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Different approaches in manipulating ratio spectra applied for the analysis of Cefprozil in presence of its alkaline-induced degradation product: A comparative study

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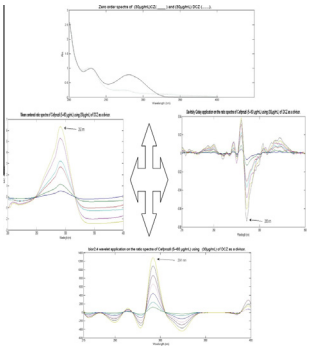
HIGHLIGHTS

- Comparative study between different aspects of manipulating ratios.
- Can be applied for severely overlapped and complex binary mixtures.
- Limitations and advantages of each aspect was explained.
- Wavelet transform technique transcended the other techniques.
- Can be applied for analysis of the dosage form with no inference of excipients.

GRAPHICAL ABSTRACT



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ABSTRACT

Four simple, accurate and precise stability-indicating spectrophotometric methods manipulating ratio spectra were developed and validated for simultaneous determination of Cefprozil (CZ) and its alkaline-induced degradation product (DCZ) without prior separation namely; ratio difference, mean centering, derivative ratio using Savitsky–Golay filter and continuous wavelet transform. The accuracy, precision and linearity ranges of the proposed methods were determined. The methods were validated and the specificity was assessed by analyzing synthetic mixtures containing the drug and its degradate. The four methods were applied for the determination of the cited drug in tablets and the obtained results were statistically compared with those of a reported method. The comparison showed that there are no significant differences between the proposed methods and the reported method regarding both accuracy and precision.

Introduction

Cefprozil(6R,7R)-7-[(R)-2-Amino-2-(p-hydroxyphenyl)acetamido]-8-oxo-3-(1-propenyl)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid monohydrate Fig. 1 is bactericidal used in the treatment of susceptible infections including upper and lower respiratory tract infections, skin and soft tissue infections. It should probably be classified as a second generation Cephalosporin, beta-lactam and other inhibitors of cell wall synthesis [1–3]. Literature survey reveals that HPLC methods were developed for the determination of Cefprozil in pharmaceutical formulations and in biological fluids [4–7]. A flow injection chemiluminescent method was also reported [8]. Spectrophotometric and colorimetric methods were

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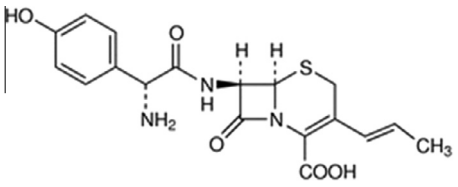

Fig. 1. Chemical structure of Cefprozil.

used for the determination of Cefprozil in pharmaceutical formulations and in biological fluids [9–18]. HPTLC method [19] and a stability indicating method by derivative ratio [20] were also described for its analysis.

The high importance of this class of drugs, in addition to the difficulty encountered during its quantitative analysis due to the chemical instability of the β-lactam nucleus prompted the authors to develop various stability-indicating methods for its analysis in pure form and in pharmaceutical formulations. Upon dividing the spectrum of a binary mixture with a spectrum of one of the two components, the spectrum of this component converts into a straight line (constant). In this paper, four different spectrophotometric methods manipulating the ratio spectra were applied for the removal of this constant namely; ratio difference spectrophotometric method [21–24], mean centering [25–28], derivative ratio using Savitsky–Golay filter [29–33] and continuous wavelet transform [34,35].

Theory

Derivative ratio using Savitsky–Golay filter (SG)

SG filters use best least squares fit polynomials to approximate data and derivatives. They can be computed very rapidly and they can provide smoothed derivatives of many orders. The central idea of SG filters is to use best least squares polynomial fits to approximate data; then use those polynomials to estimate data or derivatives.

As it is based on polynomial fitting, one can directly perform derivation on the polynomial and then obtain the weighting expression for the central point in the moving window to give the derivative spectrum.

Employing the derivative function according to the SG method for each measuring value of y_j, a new value of y'_j is computed by a weighted average. The general form of this polynomial is:

$$y'_j = \sum_{i=-m}^{i=m} \frac{C_j y_{j+i}}{N}$$

The coefficients c_j can be determined by deciding the order of the model, deciding on the window size and selecting the appropriate number from the SG tables and dividing by the normalization constant [29–33].

Continuous wavelet transform (CWT)

It is similar to Fourier transform with the advantage of having many basic functions called wavelets while the basic functions in Fourier transform are the trigonometric functions (sine and cosine). A wavelet transform is the representation of a function by wavelets. A wavelet is defined as a number of scaled and dilated functions $\Psi_{a,b}(\lambda)$ derived from a basic function $\Psi(\lambda)$. Therefore the basic function is often called a mother wavelet since it gives birth to a family of wavelets.

$$\Psi_{a,b} = \frac{1}{\sqrt{a}} \Psi\left(\frac{\lambda - b}{a}\right), \quad a \neq 0, \quad a, b \ \varepsilon \ R.$$

where (a) is the scale parameter and (b) is called translation parameter.

Due to the presence of large number of basic wavelets, wavelet transform provides a solution for almost all chemistry problems with one or more of its wavelets by choosing the suitable scaling parameter. Continuous wavelet transform (CWT) has been used over the past decade in many areas like de-noising, data compression and quantitative analysis of multicomponent systems [34–39].

Experimental

Instruments

SHIMADZU dual beam UV–visible spectrophotometer (Kyoto/Japan), model UV-1650 PC connected to IBM compatible and aHP1020 laser jet printer. The bundled software, UV-Probe personal spectroscopy software version 2.1 (SHIMADZU) was used. The spectral band was 2 nm and scanning speed is 2800 nm/min and 1 nm data interval.

Software

All signal processing methods (CWT, SG) were implemented in Matlab 8.2.0.701 (R2013b). The calculations used for SG filters were done with our own written code in Matlab. The *t*-test and *F*-test were performed using MicrosoftExcel.

Chemicals and reagents

(a) Cefprozil monohydrate was kindly supplied by GlaxoSmithKline for pharmaceuticals, Cairo, Egypt.
(b) Pharmaceutical Preparations: "Cefzil" tablets: (batch number 033762) containing 530 mg of Cefprozil monohydrate per tablet.
(c) Solvent: distilled water.

Standard solutions

Stock solution (0.5mg/mL) was prepared by transferring 0.05 gm of cefprozil monohydrate to 100 mL volumetric flask, dissolving in distilled water and the volume was then completed to the mark.

Preparation of the degradation product (DCZ): Stock solution was prepared by treating 0.05gm of cefprozil monohydrate with 10 mL 1 N NaOH and allow to stand for ten minutes at ambient temperature then neutralized with 1 N HCl and evaporated to dryness. The residue was dissolved, filtered into 100 mL measuring flask and completed to volume with the distilled water to obtain stock solution of alkaline degradate derived from 0.5 mg/mL [20]. Aliquots of different concentrations of Cefprozil degradation product (DCZ) were accurately transferred into series of 10 mL volumetric flasks and the volumes were completed to the mark with water. These solutions were scanned in range 200–400 nm and stored in the computer.

Procedure

Linearity and construction of calibration curves

Ratio difference spectrophotometric method (RDSM)

Aliquots from CZ stock standard solution were accurately measured, transferred into a set of 10 mL volumetric flasks and completed to volume with water to give (5–60 μg/mL). The zero order absorption spectrum of each solution was recorded versus water as a blank, divided by the spectrum of the degradation