Research Article

COMPARATIVE *IN VITRO* RELEASE STUDY OF SOME COMMERCIALY AVAILABLE FLUCONAZOLE TABLETS

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ABSTRACT

Sundry brands of same dosage forms are available in the Indian market with the common assertion that they are all bioequivalent. The main objective of the present study was to conduct the comparative dissolution studies of different brands of same dosage forms to determine whether all the formulations used were bioequivalent or significantly different. An Immediate release tablets dosage form disintegrate rapidly after administration with enhanced rate of dissolution. Three different brands of Fluconazole (Antifungal) of 150 mg Immediate release tablets from different manufacturers were selected in the study and dissolution testing in 6.8 pH Phosphate buffer was conducted from each brands for 30 minutes by using dissolution testing apparatus USP type-II. The result show that all brand fulfill the specification of dissolution profile and Fumycin' manufactured by Pfizer was comparatively better dissolution than other Fluconazole tablets used in experiments.

Key words: Fluconazole, Dissolution, Immediate release tablet, dosage form, comparative, Antifungal etc.

INTRODUCTION

Dissolution is a process in which solid substance solubilises in a given solvent i.e. mass transfer from solid surface to the liquid phase. *In vitro* dissolution test is the best available tool today which can at least quantitatively assure about the biological availability of drug from its formulation. Main objective of dissolution profile comparison are development of bioequivalent drug product, demonstrating equivalence after change in formulation of drug product and biowaiver of drug product of lower strength in proportion to higher dose strength drug product containing same active ingredient and Excipient.^{1,2}

Fluconazole is designated chemically as 2,4-difluoro- α , α 1 – bis(1H-1,2,4-triazol-1-ylmethyl) benzyl alcohol with an empirical formula of $C_{13}H_{12}F_2N_6O$ and molecular weight of 306.3. The structural formula is:

Fluconazole is highly selective inhibitor of fungal cytochrome P-450 and sterol-14 α -demethylation that result in inhibition of ergosterol synthesis. It is broad spectrum triazole antifungal agent that is primarily fungistatic with activity against

Cryptococcus neoformans and Candida spp. In common with other azole antifungal drug, most fungi are more susceptible in vivo. It is approved for systemic candidiasis, oropharyngeal and esophageal candidiasis and cryptococcal meningitis.

The bioavailability of oral Fluconazole is over 90% compared with IV administration is 0.8g/L and reaches concentration in CSF that are 80% of that patient serum with meningitis. Plasma protein binding is 11% and plasma half life is about 30hrs. It may alter cytochrome P-450 pathway of metabolism of some drug like warfarin and Phenytoin. Most common side effect are nausea, vomiting, bloating and abdominal discomfort.^{3,4}

The main objective of this study was to ensure that the product that are available in market meet the dissolution specification or not.

MATERIALS AND METHODS

Fluconazole standard (Drug) received from onceptPharmapvt.ltdAurangabad, India. Three Different brands of Fluconazole tablets were purchases from local retail medical shop and coded as per their brand name conaz manufactured by OrinoPharma ltd, fluka manufactured byCipla and Fumycin manufactured by Pfizer. All tablets were recently manufactured of same manufacturing year.

Preparation of standard plot

100 mg of pure drug was accurately weighed and dissolved in 10 ml of methanol solvent and diluted up to 100 ml with phosphate buffer in 100 ml volumetric flask.⁵ This was first stock solution and contains 1000 mcg/ml of drug. From first stock solution 10 ml was taken to another 100 ml volumetric flask and diluted up to the mark with phosphate buffer and

contains 100mcg/ml of drug concentration. From this second stock various other concentrations were prepared like 2mcg/ml, 4mcg/ml, 6mcg/ml, 8mcg/ml, 10mcg/ml, 12mcg/ml. absorbance values of these concentrations were measured by UV double beam spectrophotometer at 264 nm and standard graph was plotted by taking absorbance values on Y-axis and concentration values on X-axis show in Figure no.1.

In-vitro Dissolution study

The in vitro dissolution study was carried out using USP Type II dissolution apparatus. The study was carried out in 900 ml of pH 6.8 phosphate buffer solution for 1 hour. The medium was allowed to equilibrate to a temperature of $37 \pm 0.5^\circ\text{C}$. Tablet were placed in the vessel and operated at 50 rpm. At definite time intervals, 5 ml of the fluid was withdrawn; filtered and again

5ml of the fluid was replaced. Suitable dilutions were done with the dissolution fluid and the samples were analyzed using UV spectrophotometer at 261 nm⁶

RESULTS AND DISCUSSION

The response of the drug was found to be linear in the investigation concentration range and the linear regression equation was $y = 0.0982x - 0.0086$ with correlation coefficient is 0.9989

The comparative *in vitro* dissolution profiles of various commercially available Fluconazole tablets are shown in Figure 2. The *in vitro* dissolution profiles were found to be varying for each tablet, but within the prescribed limit.

Figure 1: Standard calibration curve of Fluconazole drug

Table 1: comparative in vitro dissolution profiles of Different brand of Fluconazole tablets

Time Point (Min)	conaz,	fluka	Fumycin
0	0	0	0
5	51± 1.4	50± 1.3	61± 2.4
10	58±3.2	69±3.5	64±2.5
15	71±2.2	76±2.1	76±3.6
20	83±3.6	89±2.6	89±1.4
30	96±2.8	89±3.5	100±0.2

Figure 2: comparative in vitro drug release of Different brand of Fluconazole tablets

CONCLUSION

The present study showed that fluconazole tablet marketed, Manufactured by pharmaceutical companies are of accepted limit of criteria and met standards with respect to specified parameter. The in vitro dissolution studies showed that percentage drug release of 'Fumycin' manufactured by Pfizer was better than other Fluconazole tablets used in experiments.

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