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Application of the ratio difference spectrophotometry to the determination of ibuprofen and famotidine in their combined dosage form; Comparison with previously published spectrophotometric methods

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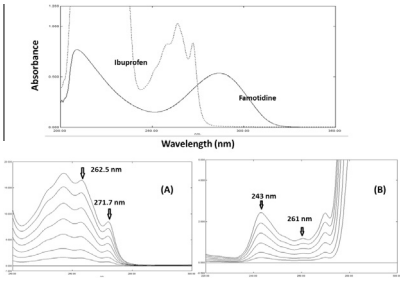
HIGHLIGHTS

- Application of the ratio difference method for the determination of ibuprofen and famotidine.
- The proposed method is simpler and does not need tedious mathematical calculations.
- The proposed method is more accurate as it does not depend on measurement at a single wavelength.
- Statistical analysis of the results showed the method is accurate and precise.
- Comparison with the previously published methods.

GRAPHICAL ABSTRACT

Ratio spectra of (A) ibuprofen using the spectrum of 2.5 μg/mL famotidine as divisor and (B) famotidine using the spectrum of 300 μg/mL ibuprofen as divisor showing wavelengths at which measurements were done.



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ABSTRACT

Ratio difference spectrophotometric method was developed for the determination of ibuprofen and famotidine in their mixture form. Ibuprofen and famotidine were determined in the presence of each other by the ratio difference spectrophotometric (RD) method where linearity was obtained from 50 to 600 μg/mL and 2.5 to 25 μg/mL for ibuprofen and famotidine, respectively. The suggested method was validated according to ICH guidelines and successfully applied for the analysis of ibuprofen and famotidine in their pharmaceutical dosage forms without interference from any additives or excipients.

Introduction

Ibuprofen (IBU) (Fig. 1a) is chemically α-methyl-4-(2-methylpropyl) benzene acetic acid, 2-(p-Isobutyl phenyl) propanoic acid, 4-Isobutyl hydratropic acid [1]. It is a non-steroidal anti-inflammatory drug (NSAIDS) which inhibits prostaglandin synthesis by blocking the enzyme cyclooxygenase (COX enzyme) that converts arachidonic acid into prostaglandin [2].

Famotidine (FAM) (Fig. 1b) is chemically3-[({2-[(diaminomethylidene)amino]-1,3-thiazol-4-yl}methyl)sulfanyl]-N′-sulfamoylpropanimidamide. It is used to block the action of histamine on the stomach cells, so decrease the production of acid by the stomach [2]. IBU and FAM are co-formulated in a mixture form used for

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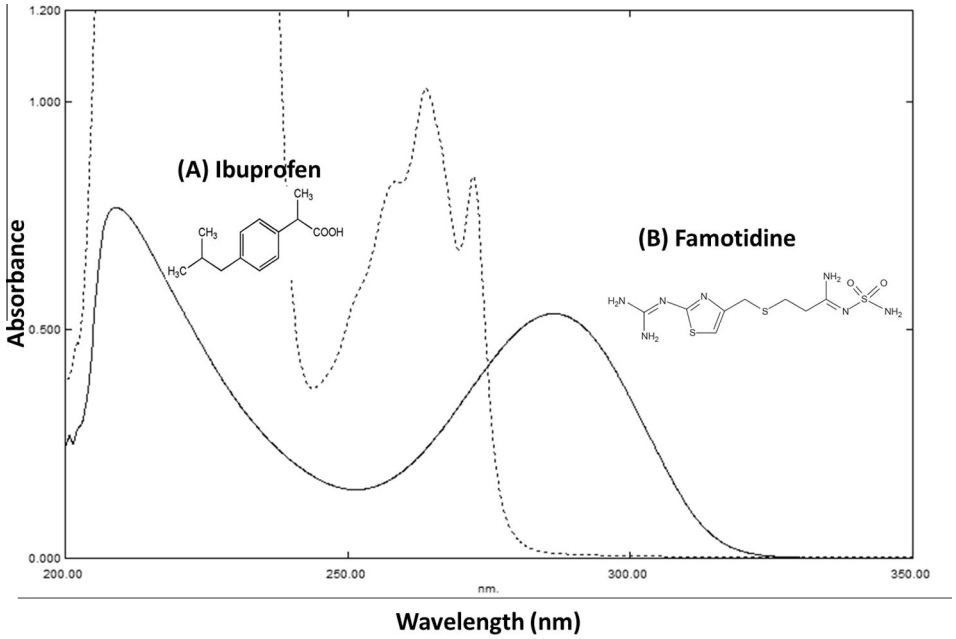

Fig. 1. Zero order absorption spectra and chemical structures of (A) ibuprofen and (B) famotidine.

the treatment of rheumatoid arthritis where FAM reduces the gastrointestinal toxicity of IBU [2].

The literature review reveals that IBU and FAM were determined in combination by spectrophotometry [1–9], HPLC [6,10–20], and TLC [20,21]. The aim of this work was to develop a ratio difference spectrophotometric method for determination of the cited drugs in combination without any interference from the additives or the excipients in pharmaceutical formulations. The developed method is simpler and more accurate than previously published spectrophotometric methods.

Experimental

Apparatus

Spectrophotometric measurements were carried out on a dual beam SHIMADZU (Kyoto, Japan) UV- Spectrophotometer, model UV-1650 PC connected with HP 600 inkjet printer.

Materials and reagents

Pure standard

Ibuprofen working standard was obtained as a kind gift sample from Kahira Company, Cairo, Egypt. The purity of IBU was reported to be 99.8%. Famotidine working standard was obtained as kind gift sample from Amoun Company, Cairo, Egypt, and its purity was reported to be 99.9%.

Pharmaceutical formulation

Duexis® tablets were purchased from the market (Batch No. 8064869, label claim: 800 mg IBU and 26.6 mg FAM) manufactured by Horizon Pharma, USA.

Chemicals and reagents

Sodium Hydroxide was obtained from Sigma Aldrich, Cairo, Egypt. Dilutions were made using double distilled.

Standard solutions

FAM stock standard solution of 1 mg/mL was prepared in methanol. FAM working standard solution of 25 μg/mL was prepared by dilution in 0.01 N NaOH.

IBU stock standard solution of 2 mg/mL was prepared in 0.01 N NaOH and used as working solution.

Laboratory prepared mixtures

Solutions containing different ratios of IBU and FAM were prepared by transferring aliquots from their standard solutions to a series of 10-mL volumetric flasks and the volume of each was completed to the mark with 0.01 N NaOH.

Procedures

Construction of the calibration curves

For famotidine; Aliquots (1, 2, 4, 6, 8 and 10 mL) of FAM working standard solution (25 μg/mL) were accurately measured, transferred into a series of 10-mL volumetric flasks and the volume was completed to the mark with 0.01 N NaOH. The zero order absorption spectra of the prepared solutions were recorded and then divided by the spectrum of 300 μg/mL ibuprofen. The peak amplitudes of the ratio spectra were measured at 243 and 261 nm (Fig. 2). Calibration graphs relating the differences in the peak amplitudes at the chosen wavelength versus the corresponding concentrations of FAM were constructed, and the regression equation was computed.

For ibuprofen; Aliquots (0.25, 0.5, 1, 1.5, 2, 2.5 and 3 mL) of IBU standard solution (2 mg/mL) were accurately measured, transferred to a series of 10-mL volumetric flasks and the volume was completed to the mark with 0.01 N NaOH. The zero order absorption spectra were recorded and then divided by the spectrum of 2.5 μg/mL of FAM. The peak amplitudes of the ratio spectra were measured at 262.5 and 271.7 nm (Fig. 3). Calibration graphs relating the differences in the peak amplitudes at the chosen wavelength versus the corresponding concentrations of IBU was constructed, and the regression equation was computed.

Analysis of laboratory prepared mixtures

The absorption spectra of the laboratory-prepared mixtures were scanned, processed as under calibration graphs and the concentration of IBU and FAM in each mixture was calculated using the specified regression equation.