High-Performance Liquid Chromatographic Method for the Analysis of Fluconazole in Pharmaceutical Preparations

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ABSTRACT

High-performance liquid chromatographic method was developed for the analysis of fluconazole in pharmaceutical preparations. The analyzed drug was separated on a reversed-phase column [Hypersil ODS column (120 x 46 mm, 5 μm particle size)], using a mobile phase containing methanol : 10 mM pH 7.0 phosphate buffer (50:50) with UV detection at 260 nm. The proposed method is specific, sensitive, reproducible and reliable. It can be successfully applied as a stability-indicating method for the determination of fluconazole in pharmaceutical preparations. With a run time of less than 2 minutes, the method is rapid and easy to use for routine analysis of fluconazole in pure form and dosage form as well as for its dissolution testing.

Key words: Fluconazole, HPLC, Pharmaceutical preparations, Dissolution

INTRODUCTION

Fluconazole[α-(2-4-difluorophenyl]-α-[1H-1,2,4-triazole-1-ylmethyl-1H-1,2,4-triazole-1-ethanol] is a synthetic triazole antifungal drug (Fig.1) (Budavaris, 2001). It is available as tablets, capsules, oral suspension and injection for treatment of oral, esophageal and vaginal candidiasis (Kalant and Walter, 1998 ; Bennett, 2001).

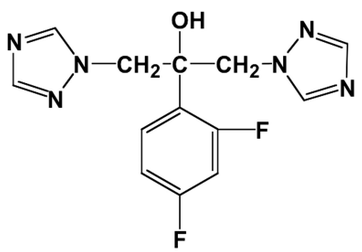

Figure 1. Chemical structure of flueonazole.

Literature reviews showed that various methods had been used to determine the fluconazole content in formulations. Those methods were high-performance liquid chromatography (Guo and Wen, 2000; Abdel-Moety et al., 2002), gas liquid chromatography (Harris et al., 1989) and spectrophotometry (El-Bayoumi et al., 1997; Kelani and Bebawy,1997). At