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RESEARCH ARTICLE

DEVELOPMENT AND VALIDATION OF NEW RP-HPLC METHOD FOR DETERMINATION OF ACETYL SULFISOXAZOLE IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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A simple and precise RP-HPLC method was developed and validated for the determination of acetyl sulfisoxazole in blood samples. Chromatography was carried out using methanol:acetonitrile:0.01M potassium dihydrogen phosphate (25:50:25 *v/v*) as the mobile phase at a flow rate 1.2 ml/min. The analyte was monitored by using PDA detector at 260 nm. The Run time was 8 min for acetyl sulfisoxazole. The proposed method was found to have linearity in the concentration range of 2-10 μg/ml.

Key words: Acetyl sulfisoxazole, Methanol, Acetonitrile, Potassium dihydrogen phosphate.

INTRODUCTION

Sulfonamides derived from sulfanilamide (*p*-aminobenzenesulfonamide) are commonly referred to as sulfa drugs. Acetyl sulfisoxazole (O'Neil *et al* 2001), chemically named as *N*-[(4-Aminophenyl)sulfonyl]-N-(3,4-dimethyl-5-isoxazolyl)acetamide (**Figure 1**), is slightly soluble in alcohol and insoluble in water. Its melting point is 125-130°C, the molecular formula is $C_{13}H_{15}N_3O_4S$ and the molecular weight is 309.35.

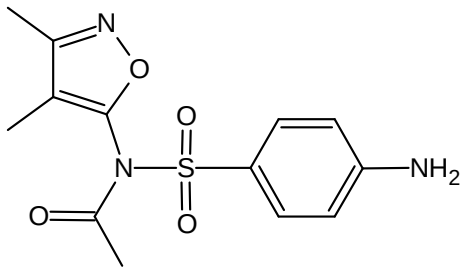

Figure 1. Structure of Acetyl sulfisoxazole

Sulfonamides are not readily biodegradable and have been detected in surface water and in secondary waste water effluents (Sharma *et al* 2006; Franek *et al* 2006; Berner and Dinh, 1992; Chien, 1988; 1989; Scott and Hollenbeck, 1991; Husson *et al* 1991; Swarbrick and Boylan, 1988; Muxlow *et al* 2001; El-Basil *et al* 1969). Most of the sulphonamides are prepared adopting Ullmann's method (Foye *et al* 2008). Literature is enriched with reports of reverse phase high performance liquid chromatographic assay to quantitated N^1-acetyl sulfisoxazole and the related manufacturing impurities such as sulfisoxazole, N^4-acetyl sulfisoxazole and N^1,N^4-diacetyl sulfisoxazole (Elrod Jr and Luka, 1982). The HPLC separations are achieved using a micro particulate octadecylsilane column with a ternary aqueous acetic acid:acetonitrile: methanol as mobile phase. Sulfonamides and erythromycin ethylsuccinate in combination in form of oral suspensions were determined using high-performance liquid chromatography and automated turbidimetry (Elrod Jr *et al* 1982).

A spectrophotometric method, involving the formation of ferric acetohydroxamate, was