Bioequivalence study of YSP Allopurinol tablet 300mg vs. the comparator, Zyloric tablet 300mg in a fasted state

Muzakkin Dewiveramartika[1], Rajan Enis Mudiliar[1], Nair Damenthi[1], Cheah Kit Yee[1], Shahridzo Siti Halimah[1], Goh Chen Zhu[2], Choo Siek Nee[2], Tan Yvonne Tze Fung[2]

[1]Clinical Research Ward, Centre for Clinical Trial, Hospital Ampang, [2]Bioxis Sdn. Bhd., Pulau Pinang

ABSTRACT

Introduction: Allopurinol is a xanthine-oxidase inhibitor primarily known for the treatment of gout. This study aims to establish the bioequivalence of the test product (YSP Allopurinol tablet) and its comparator (Zyloric Tablet). **Methods:** An open-label, single dose, randomised, two-period, two-treatment, two-sequence, crossover study was conducted under fasted conditions. Subjects were given the investigational product to swallow whole with 240ml of water, with a mouth check performed after dosing. The plasma concentration of allopurinol was measured using a validated liquid chromatography-tandem mass spectrometry (LCMSMS) method over 10 hours. Pharmacokinetic parameters AUC0-∞, AUC0-t and Cmax were determined using plasma concentration-time profiles for both preparations. Bioequivalence was evaluated based on the ASEAN guideline acceptance criteria for bioequivalence. Data acquisition and analysis were performed using the SAS package (Version 9.3, SAS Institute Inc, USA). **Results:** Thirty healthy Malay males with a mean age of 25 (SD 4.8) years old were enrolled; 27 subjects completed the trial. ANOVA analysis showed no significant differences between the AUC0-t, AUC0-∞ and Cmax for both test and reference preparation in fasted conditions. The 90% confidence intervals (CI) for the ratio of AUC0-t, (0.9161-10-.0342), AUC0-∞ (0.9030-1.0267) and Cmax (0.8213-1.0303) for Zyloric tablet over YSP Allopurinol tablet were all fell within the bioequivalence acceptance range (0.8000-1.2500). The adverse events reported, such as fever and runny nose, were unlikely to be related to the study drug. **Conclusion:** In conclusion, YSP Allopurinol tablet is bioequivalent to Zyloric tablet under fasted conditions and can be used interchangeably for the treatment of gout.