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ORIGINAL ARTICLE

Determination of phenylephrine hydrochloride and chlorpheniramine maleate in binary mixture using chemometric-assisted spectrophotometric and high-performance liquid chromatographic-UV methods

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Abstract Four methods have been developed for the simultaneous determination of phenylephrine hydrochloride and chlorpheniramine maleate without previous separation. In the first method both drugs are determined using first derivative UV spectrophotometry, with zero-crossing measurement. The second method depends on first derivative of the ratios spectra. The third method describes the use of multivariate spectrophotometric calibration for the simultaneous determination of the analyzed binary mixture where the resolution is accomplished by using partial least squares (PLS) regression analysis. In the fourth method (HPLC), a reversed-phase column and a mobile phase of methanol:water:acetonitrile (80:12:8 v/v/v/) at 0.9 ml/min flow rate have been used to separate both drugs with a UV detection at 270 nm. All the proposed methods are extensively validated. They have the advantage to be economic and time saving. All the described methods can be readily utilized for analysis of pharmaceutical formulations. The results obtained using the proposed methods are statistically analyzed and compared with some reported methods.

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1. Introduction

Phenylephrine hydrochloride is a sympathomimetic drug. It can be used as a nasal decongestant (El-Hawary et al., 1985). The most recent methods for determination of phenylephrine hydrochloride included chromatographic (Chien and Schoenwold, 1985; Wilson et al., 1985; Al-Kaysi and Salem, 1986; Lioyd et al., 1987), electrochemical (Kuz and Kramarenko, 1984; Lucy and Cantwell, 1986) and spectrophotometric (Mayers and Tayler, 1987; Baker and Lowe, 1985; Besada, 1987; Ahmed and Amin, 2007; Korany et al., 1985; Li and Lubman, 1988) techniques.

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Chlorpheniramine maleate is anti-histaminic drug (El-Hawary et al., 1985). Several methods have been reported for chlorpheniramine maleate assay including chromatographic (Seki et al., 1988; Lavagine and Zee, 1987; Lioyd and Whit, 1988) and spectrophotometric (Louhaichi et al., 2009; Fasanmda et al., 1985; Kitamura and Majma, 1983) techniques.

Recently, derivative spectrophotometry has been found to be a useful method in the determination of mixtures with two or more components having overlapping spectra and in eliminating interference from formulation matrix by using the zero-crossing techniques (Salem, 1999, 2006; Mabrouk et al., 2003).

Furthermore, ratio-spectra derivative spectrophotometric method has also been found to be useful in the estimation of drugs in their mixtures (Moor et al., 2002; Kenney et al., 2000; Shamsipur and Jalali, 2000; Cheng and Peng, 1998; Mushik et al., 1998). Such a method permits the determination of a component in their mixture at the wavelengths corresponding to a maximum or minimum and also the use of the peak-to-peak between consecutive maximum and minimum. The main advantage of derivative of the ratio-spectra method may be the chance of easy measurements in correspondence of peaks so it permits the use of the wavelength of highest value of analytical signals (maximum or minimum). Moreover, the presence of a lot of maxima and minima is another advantage by the fact that these wavelengths give an opportunity for the determination of active compounds in the presence of other active compounds and excipients which possibly interfere in the analysis.

Multivariate calibration methods applied to spectral data are being increasingly used for pharmaceutical analysis. Classical least squares (CLS) and principal components regression (PCR) analysis are the most simplest multivariate methods that can be performed with easily accessible statistical software (Mohamed et al., 2005; Abde El-Maaboud and Pakinaz, 2002; Jose Aurelia and Pablo, 2001; Hector and Alejandro, 1998).

CLS technique assumes that responses (absorbance) at each frequency (wavelengths) are proportional to component concentration units. Model errors are assumed to derive from the measurement of spectral absorbance. So CLS requires that all interfering chemical components be known and included in the calibration data set. CLS has the advantage of improved precision when using many frequencies, due to signal averaging.

Calibration is realized by recording the spectra at n-wavelengths of m standard mixtures, of known composition of c components. The spectra (absorbance or emission) are arranged into the columns of matrix Y (dimensions $n \times m$), with the composition of each mixture forming the columns of concentration matrix X ($c \times m$)

$$Y = K \cdot X \tag{1}$$

With a prior knowledge of X and by recording data for Y, then the matrix of sensitivities, K, can be calculated, but after the rearrangement of Eq. (1) to the following equation by multiplying the equation components by X^t value as:

$$Y \cdot X^t = K \cdot X \cdot X^t$$
$$K = (X \cdot X^t)^{-1} \cdot Y \cdot X^t \tag{2}$$

To avoid being under-determined, there must be measurements at more wavelengths than there are components (i.e. $n \geqslant c$). If $n > c$ then the component concentrations in an unknown mixture are obtained from its spectrum by,

$$X_{unknown} = (K^t \cdot K)^{-1} \cdot K^t y_{unknown} \tag{3}$$

This CLS method is intuitively appealing since it is based on some generally assumed relationship, e.g. Beer's law, and it can be used for moderately complex composition of the calibration mixtures, i.e. the concentration of each absorbing species. PCR is a two-step procedure, in the first step, one estimating the number of principal components by one or more of the following criteria, the percentage of explained variance, eigen value-one criterion, the Scree-test and Cross validation. They can be considered as new variables that summarize in an optimal way the variation present in the spectra, in the second step, CLS is applied to the newly obtained latent variables. When co-linearity between original variables occurs, principal component plots often allow better interpretation of the variations observed in the data set than plots of original variables selected by CLS. As modeling method, it is less performant than CLS when performing prediction within the calibration domain and when the model is indeed linear. It is more reliable if extrapolation may be required. It is a linear method, but it is able to perform quite well for moderately nonlinear data. As CLS, it is a global method (Beebe and Kowalski, 1987; Wetzel, 1983; Hernandez-Arteseros et al., 2000; Adam, 2004).

HPLC methods are useful in the determination of drugs in pharmaceutical dosage forms and biological sample. Owing to the widespread use of HPLC in routine analysis, it is important that good HPLC methods are developed and that these are thoroughly validated (Pesez and Bartos, 1974; Moffat et al., 1986; Fijalek et al., 1992).

The purpose of the present study was to investigate the utility of derivative, derivative ratio spectrophotometry, multivariate and HPLC techniques in the assay of phenylephrine hydrochloride and chlorpheniramine maleate in pharmaceutical preparations without the necessity of sample pre-treatment.

2. Experimental

2.1. Apparatus and conditions

The Hewlett–Packard liquid chromatographic system consisted of a gradient Quat pump Model G 1311 A (HP, Avondale, PA, USA) connected with an HP G 1314 A UV–VIS detector (HP, Avondale, PA, USA) operating at 265 nm, a G 1328 A (Cotati, CA) injection valve, with a 20 μl loop. The chromatographic data were collected and analyzed using HP Chem Station for LC and LC/MS system (Hewlett–Packard, Avondale, PA, USA). The chromatographic separation was performed at ambient temperature (20–22 °C) using an analytical column, Spherisorb®, 5 μm, 4.6 × 150 mm i.d. (Waters, Milford, MA, USA). The reversed mobile phase was obtained by mixing methanol:water:acetonitrile (70:22:8 (v/v/v)). The flow rate was 0.9 ml/min. Finasteride was used as an internal standard.

Spectrophotometric measurements were carried out on a computerized Spectronic Gensys 2PC, UV/Vis Spectrophotometer (Milton Roy, USA), using 1.00 cm quartz cells. The obtained spectral data were saved in PC apparatus program

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