ORIGINAL ARTICLE

Quantitative analysis of two penicillins in oral dosage form using modern high-performance liquid chromatography method

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Abstract

Context: An accurate and sensitive high-performance liquid chromatography-ultraviolet (HPLC-UV) assay method was developed for the determination of two penicillins in oral dosage form to compare the amount of active ingredients of cloxacillin (drugs1) and flucloxacillin (drug 2). **Objective:** The objective of the study was to develop a simple, sensitive, accurate, and kinetic spectroscopic method for the measurement of two penicillins in the form of oxacillin sodium monohydrate in oral dosage pharmaceutical product. **Materials and Methods:** Monohydrate capsules (500 mg) were purchased from two different commercial companies and oxacillin sodium monohydrate analar was used as a test formulations. Oxacillin sodium monohydrate concentrations were analyzed by HPLC-UV system at λ = 230 nm. The separation was achieved using the Ion Pac zorbax 300-SCX Agilent Column, 5 µm, 4.6 × 250 mm. The mobile phase consisted of water:acetonitrile:methanol (40:30:30), all with 10 mM formic acid at pH = 4.8. The comparison study for the two pencillin formulations was assessed by calculating the peak height. The standard oxacillin sodium monohydrate and other pencillins were eluted at a flow rate of 1.0 ml/min. **Results:** The recoveries were ranged within 91.0–100% and the linearity were ranged (0.3–1.5) µg/ml, (n=5) with $R^2 \geq 0.9992$ while the relative standard deviation were (RSD) ± 0.492–0.583 at room temperature 25°C. The detection lower limit of quantification was 4.44 µg/ml and lower limit of detection was 1.46 µg/ml. **Conclusion:** The proposed method was successfully applied to the determination of the drug in the pharmaceutical products and the validation of the statistical data. The results were compared to the reference method, and they showed good compatibility. There was no significant difference between the values detected by the new method and the classical method.

Key words: Penicillin, oxacillin, cloxacillin, flucloxacillin, quantitative analysis

INTRODUCTION

An isocratic liquid chromatographic method with ultraviolet (UV) detection at 230 nm is described for the determination of oxacillin sodium monohydrate injection. Chromatographic separation of two drugs was achieved on the reversed-phase column Agilent Zorbax-SCX-C18 (5 µm, 250 mm × 4.6 mm). The developed liquid chromatographic method offers a symmetric peak shape.[1-4]

Oxacillin $C_{19}H_{18}N_3NaO_5S$ [(sodium;(2S,5R, 6R)-3,3-dimethyl-6-[(5-methyl-3-phenyl-1,2-oxazole-4-carbonyl)amino]-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate] [Figure 1] is the chemical structure of oxacillin, which is an antibiotic widely used to treat diseases in humans. In this paper, a solid-phase extraction method with a high-performance liquid chromatography (HPLC-UV) is shown for the determination of oxacillin. The reversed-phase column "Agilent Zorbax-SCX-C18 (5 µm, 250 mm × 4.6 mm)" was used in the method. The performance of the solid-phase extraction procedure on trace residues is quantitatively evaluated by HPLC-UV.[5-7]

ß-lactam antibiotics represent some of the most important antibacterial agents used in humans. However, serious

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