Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy 132 (2014) 446–451

Contents lists available at ScienceDirect

Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy

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

Simultaneous determination of some anti-hypertensive drugs in their binary mixture by novel spectrophotometric methods

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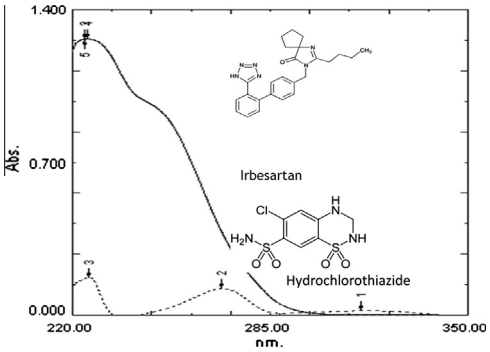
HIGHLIGHTS

- Smart, novel and simple spectrophotometric methods were successfully applied.
- They are used for simultaneous analysis of complex binary mixtures.
- They do not need a special program and could be easily applied in QC labs.
- They are having equal accuracy, precision and lower cost compared to HPLC methods.
- They are used for analysis of dosage form without any preliminary separation step.

GRAPHICAL ABSTRACT

Three simple, specific, accurate and precise spectrophotometric methods manipulating ratio spectra were developed and validated for simultaneous determination of Irbesartan (IRB) and Hydrochlorothiazide (HCT) namely; ratio subtraction coupled with constant multiplication (RS-CM), ratio difference (RD) and constant center (CC).



ARTICLE INFO

Article history:
Received 27 January 2014
Received in revised form 14 April 2014
Accepted 22 April 2014
Available online 30 April 2014

Keywords:
Irbesartan
Hydrochlorothiazide
Ratio subtraction
Constant multiplication
Ratio difference and constant center

ABSTRACT

Three simple, accurate and precise spectrophotometric methods manipulating ratio spectra were developed and validated for simultaneous determination of Irbesartan (IRB) and Hydrochlorothiazide (HCT) without prior separation namely; ratio subtraction coupled with constant multiplication (RS-CM), ratio difference (RD) and constant center (CC). The accuracy, precision and linearity ranges of the proposed methods were determined, and the methods were validated and the specificity was assessed by analyzing synthetic mixtures containing the cited drugs. The three methods were applied for the determination of the cited drugs in tablets and the obtained results were statistically compared with each other and with those of official methods. The comparison showed that there is no significant difference between the proposed methods and the official methods regarding both accuracy and precision.

Introduction

Irbesartan (Fig. 1), an anti-hypertensive is chemically designated as 2-butyl-3-[[4-[2-(2H-tetrazol-5-yl)phenyl]phenyl]methyl]-1,3-diazaspiro[4.4]non-1-en-4-one. It is used for the treatment of hypertension [1] Different analytical methods have been reported for the determination of Irbesartan, which include HPLC [2–6], spectrophotometry [7–9].

Hydrochlorothiazide (Fig. 1(b)), 6-chloro-1,1-dioxo-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide [1]. Very few HPLC methods for the determination of Hydrochlorothiazide are

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http://dx.doi.org/10.1016/j.saa.2014.04.102
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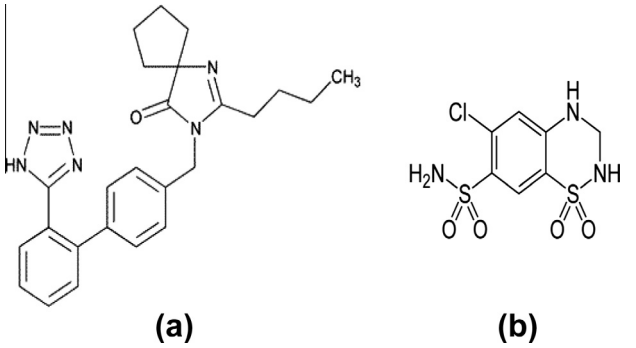

Fig. 1. Chemical structure of Irbesartan (a) and Hydrochlorothiazide (b).

reported in literature [10], spectrophotometry [11–16], electrochemistry [17].

Few methods were reported for the simultaneous determination of these components in their pharmaceutical formulations as HPLC [18–25] and spectrophotometry [18–29].

The aim of this work is to conduct a comparative study on three recently developed methods [(RS-CM), RD, CC] for the analysis of IRB and HCT in their binary mixtures. The developed methods based on utilizing of the constants of the ratio spectra which eliminate the spectral overlapping without prior separation. The new methods are very simple, accurate, precise and do not require any sophisticated apparatus or computer programs.

Theory

The theory of ratio subtraction coupled with constant multiplication method (RS-CM) [30,31], ratio difference spectrophotometric method (RD) [30,32], constant center method (CC) [31] have been published.

Experimental

Chemicals and reagents

- Pure samples were kindly donated by October Pharm, the percentage purity was found to be 100.28% and 99.83% for IRB and HCT, respectively according to the official method [1].
- Kansartan Plus tablets, Batch No. 120536A (150/12.5), 120537A (300/12.5) of IRB and HCT respectively, manufactured by CHEMIPHARM and were purchased from local market.
- Methanol E. Merck, Darmstadt, FRG. All other chemicals were of analytical grade.

Apparatus

Spectrophotometric measurements were carried out on Shimadzu1605 UVPC spectrophotometer, using 1.00 cm quartz cells. Scans were carried out in the range from 220 to 350 nm at 0.5 nm intervals.

Spectral characteristics

The absorption spectra of the two compounds were recorded over the range 220–350 nm, as shown in Fig. 2.

Solution and calibration

Stock standard solutions of IRB (1 mg/mL) and HCT (1 mg/mL) were prepared by dissolving the compounds in methanol then completing in 100 mL calibrated measuring flasks. Aliquots of the

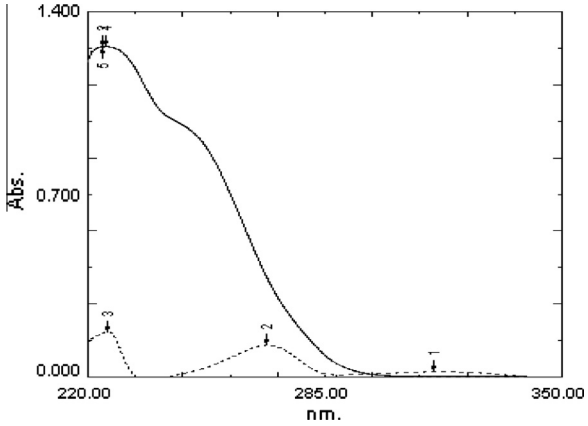

Fig. 2. Absorption spectra of 24 μg/mL Irbesartan (—) and 2 μg/mL Hydrochlorothiazide (· · ·).

prepared stock solutions were further diluted with methanol to get working solutions with final concentrations (100 μg/mL) of both.

Ratio subtraction method coupled with constant multiplication (RS-CM)

Working standard solutions containing 1–20 μg/mL HCT and 2–36 μg/mL IRB, were prepared separately in methanol. The absorption spectra of the prepared solutions were scanned and the absorbance was measured at 270 nm for HCT and 250 for IRB. Construct calibration curve relating the absorbance of the zero order spectra of HCT and IRB vs. the corresponding concentrations of them.

Ratio difference method (RD)

Working standard solutions containing 1–20 μg/mL HCT and 2–36 μg/mL IRB, were prepared separately in methanol. The absorption spectra of the prepared solutions were scanned (230–280 nm) and stored in the computer. The stored spectra were divided by the absorption spectra of 12 μg/mL IRB and 12 μg/mL HCT, respectively, where the obtained ratio spectra were recorded. Construct calibration curves for HCT and IRB by plotting the difference between the amplitudes of obtained ratio spectra at 250 nm and 260 nm, for both vs. the corresponding concentrations and the regression equations were computed.

Constant center method (CC)

Working standard solutions containing 1–20 μg/mL HCT and 2–36 μg/mL IRB, were prepared separately in methanol. The absorption spectra of the resulting solutions were measured and stored in the computer. Construct two calibration curves relating the absorbance of the zero order spectra of IRB at 250 nm versus the corresponding concentrations of IRB and HCT at 270 nm versus the corresponding concentrations of HCT, the regression equations were computed. The stored absorption spectra of IRB and HCT were divided by the absorption spectra of 12 μg/mL HCT and 12 μg/mL IRB, respectively, where the obtained ratio spectra were recorded. Construct calibration curve by plotting the difference between the amplitudes of the obtained ratio spectra at (250 nm and 260 nm) vs. the amplitudes at 250 nm for both HCT and IRB and the regression equations were computed.

Assay of laboratory prepared mixtures

Ratio subtraction method coupled with constant multiplication (RS-CM). Into a series of 10-mL volumetric flasks, transfer accurately aliquots equivalent to (20–360 μg) and (120 μg) of IRB and HCT respectively from their working solutions IRB (100 μg/mL) and