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Spectrophotometric methods manipulating ratio spectra for simultaneous determination of binary mixtures with sever overlapping spectra: A comparative study

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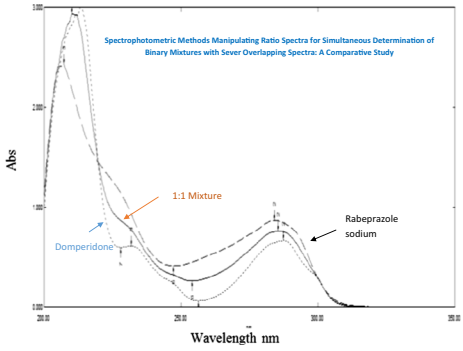
HIGHLIGHTS

- Smart and novel spectrophotometric methods were successively applied.
- They are used for simultaneous analysis of complex binary mixtures.
- Simple methods do not need a special program and could be easily applied in QC labs.
- Validated according to ICH guidelines and compared to the reported methods.

GRAPHICAL ABSTRACT



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ABSTRACT

Three simple, specific and accurate spectrophotometric methods manipulating ratio spectra were developed and validated for simultaneous determination of Rabeprazole sodium (RB) and Domperidone (DP) in their binary mixture without prior separation. Method A, is constant center spectrophotometric method (CC). Method B is a ratio difference spectrophotometric one (RD), while method C is a combined ratio isoabsorptive point-ratio difference method (RIRD). Linear correlations were obtained in range of 4–44 μg/mL for both Rabeprazole sodium and Domperidone. The mean percentage recoveries of RB were 99.69 ± 0.504 for method A, 99.83 ± 0.483 for (B) and 100.31 ± 0.499 for (C), respectively, and that of DP were 99.52 ± 0.474 for method A, 100.12 ± 0.505 for (B) and 100.16 ± 0.498 for (C), respectively. Specificity was investigated by analysis of laboratory prepared mixtures containing the cited drugs and their combined tablet dosage form. The obtained results were statistically compared with those obtained by the reported methods, showing no significant difference with respect to accuracy and precision. The three methods were validated as per ICH guidelines and can be applied for routine analysis in quality control laboratories.

Introduction

Rabeprazole sodium (RB) Fig. 1, is a proton pump inhibitor that is used in the treatment of sever gastro-oesophageal reflux disease, active peptic ulcers and Zollinger–Ellison syndrome [1,2]. It is a prodrug that requires activation in the acid environment [2]. While Domperidone (DP) Fig. 1, is a dopamine antagonist, used as an antiemetic for the short-term treatment of nausea and vomiting of various etiologies. It is also used for its prokinetic actions in dyspepsia [1,2]. RB and DP are co-formulated together in commercial tablets for abdominal disturbance.

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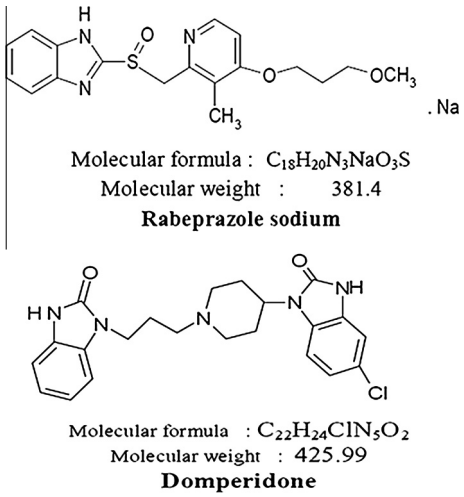

Fig. 1. Chemical structures of Rabeprazole sodium and Domperidone.

RB was determined by several methods including spectrophotometric [3–6] and spectroflourimetric methods [7,8]. TLC densitometric method [9], HPLC methods [10–12] and electrochemical methods [13,14] were also reported. While DP was determined by several methods involving spectrophotometric methods [15–18], TLC densitometric methods [19,20], HPLC methods [21–24] and electrochemical methods [25,26].

For the simultaneous determination of RB and DP spectrophotometric methods were reported using derivative technique, mean centering and dual wavelength method [27,28]. Also TLC and isocratic reversed phase HPLC methods were reported [29–32].

The aim of this work was to develop three recent, simple and precise methods to resolve the sever spectral overlap of RB and DP in their mixture and tablet dosage form, without preliminary separation by using smart formulae to cancel interferences. Consequently, conducted a comparative study between them to prove their effectiveness compared to the reported ones. The methods are very simple, accurate, precise and do not require any sophisticated apparatus or computer programs compared to the previously reported ones and of lower cost compared to chromatographic methods.

Experimental

Apparatus

Spectrophotometric measurements were carried out on Shimadzu 1605 UVPC spectrophotometer, using 1.00 cm quartz cells. Scans were carried out in the range from 220–350 nm at 0.5 nm intervals.

Reference samples

Rabeprazole sodium (RB)

Pure sample was kindly supplied by Global Nabi Co., batch number 90330; (Giza – Egypt). Its percentages purity was 100.26 ± 0.461% according to the reported method [3].

Domperidone (DP)

Pure sample was kindly supplied by Minapharm Co., batch number ZR03361PU1971; (10th of Ramadan – Egypt). Its percentage purity was 99.75 ± 0.462% according to the reported method [24].

Pharmaceutical formulations

Rabesym-D 20/10 tablets-Batch number C6960016. Each tablet is claimed to contain 20 mg of RB and 10 mg of DP. Manufactured by: Symbiosis pharmaceuticals, Pvt. Ltd. (India).

Standard solutions

RB stock standard solution: (0.2 mg/mL) in methanol for the three methods.

DP stock standard solution: (0.2 mg/mL) in methanol for the three methods.

Laboratory prepared mixtures containing different ratios of RB and DP

Into a series of 25-mL volumetric flasks, aliquots of RB and DP were transferred from their corresponding stock solutions (0.2 mg/mL) each, and then the volume was completed with methanol. That prepares mixtures containing different ratios of the two drugs.

Procedures

Spectral characteristics of RB and DP

The zero order absorption spectra of 24 μg/mL RB, 24 μg/mL DP and a (1:1) mixture containing 12 μg/mL of each RB and DP in methanol were recorded over the range 200–350 nm, as can be seen in Fig. 2.

Construction of calibration curves

Aliquots (0.5, 1.5,...,5.5 mL) from RB and DP stock solutions (0.2 mg/mL each) in methanol were accurately transferred into a series of 25-mL volumetric flasks and the volume was completed to the mark with methanol and the spectra were recorded.

For Constant center spectrophotometric method (CC)

Two calibration curves are constructed relating the absorbance of the zero order spectra of RB at 285 nm versus the corresponding concentrations of RB and DP at 288 nm versus the corresponding concentrations of DP, the regression equations were computed. The stored absorption spectra of RB and DP were divided by the absorption spectra of 8 μg/mL and 36 μg/mL DP, where the obtained ratio spectra were recorded. Construct calibration curves by plotting the difference between the amplitudes of the obtained spectra at [256.5 nm and 295 nm] and [284 nm and 289 nm], versus amplitudes at 256.5 nm and 289 nm for RB and DP respectively and the regression equations were computed.

For ratio difference spectrophotometric method (RD)

The stored spectra of RB are divided by the spectrum of 28 μg/mL DP, While DP spectra are divided by the spectrum of 8 μg/mL RB. Calibration curves are constructed by plotting the difference between amplitudes of the ratio spectra at 260 and 295 nm for RB

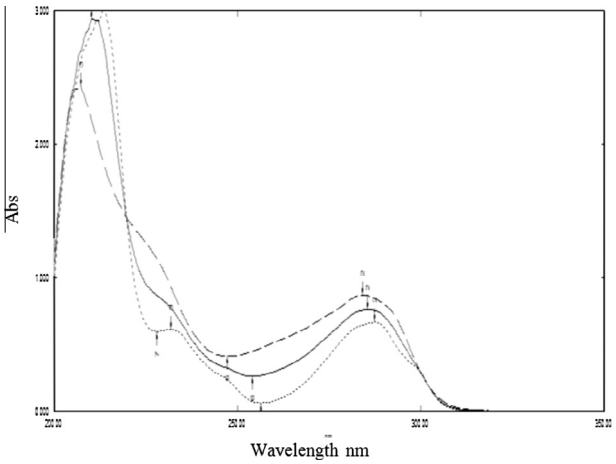

Fig. 2. Zero-order absorption spectra of 24 μg/mL of RB (----), 24 μg/mL of DP (...) and a (1:1) mixture containing 12 μg/mL of each (—) in methanol.