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# Methods Development of Fluconazole Tablets (400 Mg)

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A spectrophotometric method has been developed for the determination of fluconazole in bulk, tablet and suspension dosage forms. Solution of fluconazole in methanol glacial acetic acid solution shows maximum absorbance at 235 nm. Beers law was obeyed in the concentration range of 2.5 - 20 g/ml with molar absorptivity of 1.0815 × 10mol1cm-1.The method was applied for the analysis of the drug in the pure, tablet and suspension forms. The slope and intercept of the equation of the regression lineare 0.0310 and 0.00067 respectively. Correlation coefficient was found to be 0.9998. Results of percentage recovery showed that the method was not affected by the presence of common excipients. The proposed method is simple, sensitive, rapid, economical and could find application as an in -process quality control method for fluconazole.

*Keyword:* Fluconazole, Spectrophotometry, UV-Method, Beers Law, Lambards Law.

**INTRODUCTION:** Fluconazole is a broad spectrum anthelmintic. It is used for the treatment of Threadworm, Hookworm and Tapeworm (Jaime and William, 1988, Rang et al, 1999, International Pharmacopoeia, 1987). Chemically, fluconazole is Ethyal 4-propylthio-2H-benzimidazol (British Pharmacopoeia, 2001). The preparation and synthesis of the drug was reported by Gujunkand Theories, (1975), proceed.

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The development of reliable and affordable procedures for assay of drug substances either as pure drug or in combination remains a major research area in todays Pharmaceutical care and practice (Esimone et al., 2008). Extensive literature survey revealed that the estimation of the fluconazole in dosage and suspension forms are not available in Pharmacopoeia and therefore, require much more investigation. To the best of our knowledge, the estimation of the drug in pure form using non - aqueous titration.is described in British Pharmacopoeia. The drug is readily available in Nigeria market in tablet, bolus (Veterinary preparation) and suspension forms. The need to come up with a simple and sensitive method of analysis for the estimation of drug in pharmaceutical preparations therefore arises. The aim of the present work was to develops impel, rapid, accurate and sensitive method for the

estimation of fluconazole in bolus, tablet and suspension forms respectively.

## MATERIALS AND METHODS:

Pharmaceutical grade of fluconazole was obtained as gift from Sam Pharmaceutical Ltd, Ilorin, Nigeria. All the chemicals were of analytical reagent grade of Merck (Germany) unless otherwise specified. Doubly distilled water was used to prepare all solutions. Freshly prepared solutions were employed. Different brands fluconazole tablet, Bolus and Suspensions were purchased from Pharmacies. Lactose B.P, talcum powder, maize starch(Pharmaceutical grade) and magnesium stearate, propylene glycol, carboxyl methyl cellulose, Tween 80, titanium dioxide were obtained from Tuyil Pharmaceutical Industries Ltd. llorin, Nigeria. UV/VisCarboxyl methyl cellulose, Tween 80, Titanium Dioxide were
obtained from Tuyil Pharmaceutical Industries Ltd. llorin, Nigeria.UV/Vis Spectrophotometer (model V460) was employed for spectra.

### Methods:

fluconazole stock solution. Standard stock was prepared by dissolving 50 mg fluconazole in100 ml of methanolic glacial acetic acid to get concentration of 500g/ml. Method Development Aliquots of stock solution were further diluted with methanolicglacial acetic acid to get working solution of 2.5, 5.0, 7.5, 10.0, 12.5,15.0, 17.5, 20.0 and 22.5 g/ml and the working standards were scanned between 150 - 300 nm which shows the maximum absorbance at 235 nm. Procedure for calibration curve. Aliquots of stock solution were further diluted with methanolicglacial acetic acid to get working solution of 2.5, 5.0, 7.5, 10.0, 12.5,15.0, 17.5, 20.0 and 22.5 g/ml. Subsequently, the prepared standards were measured after standing for 5 min at max as recorded in in each case against a solvent blank similarly prepared. A calibration curve of the absorbance against the concentration of the drug was plotted. This was proof Procedure for pharmaceutical preparations For analysis of commercial formulations; twenty tablets or bolus were taken and powdered. The powder or suspension equivalent to100 mg of fluconazole was accurately weighed or measured and transferred to 100 ml volumetric flask and dissolved in 20 mlmethanolic glacial acetic acid. Then the solution was shaken for 20min. The resulting solution was further diluted to 100 ml with methanolic glacial acetic acid and filtered through what man filter
paper no. 41. 1 ml of the above solution was pipetted out into 100ml volumetric flask and made up to the mark with methanolic glacial acetic acid. The absorbance was measured at 235 nm against the blank. The amount of the drug in a sample was calculated from the calibration curve. Validation method The precision of the method for the drug was found by measuring the absorbance of 6 separate samples containing known amount of drug. The method was validated by studying the following parameters as ICH guidelines (ICH guidelines., 1995) for method validation. The slope, Intercept, correlation coefficient and optical.

## RESULTS AND DISCUSSION:

It can be seen that the spectrum fluconazole has a maximum absorbance at 235 nm in methanolic glacial acetic acid. The method obeys Beer - Lambert law within the range of 2.5 - 20 g/ml and the calibration curve showed linearity as shown in range. It can be observed from that the slope and intercept of the equation of the regression line are 0.0310and 0.00067 respectively. Correlation coefficient was found to be 0.9998.The results obtained from analysis of different brands of fluconazole tablets, bolus and suspension were in good agreement with the label claims as shown in the little difference might be due to batch variation of medicaments in tablets, bolus and suspension, instrumental errors or degradation of active ingredients with time. The precision of the method was investigatedby

repeatability. The accuracy and precision of the proposed method were established by performing intraday and inter day assays by analyzing formulation for six days subsequently and six times in same day. The standard deviations obtained by both methods are acceptable (that is within the permissible bias range)and therefore considered to be satisfactory (Annapurnaet al., 2009). The high percentage recoveries obtained for various amounts of fluconazole in formulate mixture with excipients suggested that there is no interference from any of the excipients (such as starch, lactose, titanium dioxide and magnesium stearate) as evidenced by the lack of absorbance at the specified lambda max for the excipients and blank solutions. It was observed that the % recovery increased with concentration which can be attributed to the detector (Williams, 1977) and the usual variation of absorbance with concentrations(Abdou, 1990). The results obtained were reproducible with low % RSD values. The results reported when the proposed method was compared with non - aqueous method for the estimation of fluconazole pure drug compared favorably with non - aqueous method. The non -aqueous method is generally adopted for the analysis of nitrogen - containing heterocyclic compounds when used as the basis for comparison. No difference was obtained in the spectrum of prepared standard solution of fluconazole and the standard stock solution stored at different condition of ±4°C and ambient temperature for one month (Thangabalan et al., 2009).

## CONCLUSION:

A method for the estimation of fluconazole in pure drug, solid and suspension dosage forms has been developed. From the spectrum of fluconazole as discussed. it was found that the maximum absorbance was 235 nm in methanolic glacial acetic acid. A good linear relationship (0.998) was observed in the concentration range of 2.5 - 20 g/ml. The high percentage recovery indicates high accuracy of the method. The method shows no interference from the common excipients and additives. This demonstrates that the developed spectroscopic method is simple, accurate, precise and selective for the estimation of fluconazole in solid and suspension dosage forms. Hence, the method could be considered for the determination of fluconazole in quality control laboratories.

## REFERENCE:

1. A Guidelines on Validation by Kathiresan, Annamalai University.

2. Vallidation protocols written by Suresh chondhokar, Silvessar 8th Edition.

3. GMP Practice of Vallidation-Ramaswamy, 14 Edition,CBS.

4. Analytical Method Vallidation-B.Prabhakar.

5. Analytical Method Vallidation-Kalichelvi.

6. Practical Validation Guidelines-Leister.

7. Indian Pharmacopeia.

8. British Pharmacopeia.

9. Indian journal of Pharmaceutical Research.

10. United states of pharmacopeia

11. A Text book of Method validation-Ansel,B.K.Sharma.