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COMPARATIVE *IN-VITRO* ASSESSMENT OF SOME PHARMACEUTICAL BRANDS OF FLUCONAZOLE TABLETS MARKETED IN IRAQ

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ABSTRACT

To evaluate and compare the pharmaceutical quality of different commercially available fluconazole tablet brands in Iraq. Standard quality control tests were conducted following United States Pharmacopeia (USP) and British Pharmacopeia (BP) procedures. Key parameters included weight variation, hardness, friability, content uniformity, disintegration time, and *in-vitro* dissolution. UV-Visible spectrophotometry was used for quantitative analysis of fluconazole.All brands complied with pharmacopeial criteria for weight variation, friability, content uniformity, and assay. Disintegration times were within acceptable limits for immediate-release capsules. Dissolution profiles showed ≥85% fluconazole release within 30 minutes, consistent with USP expectations for immediate-release antifungals. The tested fluconazole tablet brands marketed in Iraq met official quality specifications and can be considered pharmaceutically equivalent. Variations in disintegration and dissolution behavior likely reflect formulation differences.

KEYWORDS: Fluconazole, tablets, quality control, dissolution, pharmacopeia.

INTRODUCTION

Ensuring the quality of generic antifungal capsules is crucial for patient safety and therapeutic efficacy. Fluconazole, a synthetic antifungal agent, is widely prescribed for systemic and superficial mycoses due to its broad spectrum of activity and favorable pharmacokinetics. It is classified by the Biopharmaceutics Classification System (BCS) as a

highly soluble, highly permeable compound, making *in-vitro* dissolution a key indicator of performance for immediate-release oral tablets [1, 2].

The pharmaceutical quality of fluconazole tablets is influenced by excipient selection, manufacturing processes, and mechanical properties of the formulation. Recent research has focused on enhancing fluconazole's physicochemical properties through co-crystallization and solid dispersion strategies to improve solubility, flowability, and mechanical characteristics, which are directly relevant to tablet manufacture and *in-vitro* behavior [3]. However, advances in formulation science, commercially marketed capsules must still meet pharmacopeial quality standards. Comparative quality studies provide essential post-marketing surveillance data, confirming uniformity, mechanical integrity, and release behavior across brands available in a given market.

Drug quality control is necessary and intended to ensure the efficacy, safety and quality of medicines and other pharmaceutical products. Fluconazole, one of the highly patronized and readily affordable antifungal drug products, is marketed under various generic brands in many developing countries that are deficient in requisite infrastructure and logistics for standard drug distribution and storage. The need for routine quality assessment of its dosage forms in circulation cannot be overemphasized [4, 5]. This study examined and assessed the pharmaceutical characteristics of four distinct brands of fluconazole capsules available in Iraq by in vitro methods, following the guidelines of the USP and official standards to emphasize that all brands are equivalent in terms of pharmaceutical quality. The tablets were assessed by evaluating weight, disintegration time, release, and assay using the U.V. spectrophotometry.

MATERIALS AND METHODS

Materials

Fluconazole standard (sigma-aldrich) and multiple commercial fluconazole tablet brands (150 mg) were sourced from local pharmacies revealed in Figure 1. Analytical reagents and media were pharmacopeial grade.

Figure 1: The marketed Fluconazole Capsules tested.

Analytical Method

Stock and working solutions of fluconazole were prepared in 0.1 M HCl. Absorbance was measured using a UV-Visible spectrophotometer at the wavelength corresponding to the compound's maximum absorbance (λmax), typically around **260 nm** for fluconazole quantification [6].

Quality Evaluation Tests

Weight Variation

Ten Capsules per brand were individually weighed to assess uniformity of mass according to USP guidelines [7].

Assay

Tablets were powdered, dissolved, filtered, and analyzed spectrophotometrically to determine fluconazole content

Disintegration Time

Fill the water and maintaining the temperature 37°C ± 2 °C introduce one capsule into each tube and if directed in the appropriate general monograph, add a tube suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time. Remove the assembly from the liquid. the capsule passes the test if all of them have disintegrated. note down the time of disintegration.

Content Uniformity

Individual capsules were analyzed to verify drug content compliance [7].

***In-Vitro* Dissolution**

Dissolution was conducted using USP Apparatus II (paddle) in 900 mL 0.1 M HCl at 37 ± 0.5°C and 50 rpm. Samples were withdrawn at predetermined intervals, filtered, and analyzed spectrophotometrically. The requirement for immediate-release fluconazole is typically ≥75% release within 30 minutes [8].

Statistical analysis

Similarity of dissolution profiles of three profiles was assessed by similarity factor F2 and difference factor f1

RESULTS AND DISCUSSION

All brands met USP weight variation criteria. Assay results confirmed that fluconazole content fell within acceptable limits for immediate-release capsules. Disintegration times varied but remained within pharmacopeial limits for immediate-release formulations. The investigation revealed that the disintegration time was measured to assess the duration for a medication to break down in the stomach. The fluconazole capsules were anticipated to undergo disintegration less than 6 minutes, and based on this investigation, the average disintegration time varied between 2.5 and 5.5 minutes, shorter than the typical disintegration period of 30 minutes for capsules [7].

Table 1. the physicochemical characteristics of samples.

Brand	***Assay (%)***	***Content uniformity (%)***	***Disintegration time* (min)***
Diflucan	99.8%± 0.2	98.9% ± 0.4	4± 0.05
Diflurok	100.3%± 0.1	99.1%± 0.1	2.5± 0.02
Flux	100.2%± 0.2	96.1%± 0.2	3.5± 0.05
Fluconov	99.9%± 0.3	97.2%± 0.3	5.5± 0.05

Dissolution Profiles: All brands exhibited rapid dissolution, with ≥75% fluconazole release within 30 minutes, consistent with pharmacopeial guidelines and findings reported in recent fluconazole dissolution method studies [8].

The dissolved perecent of fluconazole after 30 min was 92%, 95%, 85%, and 86% for Diflucan, Diflurok, Flux and Fluconov respectively. Although they are within pharmacopeial limit but Diflurok was the most near to Diflucan The slight differences in dissolution behavior may be attributable to formulation variables such as excipient type and concentration. Current formulation research underscores the impact of solid dispersion and co-crystal formation on fluconazole's dissolution and mechanical properties, which reflects the broader formulation landscape for fluconazole [3].

For comparison of in-vitro dissolution profiles, the difference and similarity factors (f1and f2) were emphasized by US FDA. Similarity factor (f2) emphasizes the comparison of the relative closeness of generic to innovator brand of the drug product. The f2 parameter is commonly used to establish similarity between two dissolution profiles of generic and innovator brand, and by extension the bioequivalence of the products [9-10]. The similarity factors of the brands of fluconazole were within ≥ 50 which indicate similarity.

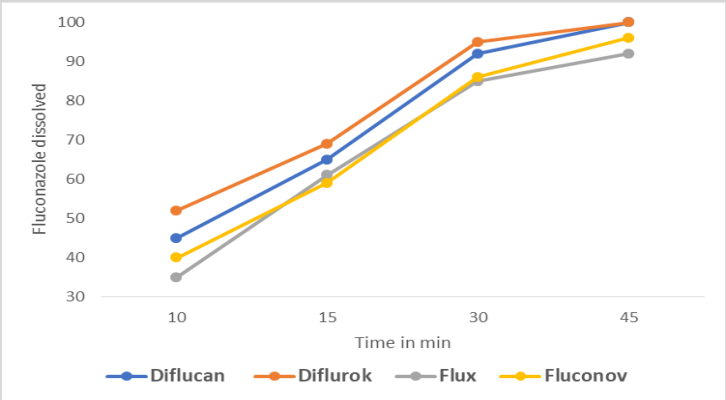

Figure 2. Dissolution of fluconazole from marketed brands (n = 6)

CONCLUSION

Fluconazole capsules marketed in Iraq satisfy key pharmacopeial quality standards, indicating pharmaceutical equivalence among the brands tested. Continuous quality surveillance is recommended to ensure sustained product performance.

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