Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy 151 (2015) 538–546

Contents lists available at ScienceDirect

Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy

journal homepage: www.elsevier.com/locate/saa

A comparative study of the novel spectrophotometric methods versus conventional ones for the simultaneous determination of Esomeprazole magnesium trihydrate and Naproxen in their binary mixture

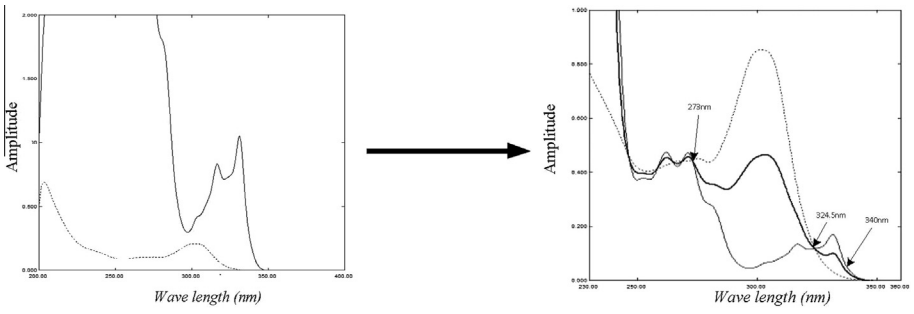
Hayam M. Lotfy [a,b], Sawsan M. Amer [a], Hala E. Zaazaa [a], Noha S. Mostafa [a,*]

[a] Analytical Chemistry Department, Faculty of Pharmacy, Cairo University, Kasr El Aini Street, 11562 Cairo, Egypt
[b] Pharmaceutical Chemistry Department, Faculty of Pharmaceutical Science and Pharmaceutical Industries, Future University, 12311 Cairo, Egypt

HIGHLIGHTS

- Two novel methods namely absorbance subtraction (AS) and ratio difference (RD).
- Three recently well established spectrophotometric methods (DW, ISP coupled with D1 and ^{1}DD) were applied.
- The proposed methods are simple accurate and precise.
- One way ANOVA statistical analysis for comparison of the proposed methods.

GRAPHICAL ABSTRACT



ARTICLE INFO

Article history:
Received 29 April 2015
Received in revised form 27 June 2015
Accepted 1 July 2015
Available online 3 July 2015

Keywords:
Esomeprazole
Naproxen
Absorbance subtraction and ratio difference

ABSTRACT

Two novel simple, specific, accurate and precise spectrophotometric methods manipulating ratio spectra are developed and validated for simultaneous determination of Esomeprazole magnesium trihydrate (ESO) and Naproxen (NAP) namely; absorbance subtraction and ratio difference. The results were compared to that of the conventional spectrophotometric methods namely; dual wavelength and isoabsorptive point coupled with first derivative of ratio spectra and derivative ratio. The suggested methods were validated in compliance with the ICH guidelines and were successfully applied for determination of ESO and NAP in their laboratory prepared mixtures and pharmaceutical preparation. No preliminary separation steps are required for the proposed spectrophotometeric procedures. The statistical comparison showed that there is no significant difference between the proposed methods and the reported method with respect to both accuracy and precision.

1. Introduction

Esomeprazole (Fig. 1a), Esomeprazole magnesium, Bis (5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl]Sulfinyl]-1H-benzimidazole-1-yl) magnesium trihydrate, the first proton pump inhibitor developed as a single optical isomer – (the *S*-isomer of omeprazole) – for the treatment of acid related diseases. It is used in the treatment of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease and Zollinger–Ellison syndrome. Literature survey reveals that there are some UV [1–3] and HPLC [4–7] methods for the determination of Esomeprazole in pharmaceutical formulations, or in human plasma by HPLC [8,9].

Naproxen (Fig. 1b), (S)-2-(6-methoxyNAPthalen-2-yl) propionic acid is used as non steroidal anti-inflammatory drug (NSAID) commonly used for the reduction of pain, fever, inflammation and stiffness caused by conditions such as osteoarthritis, kidney stones, rheumatoid arthritis, psoriatic arthritis, gout, ankylosing

* Corresponding author.
E-mail address: nohasamy2009@hotmail.com (N.S. Mostafa).

http://dx.doi.org/10.1016/j.saa.2015.07.007
1386-1425/

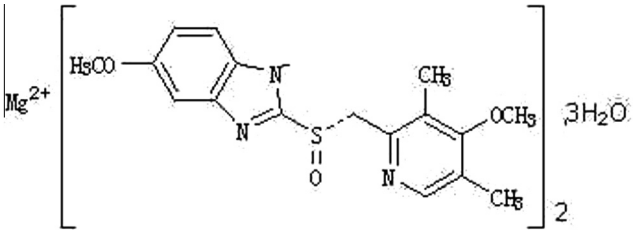


Fig. 1a. Chemical structure of Esomeprazole magnesium trihydrate.

spondylitis, menstrual cramps, tendinitis, bursitis and primary dysmenorrhea. It works by inhibiting both the COX-1 and COX-2 enzymes. Literature survey reveals that there are some UV [10–14] and HPLC [15–18], HPTLC [19], UPLC [17], LC/MS [20,21], Capillary electrophoresis [22] methods for the estimation of Naproxen in pharmaceutical formulations, and in rat serum by HPTLC [23]. The official method for independent determination of Naproxen is by acid–base titration and that for Esomeprazole magnesium is by HPLC [24].

A combination of both drugs is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Very few methods were reported for the simultaneous determination of these components in their pharmaceutical formulations including spectrophotometric methods (simultaneous equation, Q-analysis, absorption correction, absorption ratio, area under the curve, multicomponent method, zero crossing first derivative spectrophotometry, dual wavelength and ratio derivative spectrophotometry) [25–30], HPLC either in pharmaceutical dosage form [31–37], or in human plasma [38] and UPLC [39,40].

The aim of this work is to develop and conduct a comparative study on two novel methods, namely ratio difference (RD) and absorbance subtraction (AS) which used for resolving mixtures of the cited drugs versus other conventional ones namely, first derivative of ratio spectra (^{1}DD), dual wavelength (DW), and isoabsorptive (ISP) method coupled with first derivative (1D). The proposed methods were very simple, accurate, precise and did not require any sophisticated apparatus or computer programs.

2. Theoretical background

2.1. Absorbance subtraction method (AS)

This method is based on the same principles as the absorption factor method. The method could be applied for the analysis of a mixture of two drugs X and Y having overlapped spectra Intersect at isoabsorptive point and Y is extended over X, while X does not show any contribution at another wavelength (λ_2).

In this method the isoabsorptive point λ_{iso} could be used for separate quantitative estimation of each X and Y in their mixture ($X + Y$).

The determination can be done using mathematically calculated factor of one of these components. By simple manipulation step, we can get the absorbance value corresponding to X and Y, separately. So, the concentration of each component could be obtained via the isoabsorptive point regression equation without any need for a complementary method. The absorbance values corresponding to X and Y at λ_{iso} were calculated by using absorbance factor which is a constant for pure Y representing the average of the ratio between the absorbance values of different concentrations of pure Y at λ_1 (A_{iso}) to those at λ_2 (A_2) i.e. $\{A_{iso}/A_2\}$

$$\text{Absorbance of } Y \text{ in the mixture at } \lambda_{iso} = \frac{\text{abs1}}{\text{abs2}} \times \text{abs}_{\lambda_2}(X+Y)$$

$$\text{Absorbance of } X \text{ in the mixture at } \lambda_{iso} = \text{abs}_{\lambda_{iso}}(X+Y) - \frac{\text{abs1}}{\text{abs2}} \times \text{abs}_{\lambda_2}(X+Y)$$

where $\text{abs}_{\lambda_{iso}}$, abs_{λ_2} is the absorbance of Y at λ_{iso} and λ_2; abs1/abs2 is the absorbance factor and $\text{abs}_{\lambda_{iso}}(X+Y)$ and $\text{abs}_{\lambda_2}(X+Y)$ are the absorbance of the mixture at these wavelengths. The concentration of each X and Y, separately, is calculated using the isobsorptive point unified regression equation (obtained by plotting the absorbance values of the zero order spectra of either X or Y at isobsorptive point (λ_{iso}) against the corresponding concentrations X or Y respectively) [41–43].

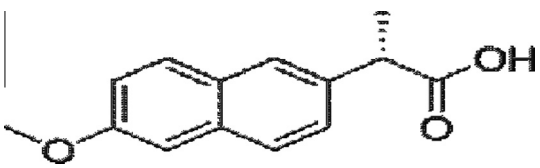


Fig. 1b. Chemical Structure of Naproxen.

3. Experimental

3.1. Standard, chemicals and solvents

Standard Naproxen and Esomeprazole magnesium trihydrate with claimed purity of 99.96% ± 1.56 and 100.31% ± 0.57, respectively according to the official methods [24]. NAP was supplied by Rameda company, Egypt. ESO was kindly donated by Multi Apex Pharmaceuticals – Egypt.

Vimovo® tablets manufactured by Astra zenica and were purchased from local market in America, claimed to contain 20 mg ESO and 500 mg NAP.

Methanol E. Merck, Darmstadt, FRG.

3.2. Instruments

- A double beam UV–visible spectrophotometer (SHIMADZU, Japan) model UV-1601 PC with quartz cell of 1 cm and UV-PC personal software version 3.7 was used. The spectral band width is 2 nm and wavelength-scanning speed 2800 nm/min.
- Sonicator, Bandelin-Sornex TK (Germany).
- Centrifugator Laboratory benchtop centrifuge Liston C 2201 (Spain).

3.3. Preparation of stock and working solution

Stock solutions of ESO (0.5 mg/mL) and NAP (1 mg/mL) were prepared by dissolving the cited drugs in methanol then completing in 100 mL calibrated measuring flasks. Aliquots of the prepared stock solutions were further diluted with methanol to a final volume of 100 mL. The diluted solutions were used as the working solutions with concentrations; ESO (100 μg/mL) and NAP (200 μg/mL).

3.4. Spectral characteristics and calibration

Standard solutions containing 5–35 μg/mL ESO and 20–160 μg/mL NAP, were prepared separately in methanol. The absorption spectra of the two compounds were scanned over the range 200–400 nm and stored in the computer, as illustrated in (Fig. 2a).