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Optimized and validated spectrophotometric determination of two antifungal drugs in pharmaceutical formulations using an ion-pair complexation reaction

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Abstract

Simple, rapid, cost-effective, sensitive and extractive spectrophotometric methods were developed for the determination of two antifungal drugs (i.e., sertaconazole nitrate (SER) and miconazole nitrate (MCO)) in pure and dosage forms. The methods are based on the formation of ion-pair complexes between the drugs and acid dyes (i.e., bromocresol purple (BCP), bromophenol blue (BPB) and methyl orange (MO)) in acidic buffer solutions. The formed complexes were extracted with chloroform and measured at 410, 416 and 427 nm for SER and at 408, 415 and 426 nm for MCO using BCP, BPB and MO, respectively. The analytical parameters and their effects on the reported systems were investigated. Beer's law was obeyed in the 1.0–20 and 1.0–24 $\mu g\,mL^{-1}$ ranges for SER and MCO, respectively. The composition of the ion pairs was determined to be 1:1. The molar absorptivity, Sandell sensitivity, limits of detection and limits of quantification were calculated. Other method validation parameters, such as precision, accuracy, robustness, ruggedness and selectivity, were satisfactory. The proposed methods have been successfully applied for the analysis of the studied drugs in their pure and dosage forms. Statistical comparison of the results with the reference methods indicated excellent agreement and no significant difference in accuracy and precision.

Keywords: Sertaconazole; Miconazole; Spectrophotometry; Ion pair complex; Acid dyes; Pharmaceutical formulations

1. Introduction

Imidazole drugs are a group of antifungal drugs that have broad-spectrum antifungal activities against a wide range of fungi that cause various mycotic infections [1]. The members of this group are structurally related and have similar physicochemical properties and mechanisms of action. The members of the imidazole group are miconazole (base or nitrate salt) and sertaconazole (base or nitrate salt) [1]. Although there are a number of imidazole drugs currently available, their efficacy may not be completely achieved for

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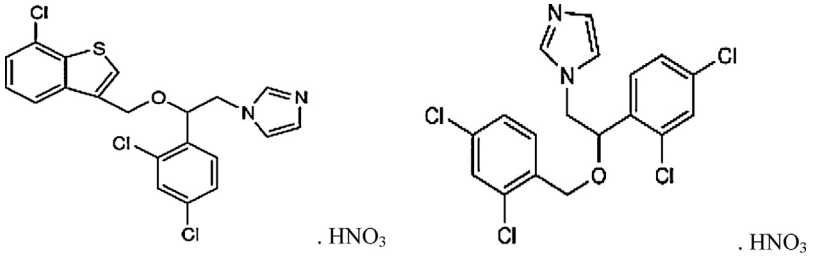

Sertaconazole nitrate (SER) Miconazole nitrate (MCO)

Fig. 1. Chemical structure of the studied antifungal drugs.

the treatment of human mycoses due to their poor water solubility and limited dissolution properties that are associated with slow drug absorption, leading to inadequate and variable bioavailability [1,2]. The chemical structures of the studied imidazoles antifungal drugs (i.e., sertaconazole (SER); (±)-1-{2,4-dichloro-β-[(7-chlorobenzo[*b*] thien-3-yl)methoxy] phenethyl}imidazole nitrate and miconazole (MCO), 1-[2,4-dichloro-β-(2,4-dichlorobenzyloxy) phenethyl] imidazole nitrate) are shown in Fig. 1.

A survey of the literature revealed that several analytical methods have been reported for the determination of the studied drugs in the pure drug form, pharmaceutical dosage forms and biological samples using liquid chromatography, either in single or combined form [3–18], capillary zone electrophoresis methods [19], electrochemical methods [20], non-aqueous titration [2], spectrofluorimetric methods [16,21] and spectrophotometric methods [21–32].

Visible spectrophotometry has remained competitive in the area of chromatographic techniques for pharmaceutical analysis due to its simplicity and cost effectiveness, sensitivity and selectivity, fair accuracy, precision and available in most quality control laboratories. In addition, this method does not require the costly instrumentation that is required for the published HPLC methods.

Extractive spectrophotometric procedures are popular due to their sensitivity in the assay of drugs, and therefore, ion-pair extractive spectrophotometry has received considerable attention for the quantitative determination of many pharmaceutical compounds [33–40].

In the current study, the development of accurate, reproducible, simple, precise, sensitive and economical extractive spectrophotometric method for the determination of both antifungal drugs (SER and MCO) in their pure and dosage forms was investigated based on the formation of chloroform soluble ion–associate complexes between the studied drugs and acid dyes (BCP, BPB or MO).

2. Experimental

2.1. Apparatus

All of the absorption spectra were recorded on a Kontron Unikon 930 (UV–vis) spectrophotometer (Germany) equipped with 10 mm matched quartz cells at a scanning speed of 200 nm/min and a band width of 2.0 nm. The pH values of the various buffer solutions were confirmed using a Hanna pH-metre instrument (pH 211) (Romania) equipped with a combined glass calomel electrode.

2.2. Materials and reagents

All of the chemicals and reagents were of analytical grade and used without further purification. In addition, all of the solutions were prepared fresh daily, and the water was doubly distilled.

2.2.1. Materials

Pure grade sertaconazole nitrate (SER) was provided by October Pharma Drug Company, Egypt, and the miconazol nitrate (MCO) working standard was supplied by Amriya Pharmaceutical Industries Co., Egypt.

2.2.2. Pharmaceutical formulations

All of the pharmaceutical preparations were obtained from commercial sources in the local markets (i.e., Dermofix cream labelled to contain 2.0 mg SER/g (October Pharma. Co., Egypt, Ferrer International, SA, Spain), Miconaz cream labelled to contain 2.0% MCO/15 g (Medical Union Pharmaceuticals, Abu-Sultan, Ismailia, Egypt), Micoban cream labelled to contain 2.0% MCO/15 g (Amriya Pharmaceutical Industries Co., Egypt)).

2.2.3. Preparation of stock standard solutions

Stock standard solutions with concentrations of 100 μg mL^{-1} and 1.0×10^{-3} mol L^{-1} of SER or MCO,