µg/ml with correlation coefficient r2= 0.999 at 281 nm.This method is economically alternative to HPLC method. The method was validated as per ICH guidelines.

No.	Parameter	Etodolac
1	Beer-Lambert's range	5-30 µg/mL
2	Wavelength	281nm
3	Slope	0.299
4	Intercept	0.018

5	Correlation coefficient	0.999

µg/ml: microgram per milliliter; nm: nanometer.

Table 1: Optical Characteristics Of Etodolac.

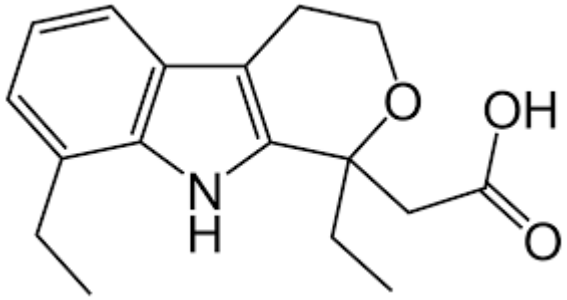

Figure 1: Structure of etodolac

CONCLUSION

Authors of the paper are grateful to the IPCA Laboratories, Mumbai for contributing to the research providing gift sample of drug. We are thankful to all the researchers in the field whose findings served as reference during our study.

CONFLICT OF INTEREST

Nil

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