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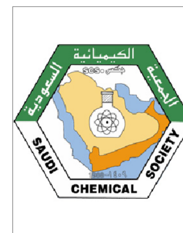

ORIGINAL ARTICLE

New spectrophotometric method for determination of cephalosporins in pharmaceutical formulations

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Abstract A simple, accurate, and precise spectrophotometric method has been proposed for the determination of three cephalosporins, namely: cefixime (cefi), cephalexine, (ceph) and cefotaxime (cefo) in pharmaceutical formulations. Proposed method is based on the derivatization of cephalosporins with 1,2-naphthoquinone-4-sulfonic (NQS). The optimum experimental conditions have been studied. Beer's law is obeyed over the concentration of 0.5–3, 0.8–2.8, and 0.2–1.2 μg/mL for cefi, ceph, and cefo, respectively.

The detection limits were 0.12, 0.168, and 0.0465 μg/mL for cefi, ceph, and cefo, respectively, with a linear regression correlation coefficient of 0.9993, 0.9993, and 0.9994 and recovery in range from 96.5–102.3, 96.04–102.22, and 97.09–99.3 for cefi, ceph, and cefo, respectively. Effects of pH, temperature, reaction time, and NQS concentration on the determination of cefi, ceph, and cefo, have been examined. This method is simple and can be applied for the determination of cefi, ceph, and cefo in pharmaceutical formulations in quality control laboratories.

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1. Introduction

Cephalosporin antibacterials are commonly used to control Gram positive and Gram negative bacterial infections. Cephalosporins are the second most important β-lactams after penicillin for treating infectious diseases (Adkinson and Weiss, 1988). Many of these manifestations, such as urticaria and exanthema, are cutaneous, but anaphylactic reactions have also been reported (Pumphrey and Davis, 1999).

Cephalosporins are derivatives of 7-aminocephalosporanic acid (7-ACA) composed of a β-lactam ring fused with a dihydrothaizine ring (Fig. 1), but differ in the nature of substituent at the 3- and/or 7-positions of the cephem ring (Delgad and Wilson, 2004; Dollery,1999).

Several methods have been described for the quantitative determination of cephalosporins included spectrophotometry (Ayad et al.,1999; Saleh et al., 2001, 2003), spectrofluorimetry (Aly et al.,1996), high performance liquid chromatography (Baranowska et al., 2006; Chen et al., 2003; De Diego Glaria et al., 2005; Misztal, 1998; Moore et al.,1991; Sørensen and

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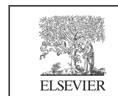

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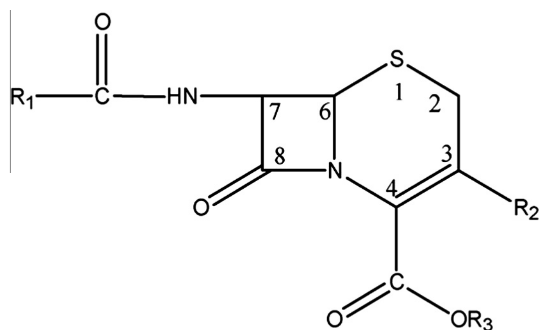

Figure 1 Cephalosporin.

Snor, 2000; Tsai and Chen, 2000), potentiometry, (Lima et al., 1998) and voltammetry (Özkan et al., 2000). These methods were time-consuming, tedious, and dedicated to sophisticated and expensive analytical instruments. Spectrophotometric methods are the most convenient techniques because of their inherent simplicity, high sensitivity, low cost, and wide availability in quality control laboratories. Unfortunately, the spectrophotometric methods that have been reported for the determination of cephalosporins in their pharmaceutical formulations were associated with some major disadvantages, such as lack of selectivity, tedious extraction procedures, and time-consumption. The official procedures in pharmaceutical preparations utilize high performance liquid chromatography (HPLC) (United States Pharmacopoeia, 2008; United States Pharmacopoeia, 2008).Therefore, the development of new alternative spectrophotometric methods for the determination of cephalosporins that can overcome the disadvantages of the existing methods is essential.

(NQS) has been used for the determination of many compounds. It is a popular spectrophotometric reagent due to its efficient reactivity with both primary and secondary amines, and high reaction rate (Darwish, 2005; Darwish et al., 2009; El-Walily et al., 2000; Hasani et al., 2007; Li and Zhang, 2008; Li and Yang, 2007; Wang et al., 2004). NQS proved to be a useful and sensitive analytical derivatizing agent for spectrophotometric analysis of pharmaceuticals bearing a primary or secondary amino group, however the use of (NQS) for spectrophotometric determination of cephalosporins was not reported. Therefore in this work a rapid spectrophotometric method for determining the content of cefi, ceph, and cefo in pharmaceutical formulations which is based on the reaction of NQS with amino group of cefi, ceph, and cefo molecules to form orange compounds, at 521, 455, and 493 nm for cefi, ceph and cefo, respectively. The chemical structure for the cephalosporins used in this study is shown in Table 1.

2. Experimental

2.1. Apparatus

All of the spectrophotometric measurements were made with a Double beam UV1800 ultraviolet–visible spectrophotometer provided with matched 1-cm quartz cells (SHIMADZU Japan) also temperature controller was used for the spectrophotometer measurements. pH meter model pH 211 (HANNA Italy) was used for adjusting pH.

2.2. Reagents and solutions

All reagents were of analytical reagent grade. Double distilled water was used in all experiments.

2.2.1. Pharmaceutical formulation

The following available pharmaceutical preparations were analyzed:

(1) Cefi capsules (AMIPHARMA laboratories, Sudan), labeled to contain 200 mg cefi per capsule.
(2) Ceph monohydrate capsules (AMIPHARMA laboratories, Sudan), labeled to contain 500 mg ceph per capsule.
(3) Cefo for injection (KILITCH drugs, India) labeled to contain 1000 mg cefo per injection.

2.2.2. Stock standard solution of cefi, ceph and cefo (1000 μg/mL)

An accurately weighed 0.1 g standard sample of the three drugs was dissolved in methanol for cefi and in double distilled water for ceph and cefo, transferred into a 100 mL standard flask and diluted to the mark with methanol for cefi and with double distilled water for ceph and cefo and mixed well. This stock solution was further diluted to obtain working solutions in the ranges of 0.5–3, 0.8–2.8, and 0.2–1.2 μg/mL for cefi, ceph, and cefo, respectively.

2.2.3. Sodium 1,2-naphthoquinone-4-sulfonic solution (0.4%, 0.5% w/v)

An accurately weighed 0.4 g and 0.5 g of NQS was dissolved in double distilled water, transferred into a 100 ml standard flask and diluted to the mark with double distilled water and mixed well to prepare (0.4%, 0.5% w/v), respectively. The solution was freshly prepared and protected from light during use.

2.2.4. Buffer solutions

Buffer solution of pH 12.0 was prepared by mixing 25 mL of 0.2 M KCl with 12 mL of 0.2 M NaOH, and buffer of pH 13.0 was prepared by mixing 25 mL of 0.20 M KCl solution with 65 mL of 0.20 M NaOH solution, in 100 mL volumetric flask and adjusted by a pH meter. Buffer solutions of different pH value were also prepared according to literature method.

2.2.5. Sample solutions

The contents of 20 capsules or the contents of 20 injection powder were evacuated and well mixed. Then an accurately weighed amount equivalent to 100 mg was transferred into a 100 mL calibrated flask, and dissolved in about 40 mL in methanol for cefi and in double distilled water for ceph and cefo. The contents of the flask were swirled, sonicated for 5 min, and then completed to volume with methanol for cefi and with double water for ceph and cefo. The contents were mixed well and filtered rejecting the first portion of the filtrate. The prepared solution was diluted quantitatively with methanol for cefi and with double distilled water for ceph and cefo to obtain a suitable concentration for the analysis.

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