

UV Spectrophotometric Assay Method for the Determination of Fluconazole Capsules

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Abstract

A very simple, accurate, rapid and economical UV spectrophotometric method was developed for the estimation of fluconazole. The UV method permits a simple, rapid and economical quantitation of fluconazole in capsule dosage form only. The maximum absorbance of fluconazole was found to be 210 nm. Fluconazole, which is available in Karachi in different brands within the pharmacies, was collected and used for this assay method. The results showed that the assay results of the two brands were in range. This study would turn out to be very beneficial and with this simple and accurate method, one can easily determine fluconazole.

Keywords

Fluconazole, Spectrophotometer, Assay

Subject Areas: Pharmacology, Public Health

1. Introduction

Fluconazole (FLK) is chemically known as [2-(2,4,-difluorophenyl)-1,3-bis(1H1,2,4,-triazol-1-yl)propan-2-ol] [1]. FLK is an official drug in United States Pharmacopeia [2], European Pharmacopeia [3] and British Pharmacopeia [4]. It is a synthetic bis-triazole derivative broad-spectrum antifungal drug and has been shown to be effective against a wide range of superficial fungal infections and systemic fungal infections, following both oral and intravenous administration [5]. It is recommended for the treatment of oropharyngeal, esophageal, or vulvovaginal candidiasis and prophylaxis treatment of disseminated and deep organ candidiasis [6]. Yeast infections have been prevented in patients who are likely to become infected, because these patients are being treated with chemotherapy or radiation therapy by this drug before a bone marrow transplant [7] [8]. FLK is a highly selective inhibitor of fungal cytochrome P450 sterol C-14 (x-demethylation). Hence, this drug performs its action by inhibiting the synthesis of ergosterol, therefore blocking the cell membrane formation [9] (Figure 1).

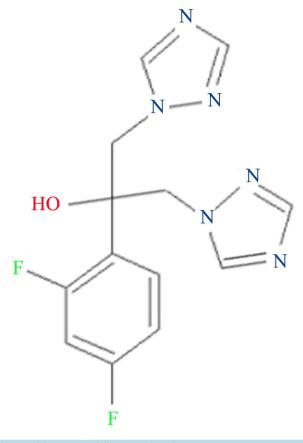


Figure 1. Structure of fluconazole [10].

The literature survey revealed the availability of many techniques for the determination of FLK by assay methods in pharmaceuticals. Quantification of FLK both alone as well as in combined formulations has been achieved by high-performance liquid chromatography (HPLC) [11]. UV-Visible-Spectrophotometry [12] and High Performance Thin Layer Chromatography (HPTLC) [13] are also reported for the quantification of FLK in formulations. A number of ultra performance liquid chromatographic methods have also been reported for the assay of FLK in mixed pharmaceuticals [14]. In recent years, there has been an increasing tendency observed towards development of stability-indicating assays [15] [16].

In 2014, Singh *et al.* [17] developed and validated new HPLC-methods for the determination of FLK. Also Sadasivudu *et al.* [18] in 2009 and Zhang *et al.* [19] in 2008 developed the HPLC methods for FLK estimation. In 2012, Alizadeh *et al.* [20] developed a rapid and simple spectrophotometric method to determine the concentration of FLK, Ketoconazole and Clotrimazole. Also Singh *et al.* [21] in 2011 developed and validated a sensitive and accurate UV-spectrophotometric method for the estimation of FLK in raw material and in tablets.

Spectrophotometric technique is based on measuring the absorption of a monochromatic light in the near ultraviolet region (200-380 nm). The aim of the study is to develop a simple, rapid, precise and economical UV spectrophotometric method for the determination of FLK in capsule dosage form.

2. Materials and Methods [22]-[25]

2.1. Instruments

For the measurement of Absorbance, Spectrophotometer (Schimadzu UV-1800 Spectrophotometer) was used and for the weighing of this method Digital Balance was used. Sonicator was also used in this assay method. For weighing, analytical balance was also used for this and an ultrasonic bath (Ultrasonic LC60H Elma Japan) was used as well.

2.2. Reagents and Chemicals

All chemicals were used as Analytical Grade and FLK's brands sample were searched from different pharmacies for the usage. De-ionized water was used throughout the investigation.

2.3. Preparation of Fluconazole Solution of Different Brands

Separately weigh each capsule of the two brands of FLK. Take out the powdered material by removing cap of the capsules. Accurately weighed powder equivalent to 20 mg of FLK in a tare beaker for each brand *i.e.* FLK -01 and FLK -02 and was sonicated for 20 min in an ultrasonic bath for the complete dissolution of the FLK, the content was then diluted to the mark with the de-ionized water, mixed well and filtered using a 0.22 μ m ny-lon membrane filter paper. Then these solutions were transferred into four different 100 ml volumetric flasks. Finally make-up the volume with de-ionized water to 100 ml for each sample. This stock solution is used to make further dilutions of individual brands in concentration of about 50, 25, 12.5 and 6.25. All these solutions are then determined for their absorbance by using UV-Visible spectrophotometer, the absorbance of solutions of each brand of FLK was determined at wavelength max of 210 nm using blank as de-ionized water. The absorbance of the two brands are given in Table 1 and Table 2.

3. Results and Discussions

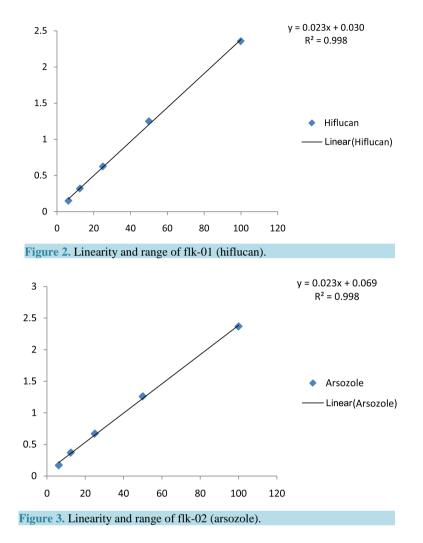
The UV method permits a simple, rapid and economical quantitation of fluconazole in capsule dosage form only. The λ max was found to be 210 nm. A very simple and economical method was developed to find the estimation of FLK which was carried out by using spectrophotometer on the two different brands of fluconazole available in Karachi pharmacies. Five different dilutions of the two brands were prepared (100 ppm, 50 ppm, 25 ppm, 12.5 ppm and 6.25 ppm) and their absorbance is shown in **Table 1** and **Table 2**. The results of % assay were found in range; the results of their percent assay are shown in **Table 3**, and regression equation and regression line are obtained. For the detection of linearity, absorbance of these prepared different solutions of 100 ppm, 50 ppm, 25 ppm and 6.25 ppm and 6.25 ppm was taken. For linearity we use different concentrations from 100 ppm to 6.25 ppm and graph shows linear relationship between absorbance and concentration (**Figure 2** and **Figure 3**).

Table 1. Absorbance of flk-01.		
Concentration ppm	Absorbance at 210 nm	
100	2.356	
50	1.25	
25	0.625	
12.5	0.32	
6.25	0.15	

Table 2. Absorbance of flk-02.		
Concentration ppm	Absorbance at 210 nm	
100	2.366	
50	1.26	
25	0.67	
12.5	0.37	
6.25	0.17	

Table 3. Results of % assay of different brands.

Brand name	Absorbance at 210 nm	% Assay
FLK-01	2.356	100.68
FLK-02	2.366	101.10



Squared correlation coefficient of each brand is shown which should not be less than 0.99. Squared correlation coefficient values of all the brands of FLK are well within the limit. In all results we find acceptable degree of linearity. All three brands of FLK showed linear relation with their dilution (Figure 2 and Figure 3).

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Abbreviations

FLK: Fluconazole FLK-01: Fluconazole Brand 01 FLK-02: Fluconazole Brand 02