**Research Article** **CODEN: AJPAD7** **ISSN: 2321 - 0923**

**Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry**

**Journal home page: www.ajpamc.com**

https://doi.org/10.36673/AJPAMC.2025.v13.i03.A08

# SPECTROPHOTOMETRIC DETERMINATION OF FLUCONAZOLE: A SUSTAINABLE APPROACH

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## ABSTRACT

A simple, eco-friendly and validated UV-Visible spectrophotometric method was developed for quantitative estimation of fluconazole in tablet formulations, employing distilled water as solvent in alignment with green chemistry principles. Absorbance was measured at 261nm using a Shimadzu UV-1800 spectrophotometer. The proposed method was validated according to ICH Q2 (R1) guidelines, assessing specificity, linearity, accuracy, precision, robustness and ruggedness. The calibration curve showed linearity over 15-90 ppm with a correlation coefficient greater than 0.99. Recovery studies confirmed accuracy within 98-102%, while precision showed RSD values below 2%. The assay of marketed tablets (Fluka 150) indicated a purity of 101.75%. Assessment using the AGREE metric yielded a greenness score of 0.79, confirming strong environmental compatibility. The proposed method offers a reliable, sensitive and sustainable approach for the routine analysis of fluconazole in pharmaceutical dosage forms.

## KEYWORDS

Fluconazole, Spectrophotometry, UV-Visible analysis, Green chemistry, Method validation and AGREE metric.

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## INTRODUCTION

Fungal infections present a growing global health challenge, necessitating the use of potent antifungal agents for effective management[1]. Fluconazole, a triazole derivative, exhibits excellent antifungal activity against a broad range of pathogenic fungi and is widely used due to its favorable pharmacokinetic and safety profile[2]. However,

analytical methods reported for fluconazole determination often rely on organic solvents that are hazardous to both human health and the environment[3].

In line with the principles of green analytical chemistry, there is an increasing demand for analytical methods that minimize environmental impact while maintaining high analytical performance[4]. UV-Visible spectrophotometry offers a simple, rapid, and cost-effective technique for pharmaceutical analysis, making it suitable for sustainable routine quality control[5].

The present study aims to develop and validate an environmentally conscious UV-Visible spectrophotometric method for fluconazole estimation in tablets using distilled water as solvent. The developed method adheres to ICH validation parameters[6] and is evaluated for environmental sustainability using the Analytical Greenness (AGREE) tool[7].

## MATERIALS AND METHODS

### Chemicals and Reagents

All chemicals used were of analytical grade. Distilled water served as the primary solvent for solution preparation according to green chemistry principles. Commercial fluconazole tablets (Fluka 150) were used for analysis.

### Instrumentation

Absorbance was recorded using a Shimadzu UV-1800 double-beam spectrophotometer with matched 1 cm quartz cuvettes. All instruments including analytical balance and ultrasonicator were calibrated prior to use.

### Preparation of Standard and Sample Solutions

A stock solution of fluconazole (1000µg/mL) was prepared by dissolving 100 mg of pure drug in 100 mL of distilled water. Serial dilutions were made from this stock solution to obtain standard concentrations of 15-90µg/mL.

Twenty tablets of Fluka 150 were weighed, powdered and blended uniformly. A quantity of powder equivalent to 100mg fluconazole was dissolved in 100mL of distilled water, sonicated for 10 minutes, and filtered through Whatman filter paper No.41. The filtrate was suitably diluted to obtain a sample concentration of 30µg/mL.

### Selection of Wavelength

A standard fluconazole solution was scanned from 200-400nm against water as blank. The drug exhibited maximum absorbance at 261nm, which was selected as the analytical wavelength for all experiments.

## RESULTS AND DISCUSSION

### Specificity

There was no interference from the tablet excipients at 261nm, which confirmed the specificity of the method for fluconazole determination.

### Linearity

A linear correlation was observed between absorbance and concentration within the 15-90µg/mL range, following Beer-Lambert's law. The correlation coefficient ($R^2 = 0.998$) indicated excellent linearity.

### Accuracy

Recovery studies were conducted at three levels (80%, 100% and 120%) by spiking pre-analyzed samples. The mean recovery ranged from 98.5% to 100.9%, demonstrating the method's accuracy.

### Precision

Repeatability and intermediate precision data at 30µg/mL showed RSD values below 2%, confirming method precision.

### Ruggedness

Analysis performed by two analysts produced consistent absorbance values, confirming ruggedness.

### Assay

The assay of the marketed tablet (Fluka 150) using the developed method revealed a percentage purity of 101.75%, confirming method applicability.

### Greenness Assessment

The greenness of the proposed method was evaluated with the AGREE metric, which integrates the 12 principles of green analytical chemistry[7]. The method achieved an AGREE score of 0.79, reflecting strong environmental compliance due to the use of water as an eco-friendly solvent, minimal

reagent consumption and lack of toxic waste generation.

**Table No.1: Linearity Data**

| S.No | Concentration | Absorbance |
|---|---|---|
| 1 | 15ppm | 0.033 |
| 2 | 30ppm | 0.055 |
| 3 | 45ppm | 0.076 |
| 4 | 60ppm | 0.094 |
| 5 | 75ppm | 0.110 |
| 6 | 90ppm | 0.130 |

**Table No.2: Data Table with statistical validation for recovery studies**

| S.No | % Level | Amount Spiked (µg/ml) | Amount Recovers (µg/ml) | % Recovery | Mean Recovery |
|---|---|---|---|---|---|
| 1 | 80 | 24 | 23.82 | 99.250 | 99.430 |
| | | 24 | 23.91 | 99.625 | |
| | | 24 | 23.45 | 98.542 | |
| 2 | 100 | 30 | 29.88 | 99.600 | Standard Deviation 0.9105 |
| | | 30 | 29.34 | 98.467 | |
| | | 30 | 29.54 | 98.467 | |
| 3 | 120 | 36 | 36.31 | 100.861 | Relative SD 0.916 |
| | | 36 | 35.74 | 99.278 | |
| | | 36 | 36.28 | 100.778 | |

**Table No.3: Precision Data table**

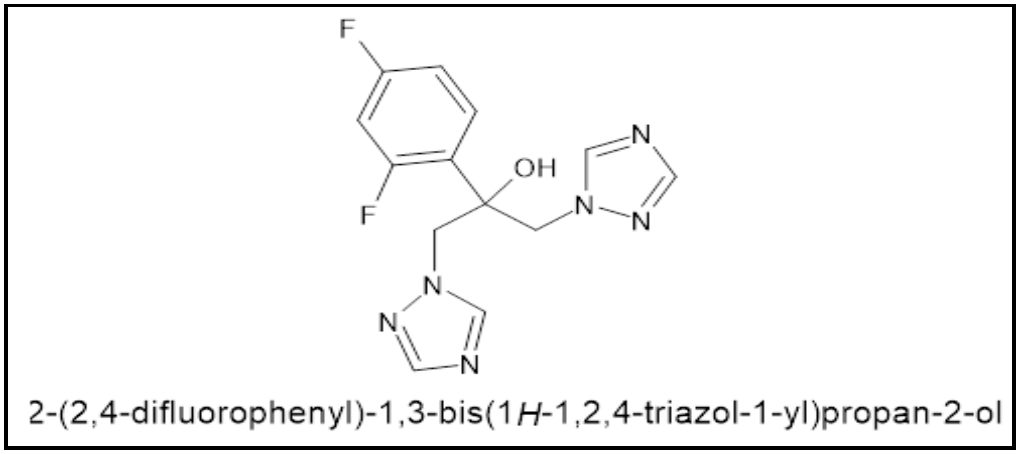
| S.No | Absorbance |
|---|---|
| 1 | 0.055 |
| 2 | 0.056 |
| 3 | 0.054 |
| 4 | 0.055 |
| 5 | 0.056 |
| 6 | 0.057 |
| Mean | 0.056 |
| S. D. | 0.001 |
| % RSD | 1.890 |

**Table No.4: Statistical validation for Ruggedness of Method**

| S.No | Analyst-1 | Analyst-II |
|---|---|---|
| 1 | 0.056 | 0.057 |
| 2 | 0.055 | 0.056 |
| 3 | 0.054 | 0.055 |
| 4 | 0.055 | 0.055 |
| 5 | 0.054 | 0.056 |
| 6 | 0.056 | 0.055 |
| Mean | 0.055 | 0.055667 |
| S. D. | 0.000894 | 0.000816 |
| % RSD | 1.626231 | 1.46676 |

**Table No.5: Result of assay for marketed product**

| S.No | - | Absorbance | % Assay |
|---|---|---|---|
| 1 | Working Standard | 0.562 | -- |
| 2 | Dosage Form (Fluka 150) | 0.573 | 101.60% |




2-(2,4-difluorophenyl)-1,3-bis(1*H*-1,2,4-triazol-1-yl)propan-2-ol

**Figure No.1: Chemical structure of fluconazole**

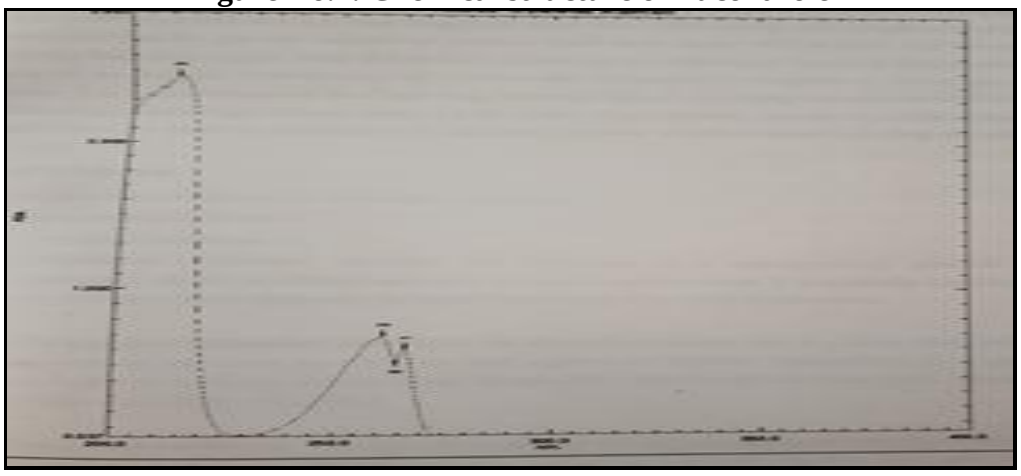


**Figure No.2: 2UV Absorption spectrum of fluconazole**

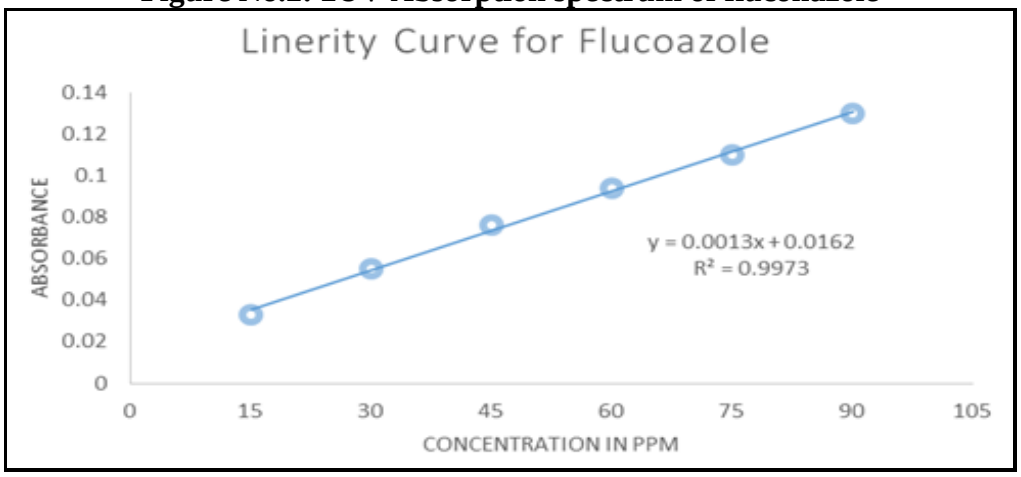



**Figure No.3: Calibration curve for fluconazole**

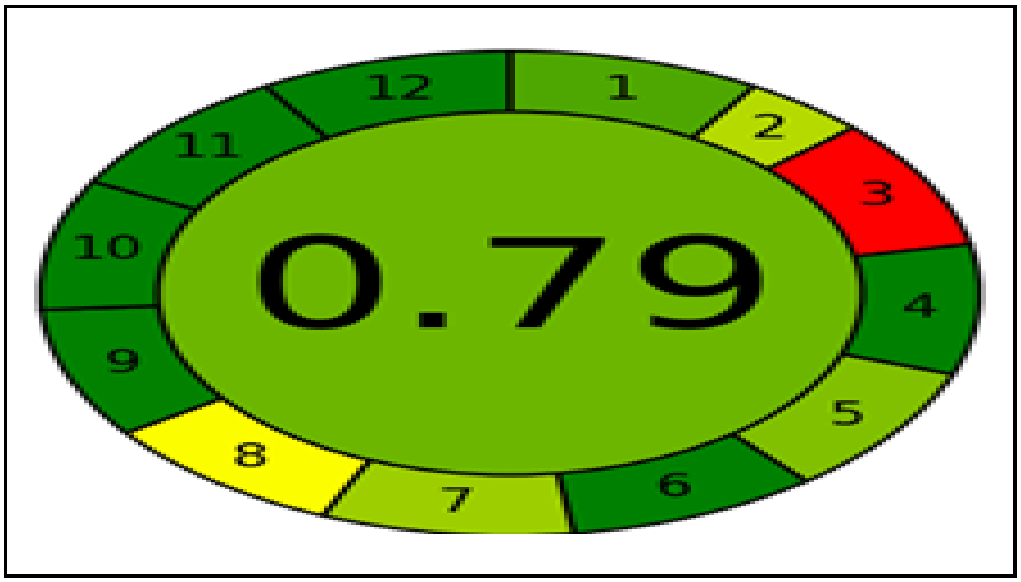



**Figure No.4: AGREE greenness score for proposed method**

**SUMMARY**

A simple, robust and environmentally sustainable UV-Visible spectrophotometric method for the quantitative estimation of fluconazole in tablet dosage forms has been successfully developed and validated. The method exhibited high accuracy, precision and reproducibility in accordance with ICH guidelines. Substitution of organic solvents with distilled water significantly reduced environmental impact, achieving an AGREE score of 0.79. The method is well-suited for routine quality control and stability testing of fluconazole in pharmaceutical formulations, supporting green analytical practices.

**CONCLUSION**

A reliable and environmentally sustainable UV-Visible spectrophotometric method for the quantitative analysis of fluconazole in tablet formulations has been successfully developed and validated. This green approach utilizes distilled water as the solvent, ensuring minimal ecological impact and high safety in laboratory practice. The method demonstrated excellent specificity, linearity, accuracy, precision, robustness and ruggedness in accordance with ICH guidelines. Consistent recoveries and low RSDs affirm its reproducibility and reliability for routine pharmaceutical quality control. Greenness assessment using the AGREE metric further confirms the strong environmental profile of the method, supporting its wide adoption for sustainable analytical applications in pharmaceutical laboratories.

**ACKNOWLEDGEMENT**

The authors express gratitude to the Management and Principal of Channabasweshwar Pharmacy College (Degree) Latur for providing research facilities and support.

**CONFLICT OF INTEREST**

The authors declare no conflict of interest.

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**Please cite this article in press as:** Moein Sharfodin Attar, *et al*. Spectrophotometric determination of fluconazole: A sustainable approach, *Asian Journal of Pharmaceutical Analysis and Medicinal Chemistry*, 13(3), 2025, 52-57.