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Comparative Study of in-Vitro Release of Fluconazole Tablet as Generic and Branded

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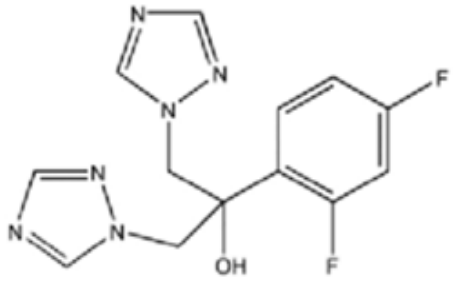
Abstract:- The branded drugs are the patent protected.The branded drugs are marketed under a unique proprietary name given by the company.The generic drugs are off the patent.The generic drugs are marketed under the generic name of the drugs . The branded drugs are costly where as the generic drugs are cheap.There is no big difference between the generic and branded drugs.we taken fluconazole as for study purpose.The fluconazole tablet contain NLT 90.0%and NMT 110.0% of the labelled amount of the fluconazole.The fluconazole is the antifungal medication used for a number of the fungal infection eg.. candidiasis, blastomycosis, coccidiodomycosis etc.The boiling point is 579.8°c.The plasma half life of fluconazole is approximately 30hours. The dissolution time of fluconazole is 30 min.Fluconazole is available as either an oral or intravenous form and oral administration has a bioavailability of approximately 90%relative to intravenous administration.

Keywords: *Fluconazole, Dissolution time, Disintegration, Tablet.*

I. INTRODUCTION

Antifungals also known as antimycotics,are pharmaceutical fungicide or fungistatic agents used to treat and prevent mycosis such as athletes foot ringworm, candidiasis, serious systemic infections such as cryptococcal meningitis and others.Fluconazole is available as tablets and capsules for oral administration.

It is designated chemically as 2(2,4diflurophenyl)1,3bis(1-H,2,4-triazol-1-yl)propan-2-ol) with a molecular weight of 306.3.Fluconazole is highly selective inhibitor of fungal cytochrome P-450 and sterol-14 α-demethylationthat result ininhibition of ergosterol synthesis.



Fluconazole is white crystalline solid which is slightly soluble in water, soluble in alcohol and acetone, readily soluble in methanol and very slightly soluble in toluene.It has a chemical formula ofC13H12F2N6O.

The aim of the this study was to investigate the in-vitro release of different generic and branded fluconazole tablet which are available in the market.

II. MATERIALS AND METHODS

The branded and generic tablet of fluconazole were purchased from retail pharmacy of baramati and labelled as their name fluka-150 manufactured by cipla pharmaceutical and flucobig-150 manufactured by pure and cure healthcare pvt. Ltd.All tablets were recently manufactured of same manufacturing.Theire qualitative and quantitative tests are carried out.

➢ *Reagent used*

Hydrochloric acid, sodium hydroxide pellet, distilled water etc.

➢ *Methods*

- *Physical Appearance*

Negligible variation in the description, Thickness, Length and breadth was observed within batches.

- *Weight Variation*

The weight of tablet dosage form is measured to check the proper amount of active ingredient in the tablet. Analytical grade weighing balance is used to measure the individual as well as average weight of the tablet and mean standard deviations.

- *Hardness Testing*

This test was performed on 10 tablets of each batch.Hardness can be correlated to release rate or bioavailability.The ERWEKA tester tests a tablet placed on the lower anvil and a weight moving along a rail transmits pressure slowly to the tablet.

- *Disintegration Test*

Using a disintegration test apparatus (model 2T 200 Er-weka, Germany)the disintegration time of six tablets of each sample of each brand and generic was evaluated. A 500.0 ml volume of 0.1N hydrochloric acid placed in a 1.0 L beaker and immersed in a water bath at 37+-1°c was used as the disintegration fluid. A tablet from generic and branded

singly kept in cylindrical tube and guided with a glass disc. The time taken for the complete breakdown of the last tablet and it's fragments passing completely through the wire mesh at the bottom of disc was noted.

- *Friability Test*

The Friability Test was designed to evaluate the ability of the tablet to withstand breakage during packaging, handling and shipping. After physical inspection and dusting ten tablets are weighed and placed in the Friability apparatus where they are exposed to rolling and repeated shocks as they falls 6 inches in each term within the apparatus.After 100 revolutions the tablets are weighed.The loss due to abrassion is measure of tablet Friability.Maximum weight loss is not more than 1%of the initial weight of tablet.

- *Dissolution Test*

In-vitro dissolution studies were carried out using a dissolutions appratus USP (paddle type)at a paddle speed of 50rpm.The dissolution medium was 900 ml of 0.1N hydrochloric acid PH 1.2which was maintained at 37+-1°c.one tablet randomly selected from each of the brands and generic and placed in the dissolution media and 5 ml sample withdrawn at intervals of 5,10,20,30,40,50,60 min for the fluconazole drug.5 ml of fresh dissolution medium was used to replace each of the withdrawn samples immediately .The withdrawn samples were filterded and their absorbance was determined at maximum wavelength of 262nm using UV-VIS spectrophotometer.

- ✓ *Amount of drug release=concentration ×volume of Dissolution medium× dilution factor*
- ✓ *%content= actual content/ amount of API ×100*

III. RESULTS AND DISCUSSION

Table 1 Results of Physical Assessment of Fluconazole Tablet

Tablet	Label claim	Mfg.date	Expiry date	Batch number
Fluka-150	150	10/2022	09/2025	C121569
Flucobig-150	150	09/2022	07/2024	PXCA206

The physical assessment shows that the brands of commercially available fluconazole used in study are registered with NAFDAC.The batch number, manufacturing date were clearly mentioned.All the test of the tablet carried before the expiry date.

Weight variation test is done to know the amount of drug in the tablet.The mean weight of fluka is 272mg and mean weight of flucobig is 329 mg.The maximum percentage difference in fluka is 7.5%and in flucobig is 5%Not more than two of the tablets differ from the average weight by more than %error listed and no tablet differ by more than double that percentage.All samples studied fells within USP standard.

According to USP uncoated tablet are expected to disintegrate within 15 min .Fluka shows the disintegration time is 4 min and flucobig shows the 2 min.Here fluka take longer time than flucobig.

Table 2 Dissolution Profile of Fluconazole

Time Point (Min)	Flucobig -150	Fluka-150
0	0	0
5	61+-2.4	50+-1.3
10	64+-2.5	69+-3.5
15	76+-3.6	76+-2.1
20	89+-1.4	89+-2.6
30	100+-0.2	89+-3.5

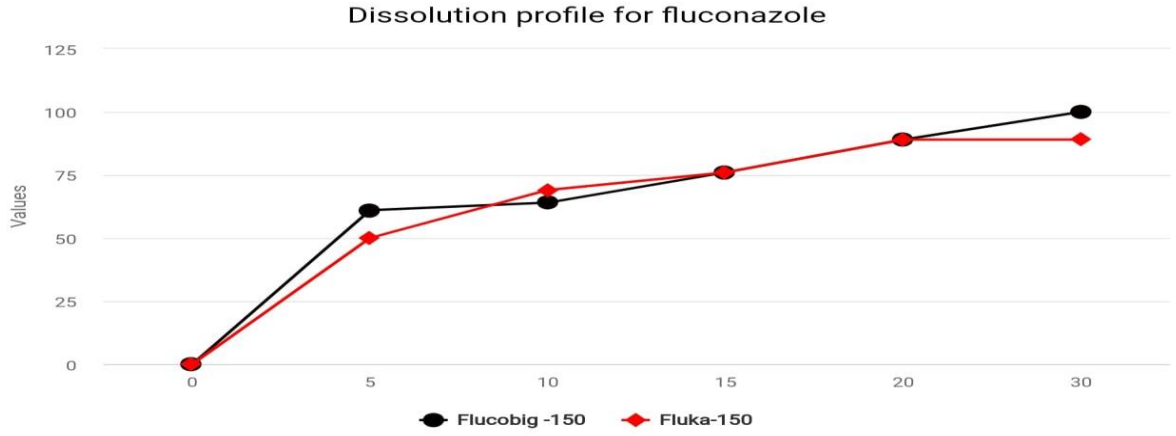


Fig 1 Dissolution Profile Fluconazole

The percentage of Friability of fluka was found to be 1.27% and the percentage of Friability of flucobig was found to be 1.30%.

IV. CONCLUSION

The result of comparative study of fluka-150 and Flucobig -150 as the generic and branded give that not much difference in there properties. The difference between this two tablets are within the acceptable range.

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