P8 BIOEQUIVALENCE STUDY OF CEFOPERAZONE AND SULBACTAM INTRAMUSCULAR INJECTION

Taesotikul W[1], Kaewvichit S[1], Niwatananun W[1], Thongsawat S[2], Daungrat C[1]

[1]*Faculty of Pharmacy,* [2]*Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand*

The objective of this study is to perform a bioequivalence study of cefoperazone and sulbactam between Sulcef® injection (Siam Pharmaceutical Co. Ltd., Thailand) and Sulperazone® injection (Pfizer), the innocator product. The study was performed in 24 Thai healthy male volunteers who intramuscularly received a single dose of 1.0 g cefoperazone and sulbactam injection (0.5 g of cefoperazone and 0.5 g of sulbactam). Double blind randomized cross-over design was used. Blood samples were collected before and after intramuscular injection for 12 hours and determined for cefoperazone and sulbactam plasma concentration by validated HPLC methods. (Accuracy, Precision, Specificity, %Recovery, Linearity, Stability)

When statistics were tested as stated in USP 28 guideline for bioequivalence study, US- FDA guideline 2004 and validated HPLC methods: 90% confidence interval of the log of ratio of either C_{max} or AUC_{last} or AUC_{inf} of both cefoperazone and sulbactam between Sulcef® and Sulperazone® injection were within the range of 0.80-1.25. Therefore, it can be indicated that the 1.0 g cefoperazone and sulbactam injection of Sulcef® and Sulperazone® used in this study are bioequivalent.