ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Simultaneous Estimation of Etoricoxib and Paracetamol in Combined Tablet Dosage Form

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ABSTRACT

A simple, precise and accurate spectrophotometric method has been developed for simultaneous estimation of etoricoxib and paracetamol in combined dosage form using multicomponent mode of analysis. It involves the measurements of absorbance at five selected wavelengths 235 nm, 243 nm, 264 nm, 284 nm and 295 nm using methanol and hydrochloric acid (0.2 N) as a solvent. Linearity was observed in the range of 1-50 µg/mL for mixture. The recovery studies confirmed the accuracy of the proposed method. The results were validated as per ICH guidelines.

Key words: Etoricoxib, Paracetamol, Multicomponent mode

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ISSN: 0975-8585

INTRODUCTION

Etoricoxib is a new non-steroidal anti-inflammatory drug (NSAID) with selective COX-2 inhibitory activity. Chemically it is 5-chloro-2-(6-methylpyridin-3-yl)-3-(4-methylsulfonylphenyl) pyridine. It is commonly used for osteoarthritis, rheumatoid arthritis, primary dysmenorrhoea, postoperative dental pain and acute gout. This drug is not official in any pharmacopoeia. Paracetamol is 4-hydroxy acetanilide used as antipyretic agent. Literature survey revealed that some analytical methods have been used for individual estimation of etoricoxib like spectrophotometric, HPLC and HPTLC. Paracetamol is official in IP, BP and USP. There are many reported UV spectrophotometry and HPLC methods for determination of paracetamol in bulk drugs, formulation and biological fluids. It has been found that no method is reported for the simultaneous estimation of etoricoxib and paracetamol in combined dosage form [1-15].

MATERIAL AND METHOD

Materials

The pure drug samples of etoricoxib (99.83%) and Paracetamol (98.37%) were obtained from Cadila Ltd., Raigad, (M.S), India. and Zim Laboratories, Kalmeshwar India. Methanol AR grade and hydrochloric acid (0.2 N) were used throughout the experimental work. Tablets were purchased from local market (Nucoxia-P tablet), containing etoricoxib 60 mg and Paracetamol 500 mg per tablet.

Instruments

All Absorbance measurements were made on Shimadzu model UV 1601 double beam UV-Visible spectrophotometer with matched quartz cuvettes.

Standard stock solution

Standard stock solutions of etoricoxib (1mg/mL) and Paracetamol (1mg/mL) were prepared in methanol and further dilutions were carried out in hydrochloric acid (0.2 N) to get the concentration 2µg/mL and 16.6 µg/mL.

Method

a) Selection of sampling wavelength

Solutions of etoricoxib (2 µg/mL) and Paracetamol (16.6 µg/mL) were scanned under the range of 400-200 nm. Overlying spectra was obtained. Sampling wavelengths 235 nm, 243 nm, 264 nm, 284 nm and 295 nm were selected on trial and error basis.

ISSN: 0975-8585

b) Study of Beer lambert's law

Solution of etoricoxib (1mg/mL) and paracetamol (1mg/mL) were diluted with hydrochloric acid (0.2 N) to get final concentration in the range of mixed standard as fallows.

Laboratory Mixture

Drugs	Concentration in µg/mL				
	1	2	3	4	5
Etoricoxib	1	2	3	4	5
Paracetamol	8.3	16.6	24.8	33.1	41.2

All the mixed standard solutions were scanned over the range of 400-200 nm in the multicomponent mode, using five sampling wavelengths as selected on trial basis as given above. An overlain spectrum of the mixed standard solutions was given in Fig. 1. The graph was plotted as concentration verses absorbance and it was found to be linear for both the drugs (Fig. 2).

c) Analysis of tablet formulation

Twenty tablets were weighed and finely powdered and finely powdered. An accurately weighed quantity of powder equivalent to 50 mg of etoricoxib was transferred to 50 mL volumetric flask and dissolved in 25 mL methanol. It was diluted up to the mark with with methanol. The solution was filtered through whatmann filter paper no.41. The resulting solution was further diluted with hydrochloric acid (0.2 N) to get concentration within concentration range of mixed standards. This solution was subjected to analysis in the multicomponent mode of instrument at selected wavelength. The result of analysis is shown in Table 1.

d) Validation of method

The proposed method was validated on the basis of parameters namely accuracy, precision, linearity and range and ruggedness. The accuracy of the method was ascertained by carrying out recovery studies using standard addition method and found to be satisfactory. The result of recovery study is shown in Table 1.

TABLE NO.1: ASSAY OF FORMULATIONS AND RECOVERY STUDIES

Formulation*	% label claim**	% recovery**
Etoricoxib	98.95±1.45	98.85±0.584
Paracetamol	101.68±1.18	99.39±0.302

* Nucoxia-P tablet - each tablet contains etoricoxib 60 mg and Paracetamol 500 mg
** indicates mean of five determinations.

ISSN: 0975-8585

The precision of an analytical method was as SD or RSD. Linearity and range was carried out in the range of 1-50 µg/mL and absorbance was recorded at selected wavelength. The linearity of graph is shown in Fig 2. Ruggedness test was carried out under different conditions by repeating the procedure under different conditions, i.e., on different days, at different time and by different analysts.

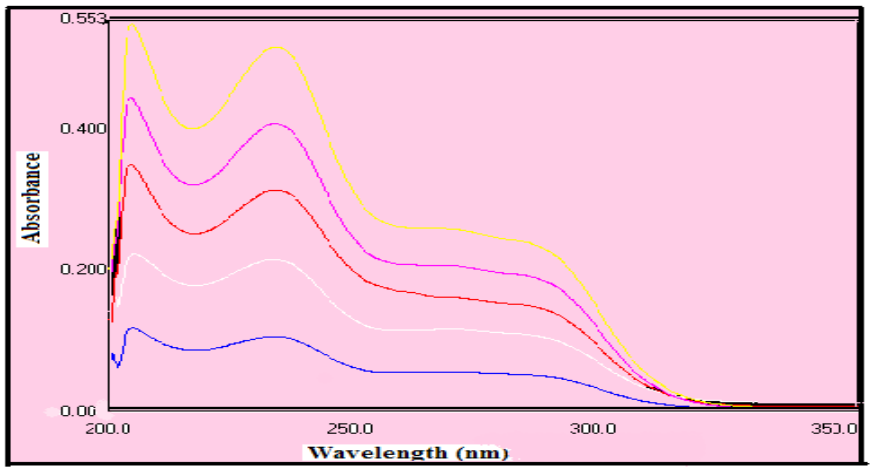

Fig. 1: Overlain Spectrum laboratory mixtures

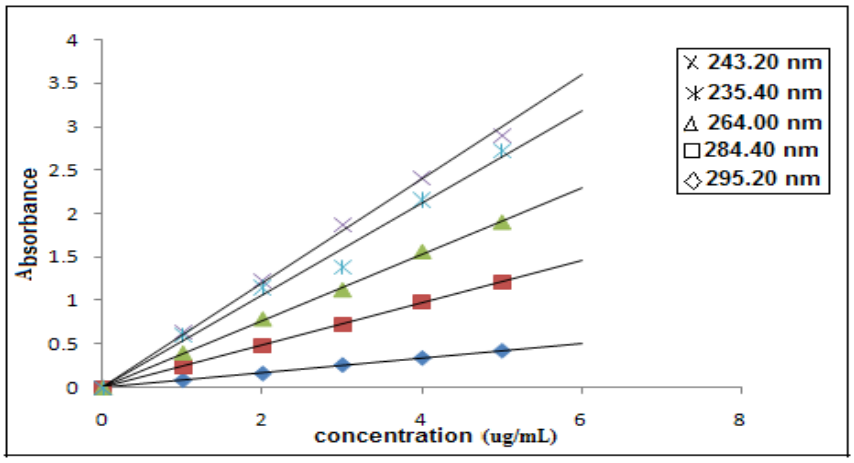

Fig. 2: Beer Lambert's law plot

DISCUSSION

The proposed method for estimation of etoricoxib and paracetamol in combined dosage forms was found to be simple, accurate, economical and rapid. The method was validated as per the ICH guidelines. The values of SD and RSD are within the prescribed limit of 2%, showing high precision of method and recovery was close to 100% for both the drugs.

ACKNOWLEDGEMENTS

The authors are thankful to M/S Cadila Ltd., Raigad, and Zim Laboratories, Kalmeshwar for providing gift sample of drugs.

ISSN: 0975-8585

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