

Research Article

# Open-Label Crossover Oral Bioequivalence Pharmacokinetics Comparison of a Single Dose of Super-bioavailable Itraconazole 130 mg and Innovator SUBA®-Itraconazole Capsules 130 mg (2 x 65 mg) in Healthy Adults Under Fed Conditions

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## Abstract

**Introduction:** Itraconazole (ITZ), an antifungal agent taken orally, demonstrates intricate and variable absorption kinetics, significantly impacted by food intake. The invention of Super-Bioavailable Itraconazole (SITZ) has led to a surge in various brands offering different dosages of SB ITZ, overcoming barriers associated with conventional itraconazole. Hence, this study was planned to evaluate the bioequivalence of Itraconazole Capsules 130 mg (Test) of Glenmark Pharmaceuticals Ltd, India, with Innovator SITZ 130 mg (2x 65 mg; Reference) in healthy, adult, male, human subjects under fed condition in addition to safety and tolerability.

**Materials and methods:** A total of 36 subjects were enrolled in an open-label, balanced, randomized, two-treatment, two-sequence, two-period, two-way crossover, single dose oral bioavailability study which was conducted in healthy, adult, human male subjects under fed conditions. Test and reference product were administered sequentially. 22 blood samples per subject were collected as pre and post dose within 2 hours of intake of food. The concentrations of ITZ and Hydroxy-itraconazole (OH-ITZ) in plasma were measured by High-Performance Liquid Chromatography-Tandem Mass Spectrometry (HPLC-MS/MS). Assessment of bioequivalence was done on the basis of the 90% CIs of the differences of least squares treatment means for Ln-transformed  $C_{max}$  and  $AUC_{0-t}$  of ITZ obtained after single-dose administration under fed conditions for Test (T) vs Reference (R)

**Results:** The mean value of the area under curve ( $AUC_{0-t}$ ) of test drug (SITZ 130 mg) was 4604.98 ng.hr/mL whereas for reference drug (SITZ, 2 x 65 mg), it was 4812.04 ng.hr/mL which was statistically non-significant. The Pharmacokinetic parameters for OH-ITZ measured from both formulations followed a pattern in terms of bioavailability similar to that for the ITZ plasma blood levels for the test/reference ratios for  $C_{max}$  (100.88%) and  $AUC_{0-t}$  (97.44%). Subjects crossed over from one period of administration of either test or reference drugs to a second period with dosing with the opposite drug attained higher  $C_{max}$  and  $AUC_{0-t}$  values for ITZ, than the same subjects administered reference drug in this study. The administration of both the drugs were well

tolerated by all the subjects with no added adverse events

**Conclusion:** The pharmacokinetics activity was found to be comparable and bioequivalent between test product at 130 mg dose and innovator itraconazole 130 mg (2x 65 mg). Also, both the drugs were found to be safe and well tolerated with no adverse effects.

**Keywords:** Itraconazole; Super-Bioavailable Itraconazole; Antifungal Drug; Adults; Oral Bioequivalence Pharmacokinetics

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## Introduction

In recent years, the incidence of dermatophytosis has increased rapidly in India, necessitating the prescription of systemic antifungal drugs. Due to this change, the majority of dermatologists in India rely on several empirically based treatment strategies such as high-dose antifungal drugs and long-term treatments [1]. Itraconazole (ITZ) is the most commonly prescribed systemic antifungal drug due to its efficacy, but it has poor gastrointestinal tolerability, variable intra- and inter-patient bioavailability and poor absorption [1-3]. Its use is limited because it must be taken with food to improve its effectiveness. In a study on serum concentrations of ITZ by Wiederhold, et al., serum concentrations above 500 ng/ml which is the established reference value in invasive fungal infections were found in only 56.7% of patients [4,5].

A new formulation, Super Bioavailable ITZ (SITZ), was marketed as 50 mg capsules in many countries and as 65 mg capsules in the United States [1]. This new formulation contains a solid dispersion of ITZ in a pH-dependent polymer matrix called as hydroxypropyl methylcellulose phthalate and is said to improve both dissolution and intestinal absorption, overcoming the pharmacokinetic challenges associated with Conventional ITZ (CITZ). In India, SITZ 130mg was approved by the Central Drug Standard Control Organization (CDSCO, central licensing authority) in 2021 [1].

The objective of this study was to compare the bioavailability of test product; Itraconazole Capsules 130 mg of Glenmark Pharmaceuticals Ltd., India, with reference product; TOLSURA® (Itraconazole capsules) 65 mg (2x 65 mg) of Mayne Pharma Greenville, in healthy, adult, male, human subjects under fed condition in addition to safety and tolerability.

## Material and Methods

**Study participants.** Subjects enrolled in this study were healthy males between 18 to 45 years of age with Body Mass Indexes (BMIs) of between 18.0 and 29.9 kg/m<sup>2</sup> and with normal vital signs, laboratory values and Electrocardiograms (ECG). Subjects were excluded from the study if there was a known history or presence of clinically significant conditions or diseases or if they were on concomitant medications (prescription medications). Ethics Committee (EC) approval was obtained from Suraksha Ethics Committee (Reg. no. ECR/644/Inst/MH/2014/RR-17). Written consent was obtained from all subjects prior to study procedure.

### *Clinical Study Medications*

The drug products used to demonstrate bioequivalence were Itraconazole Capsules 130 mg of Glenmark Pharmaceuticals Ltd., India as a Test product (T) and TOLSURA (Itraconazole capsules) 130 mg (2x 65 mg) of Mayne Pharma Greenville as a Reference product (R).

### *Clinical Study Designs*

An open-label, balanced, randomized, two-treatment, two-sequence, two-period, two-way crossover, single dose oral bioavailability study was conducted in healthy, adult, human male subjects under fed conditions. Thirty-six subjects were enrolled for this study and there was a washout period of 10 days between the successive dosing of the study. Test product 'T' and Reference product 'R' were administered to each subject during both the periods of the study using two sequences (RT and TR). These two sequences were determined according to a SAS® software (version 9.4) generated randomization schedule.

After an overnight fast of at least 10 hours, in the morning subjects received high-fat, high-calorie, non-veg breakfast 30 minutes prior to dosing. Either of the study drug, allocated as per the randomization schedule, was administered orally to each subject in a sitting position with approximately 240 mL of water followed by a thorough mouth check to ensure that the drug was swallowed completely.

A total of 22 blood samples per subject were collected at scheduled sampling points as; pre-dose (0 hour) blood sample within 02 hours prior to high-fat, high-calorie, non-veg breakfast and post-dose blood samples at 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 10, 12, 18, 24, 36, 48, 72 and 96 hours in pre-labelled K2EDTA – vacutainers via an indwelling cannula placed in one of the forearm veins of the subjects. The concentrations of ITZ and Hydroxy-itraconazole (OH-ITZ) in plasma were measured by high-performance liquid chromatography-tandem mass spectrometry (HPLC-MS/MS).

All subjects were evaluated for the frequency and severity of adverse events (AEs) to determine the safety of the formulations. All treatment related adverse events (TEAEs) were reported with respect to severity, duration, relationship to study drugs and action taken. Vital signs measurements (Pulse Rate [PR], Respiration Rate [RR], Blood Pressure [BP] and temperature) along with a physical examination, Electrocardiogram (ECG) recordings, clinical laboratory tests (liver and kidney function tests) were performed.

### Statistical Analysis

Pharmacokinetic (PK) parameters were estimated using  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  as primary parameters and  $T_{max}$ ,  $K_{el}$ ,  $T_{1/2}$  and  $AUC_{Extrapolation}$  as secondary parameters. Statistical analysis was done using SAS® Software version 9.4 or higher of SAS Institute Inc., USA. PROC GLM procedure of SAS was followed for the log-transformed pharmacokinetic parameters  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  for ITZ [Test (T) vs. Reference (R)] and its active metabolite, OH-ITZ using ANOVA.

The Intra subject variability, Power, Ratio analysis and its 90% Confidence Interval (90% CI) were computed for log-transformed pharmacokinetic parameters  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  for ITZ (Test (T) vs. Reference (R)). For the metabolite, OH-ITZ, individual and mean concentrations, individual and mean pharmacokinetic parameters and geometric means and ratios of means for  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  were calculated as supportive data.

Assessment of bioequivalence was done on the basis of the 90% CIs of the differences of least squares treatment means for Ln-transformed  $C_{max}$  and  $AUC_{0-t}$  of ITZ obtained after single-dose administration under fed conditions for Test (T) vs. Reference (R). The acceptance criteria for bioequivalence were considered as 80% - 125%.

## Results

### Demographic and Other Baseline Characteristics

All the subjects admitted into the study fulfilled the inclusion criteria and exclusion criteria. All the subjects were of normal health based on general physical examination and laboratory test reports. None of the subjects had any relevant or significant previous medical history that could affect the study results. A total of 33 subjects were completed the clinical phase of the study and 33 subjects considered for PK and statistical analysis (Table 1).

|                                          |                              |
|------------------------------------------|------------------------------|
| <b>N</b>                                 | 33                           |
| <b>Male N (%)</b>                        | 100%                         |
| <b>Mean age (years); SD</b>              | 35.4 ± 5.46 (20 - 44)        |
| <b>Mean height (m); SD</b>               | 1.67 ± 0.06 (1.5-1.7)        |
| <b>Mean weight (kg); SD</b>              | 68.9 ± 8.71 (52-85)          |
| <b>BMI (kg/m<sup>2</sup>); Mean ± SD</b> | 24.72 ± 2.70 (18.82 - 29.06) |

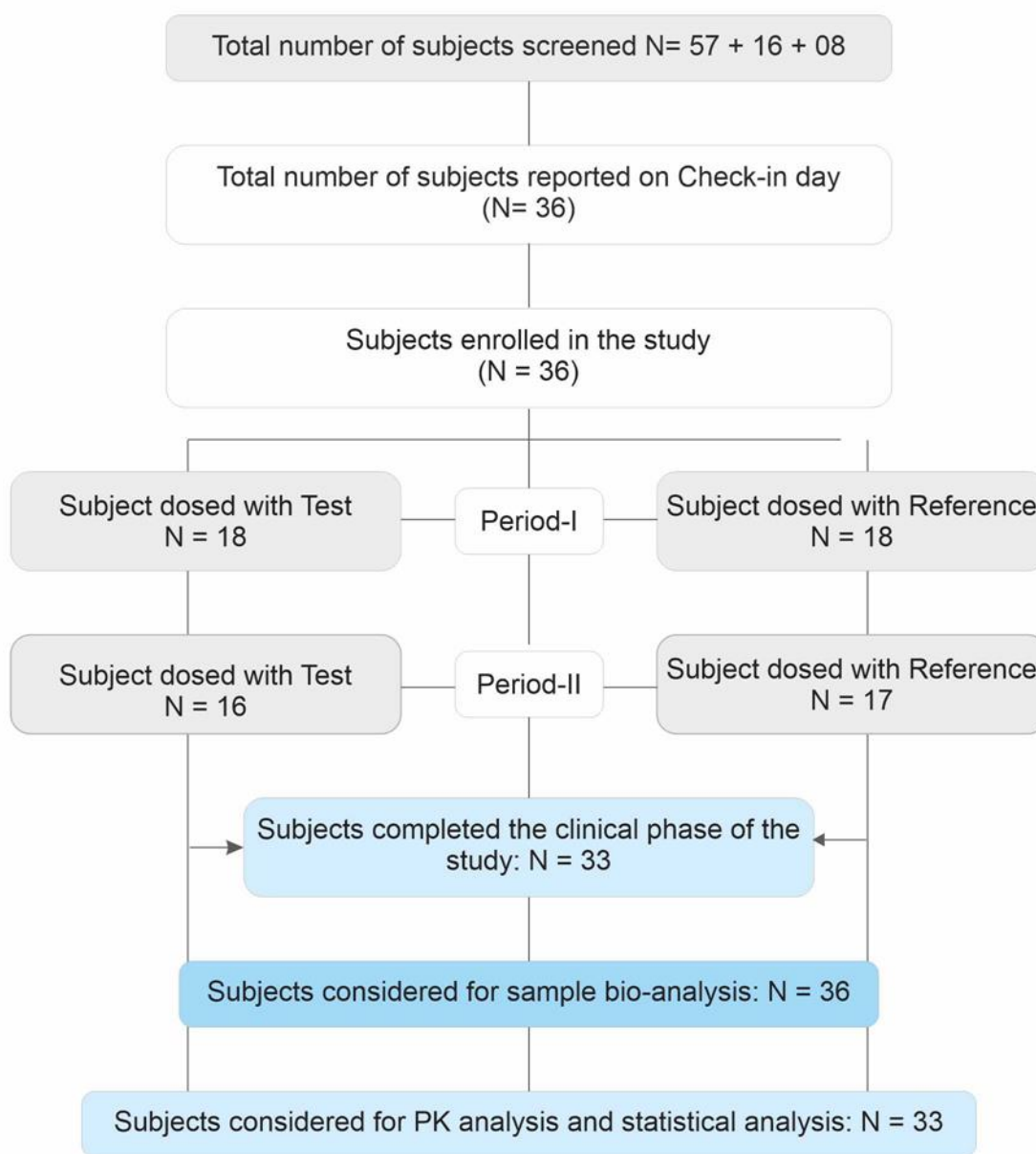
**Table 1:** Demographic information for subjects.

The results of the PK and statistical analyses for ITZ and OH-ITZ are shown in Table 2. The mean value of the area under curve ( $AUC_{(0-t)}$ ) of test drug (SITZ 130 mg) was 4604.98 ng.hr/mL whereas for reference drug (SITZ, 2 x 65 mg), it was 4812.04 ng.hr/mL. Administration of test drug was found to have 95.70%  $AUC_{(0-t)}$  for ITZ compared to reference drug which was non-significant.

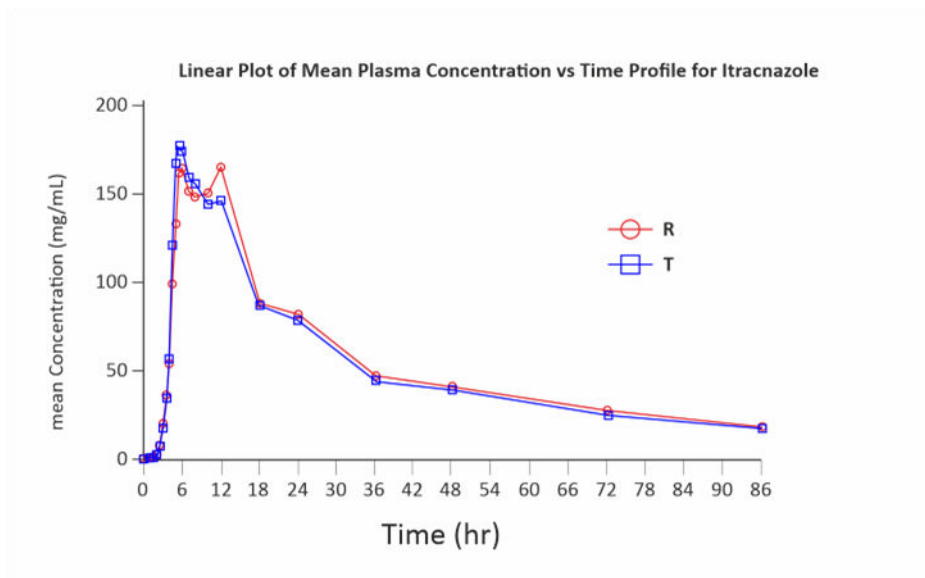
The geometric mean maximum peak concentration of drug ( $C_{max}$ ) for test drug was 229.39 ng/mL ITZ, which was about 5% higher than the ITZ level of 219.26 ng/ml reached with reference drug. The PK parameters for OH-ITZ measured from both formulations followed a pattern in terms of bioavailability similar to that for the ITZ plasma blood levels for the test/reference ratios for  $C_{max}$  (100.88%) and  $AUC_{(0-t)}$  (97.44%) (Table 2). All PK parameters were within the 90% Confidence Interval (CI). Fig. 1 shows mean concentration of ITZ (ng/mL) of both the drugs against different time intervals whereas Fig. 2 depicts the same for OH-ITZ (Fig. 3, Table 3).

|                          | Results for ITZ       |           |               |              | Results for OH-ITZ    |           |               |              |
|--------------------------|-----------------------|-----------|---------------|--------------|-----------------------|-----------|---------------|--------------|
|                          | Geometric mean values |           |               |              | Geometric mean values |           |               |              |
| Parameter                | Test                  | Reference | T/R Ratio (%) | 90% CI       | Test                  | Reference | T/R Ratio (%) | 90% CI       |
| $C_{\max}$ (ng/mL)       | 229.39                | 219.26    | 104.62        | 93.19-117.46 | 241.58                | 239.47    | 100.88        | 95.15-106.96 |
| $AUC_{(0-t)}$ (ng.hr/mL) | 4604.98               | 4812.04   | 95.7          | 87.98-104.09 | 9215.89               | 9457.53   | 97.44         | 89.77-105.78 |

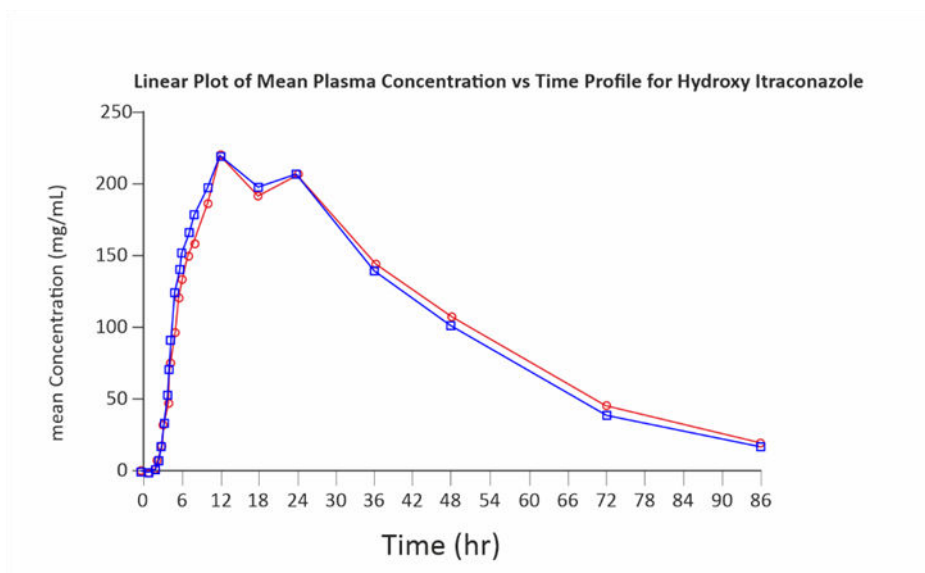
**Table 2:** Pharmacokinetic (PK) and statistical analyses of itraconazole and hydroxyitraconazole.



**Figure 1:** Flow chart of the study.



**Figure 2:** Linear plot of mean plasma concentration vs time profile for itraconazole.



**Figure 3:** Linear plot of mean plasma concentration vs time profile for Hydroxy-itraconazole.

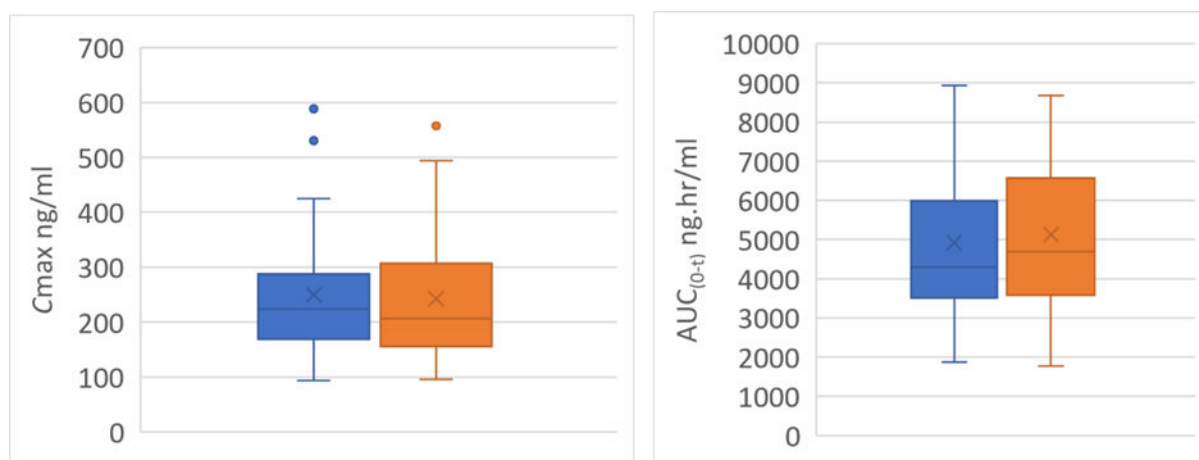
| <b>Itraconazole</b>           | <b>Mean (SD)</b>  |                    |               |
|-------------------------------|-------------------|--------------------|---------------|
| Variable                      | Test (T)          | Reference (R)      | Ratio T/R (%) |
| $C_{max}$ (ng/mL)             | 249.34 ± 111.63   | 242.55 ± 115.12    | 111.71        |
| $AUC_{(0-t)}$ (ng.hr/mL)      | 4922.36 ± 1878.01 | 5124.25 ± 1771.96  | 99.6          |
| $AUC_{(0-\infty)}$ (ng.hr/mL) | 6040.24 ± 2317.74 | 6442.72 ± 2718.37  | 100.78        |
| $T_{1/2}$ (hr.)               | 42.37 ± 15.81     | 43.98 ± 21.55      | 101.75        |
| $T_{max}$ (hr.)               | 7.88 ± 3.34       | 9.12 ± 5.03        | 95.56         |
| $K_{el}$ (1/hr.)              | 0.02 ± 0.01       | 0.02 ± 0.01        | 106           |
| % $AUC_{Extrapolated}$ (%)    | 17.75 ± 8.18      | 17.86 ± 9.75       | 109.08        |
| <b>Hydroxy-itraconazole</b>   | <b>Mean (SD)</b>  |                    |               |
| Variable                      | Test (T)          | Reference (R)      | Ratio T/R (%) |
| $C_{max}$ (ng/mL)             | 249.84 ± 66.30    | 246.26 ± 57.89     | 102.62        |
| $AUC_{(0-t)}$ (ng.hr/mL)      | 9820.02 ± 3562.82 | 10004.53 ± 3272.70 | 100.99        |

|                                                                                                                                                                                                                                                                                                                                                     |                    |                    |        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|--------|
| AUC (0-∞) (ng.hr/mL)                                                                                                                                                                                                                                                                                                                                | 10382.57 ± 3981.70 | 10716.39 ± 3798.45 | 100.34 |
| T <sub>1/2</sub> (hr.)                                                                                                                                                                                                                                                                                                                              | 18.41 ± 5.29       | 19.17 ± 6.88       | 100.4  |
| T <sub>max</sub> (hr.)                                                                                                                                                                                                                                                                                                                              | 12.39 ± 4.78       | 14.17 ± 6.25       | 99.69  |
| K <sub>el</sub> (1/hr.)                                                                                                                                                                                                                                                                                                                             | 0.04 ± 0.01        | 0.04 ± 0.02        | 104.03 |
| %AUC <sub>Extrapolated</sub> (%)                                                                                                                                                                                                                                                                                                                    | 4.76 ± 3.41        | 5.75 ± 4.62        | 113.33 |
| SD: Standard Deviation; C <sub>max</sub> : maximum concentration; AUC <sub>(0-t)</sub> : Area under the concentration-time curve over the dosing interval; AUC (0-∞): Area under the curve to infinity; T <sub>1/2</sub> : Terminal half-life; T <sub>max</sub> : Time of maximum observed concentration; K <sub>el</sub> : Terminal rate constant. |                    |                    |        |

**Table 3:** Mean pharmacokinetic parameters for test and reference drugs for itraconazole and hydroxyl-itraconazole.

The mean pharmacokinetic parameters for test and reference drugs for ITZ and OH-ITZ are summarized in Table 3. Hydroxyitraconazole data was analysed statistically and used only as supportive data.

Subjects crossed over from one period of administration of either test or reference drugs to a second period with dosing with the opposite drug. Eighteen of 33 and 16 of 33 healthy subjects administered test drug attained higher C<sub>max</sub> and AUC<sub>(0-t)</sub> values, respectively for ITZ, than the same subjects administered reference drug in this study (Fig. 3,4). Whisker plots showed mixed values for both the parameters when subjects were administered either of the drugs.



**Figure 4:** Crossover PK data for the geometric mean plasma C<sub>max</sub> (left) and AUC<sub>(0-t)</sub> (right) values for itraconazole achieved with test and reference drugs. Data are represented as whisker plots for both the groups.

#### Safety and Tolerability

The administration of both the drugs were well tolerated by all the subjects with reporting of no adverse events with either of the drugs.

#### Discussion

Bioequivalence studies form an essential core in the development of new drug [6,7]. According to United States Food and Drug Administration (US FDA) and Central Drugs Standard Control Organization (CDSCO), two drugs are considered bioequivalent if 90% CI of Geometric Mean Ratio (GMR) of primary PK (C<sub>max</sub>, AUC<sub>(0-t)</sub>) variables fall within the range of 80%-125% [8,9]. As per the European Medicines Agency (EMA) and CDSCO guidelines, a randomized, two period, two sequence, single dose, crossover design must be used for the comparison of two drug formulations. The current study was conducted in accordance with CDSCO recommendations [9,10]. In bioequivalence study, CDSCO recommends a washout interval which should ideally be equal to or more than 5 half-lives of the moieties to be measured [9]. Similarly, in our study to avoid any residual or carry over effect, a washout period of 10 days between period I and period II was considered.

In 1992, Conventional Itraconazole (CITZ) was approved for systemic fungal infection which was the first mold-active oral azole [11,12]. However, this formulation has a limited bioavailability of 55% in dissolved form and must be taken with a complete meal

or with an acidic beverage. An oral solution of ITZ was developed and approved in 1997 to overcome these issues [13]. Though this oral solution had no food interaction but still absolute bioavailability remained to only about 72% and many patients found this solution unpalatable [11]. Finally, in 2014, super-bioavailable itraconazole; SUBA®-itraconazole was developed and approved to solve these issues which provided a more consistent ITZ concentration. Moreover, this formulation was food independent and was less affected by gastric acid-suppressive agents.

In the current study, geometric mean of  $C_{max}$  of test drug was 104.62% and 100.88% of reference drug for ITZ and OH-ITZ respectively while in case of  $AUC_{(0-t)}$ , it was 95.70% and 97.44% for ITZ and OH-ITZ respectively. Statistical analysis of these PK variables revealed bioequivalence, with CIs being completely inside the acceptance criteria of 80-125% as suggested by CDSCO [9]. Following administration of test and reference drugs, the peak concentration levels of itraconazole were achieved at 8 h and 9 h, respectively. Other parameters including  $C_{max}$ ,  $K_{el}$  and  $T_{1/2}$  for test and reference product compared well and were within bioequivalence criteria.

Bioavailability of a drug is defined as the extent and rate to which the active drug ingredient or active moiety from the drug product is absorbed and becomes available at the site of drug action. In addition, for the efficacy of any anti-fungal drugs, its AUC/MIC ratio should be correlated [7]. In a recently published clinical study, SITZ 130 mg was found to be bioequivalent to CITZ 200 mg once daily dosing. This indicates that similar therapeutic effect was proven with almost 35% lesser drug as compared to CITZ [1]. With regards to safety, from this study, the test drug was found to be safe and well tolerated which is in line with historical data [7].

## Conclusion

The test drug, Itraconazole Capsules 130 mg of Glenmark Pharmaceuticals Ltd. was found to be bioequivalent with the reference drug, TOLSURA® (Itraconazole capsules) 130 mg (2x 65 mg) of Mayne Pharma Greenville, under fed conditions. The pharmacokinetics activity is comparable between test product at 130 mg dose and reference product of innovator itraconazole 130 mg (2x 65 mg). In addition, it was found to be safe and well tolerated with no adverse effects.

## Conflicts of Interests

The authors declare that there is no conflict of interest for this paper.

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