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Simultaneous determination of a binary mixture of pantoprazole sodium and itopride hydrochloride by four spectrophotometric methods

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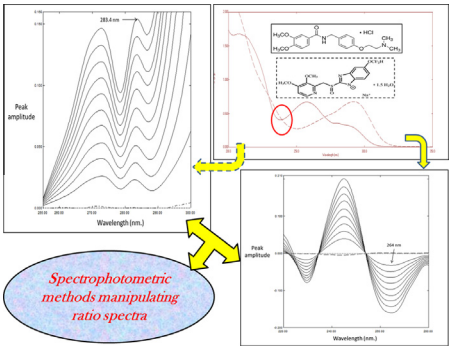
HIGHLIGHTS

- We applied new spectrophotometric methods for determination of the studied mixture.
- Green, safe, economic, highly accurate and reproducible methods.
- The novel ratio difference and isoabsorptive point revealed higher selectivity.

GRAPHICAL ABSTRACT



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ABSTRACT

Four simple, sensitive, accurate and precise spectrophotometric methods were developed for the simultaneous determination of a binary mixture containing Pantoprazole Sodium Sesquihydrate (PAN) and Itopride Hydrochloride (ITH). Method (A) is the derivative ratio method (^{1}DD), method (B) is the mean centering of ratio spectra method (MCR), method (C) is the ratio difference method (RD) and method (D) is the isoabsorptive point coupled with third derivative method (^{3}D). Linear correlation was obtained in range 8–44 μg/mL for PAN by the four proposed methods, 8–40 μg/mL for ITH by methods A, B and C and 10–40 μg/mL for ITH by method D. The suggested methods were validated according to ICH guidelines. The obtained results were statistically compared with those obtained by the official and a reported method for PAN and ITH, respectively, showing no significant difference with respect to accuracy and precision.

Introduction

Pantoprazole Sodium Sesquihydrate (PAN) (Fig. 1a) is classified as one of the proton pump inhibitors. It inhibits secretion of gastric acid by irreversibility blocking the enzyme system of hydrogen/potassium adenosine tri-phosphatase (H^+/K^+ ATPase), the 'proton pump' of the gastric parietal cell. It is used in aspiration syndromes, dyspepsia, gartro-oesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison syndrome [1]. Itopride Hydrochloride (ITH) (Fig. 1b) is a substituted benzamide which possesses parasympathomimetic activity as well as dopamine-receptor antagonist with anticholinesterase activity. It has been used for its prokinetic and antiemetic properties. It stimulates the motility of the upper gastrointestinal tract without affecting gastric, biliary, or pancreatic secretion and increases gastric peristalsis, leading to accelerated gastric emptying. Thus it is used in disorders of decreased gastrointestinal motility such as gastroparesis or ileus; in gastro-oesophageal reflux disease and dyspepsia; and in nausea and vomiting associated with various gastrointestinal disorders. It

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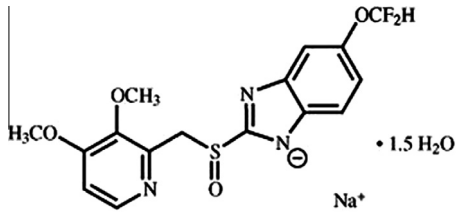
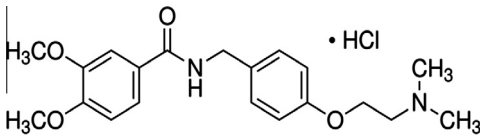


(a)

Fig. 1a. Chemical structure of pantoprazole sodium sesquihydrate, $C_{16}H_{14}F_2N_3NaO_4S.1½H_2O$, molecular Weight = 432.4 [30].



(b)

Fig. 1b. Chemical structure of itopride HCl, $C_{20}H_{26}N_2O_4$.HCl, molecular weight = 394.9 [31].

may be used to stimulate gastric emptying during radiographic examinations and in the management of aspiration syndromes [2]. Therefore both PAN and ITH are co-formulated together for the treatment of gastric hypersecretory conditions and associated gastrointestinal disorders. Several analytical methods have been developed for the determination of PAN in pharmaceutical preparations such as spectrophotometric methods [3–6], HPLC methods [7–10], HPTLC-densitometric methods [11,12] and liquid chromatographic-tandem mass methods (LC–MS/MS) [13,14]. Also several methods have been reported for the determination of ITH in pharmaceutical preparations such as spectrophotometric methods [15–17], HPLC methods [18–20], HPTLC-densitometric methods [21,22] and spectroflourimetric methods [23]. Simultaneous determination of PAN and ITH has been achieved by different spectrophotometric methods [24–26], HPLC methods [27,28], HPTLC-densitometric methods [29], spectroflourimetric methods [23]. The proposed methods aim to develop simple, accurate, precise and time saving methods manipulating the advantages of green chemistry for the routine analysis of PAN and ITH in their pharmaceutical formulations with no need for prior separation.

Experimental

Apparatus

- SHIMADZU dual beam UV–visible spectrophotometer, model 1601 PC connected to an IBM compatible personal computer (PC) and HP-600 inject printer. The bundled software, UV-PC personal spectroscopy software version (3.7). The spectral band width was 0.2 nm with wavelength scanning speed of 2800 nm/min., (Shimadzu, Kyoto, Japan).
- Matlab® version 7, release 14.

Pure samples

Pure sample of Pantoprazole Sodium Sesquihydrate (PAN) was supplied by National Organization for Drug Control and Research (NODCAR), Giza, Egypt. Itopride Hydrochloride (ITH) pure sample was supplied by Eva pharma, Cairo, Egypt. Their purity were checked and found to be 100.66 ± 0.626 for PAN according to the British pharmacopoeia official method [30] which is a non-aqueous potentiometric titration method. ITH purity was found to be 99.87 ± 0.852 according to the reported method [16] which is a direct zero order spectrophotometric method.

Pharmaceutical formulation

Pantocid IT® capsules, batch number BSL0053, manufactured by Sunpharma Sikkim, Mumbai, India. Each capsule is claimed to contain 40 mg of PAN and 150 mg of ITH. It was purchased from India.

Standard solutions

- PAN stock standard solution (1 mg/mL) in double distilled water.
- PAN working standard solution (0.1 mg/mL) in double distilled water.
- ITH stock standard solution (1 mg/mL) in double distilled water.
- ITH working standard solution (0.1 mg/mL) in double distilled water.

Laboratory prepared mixtures containing different ratios of PAN and ITH

Into a series of 10-mL volumetric flasks, aliquots of PAN and ITH were transferred from their corresponding working solutions and then the volumes were completed to the mark with double distilled water in order to prepare mixtures containing different ratios of the two drugs including the ratio available in the pharmaceutical formulation.

Procedures

Spectral characteristics of PAN and ITH

The zero-order (^{0}D) absorption spectra of PAN and ITH (8 and 30 μg/mL) respectively were scanned against double distilled water as a blank and then recorded over the range of 200–400 nm.

Construction of calibration curves

Accurately measured aliquots (0.8, 1.2, 1.6 … 4.4 mL) of PAN working standard solution (0.1 mg/mL) and accurately measured aliquots (0.8, 1.2, 1.6 … 4.0 mL) of ITH working standard solution (0.1 mg/mL) were transferred into two separate series of 10-mL volumetric flasks and the volumes were completed to the mark with double distilled water. For determination of ITH in method D by third derivative spectrophotometric method, aliquots used were (1.0, 1.2, 1.6 … 4.0 mL). The U.V. absorption spectra of the prepared solutions were recorded from 200 to 400 nm, and stored in the computer.

Method A; Derivative ratio method (^{1}DD). For the determination of PAN, the stored absorption spectra of PAN were divided by the spectrum of 24 μg/mL of ITH, and the ratio spectra were obtained. Then the first derivative of the obtained ratio spectra (^{1}DD) was obtained with $\Delta\lambda = 4$ and scaling factor = 1. The amplitudes of the first derivative peaks were measured at 283.4 nm.

For the determination of ITH, the stored absorption spectra of ITH were divided by the spectrum of 24 μg/mL of PAN, and the ratio spectra were obtained. Then the first derivative of the obtained ratio spectra (^{1}DD) was obtained with $\Delta\lambda = 4$ and scaling factor = 1. The amplitudes of the first derivative peaks were measured at 264.0 nm.

Linear relationships relating the peak amplitudes at 283.4 and 264.0 nm to the corresponding concentrations of PAN and ITH