
Joint Statistics Seminar

The Hong Kong University of Science and Technology

Bioequivalence : Concepts and Statistical Assessment

by

Professor Sang-Gue Park

Chung-Ang University

Date: May 11, 2007 (Friday)

Time: 4:00 p.m. - 5:00 p.m.

Venue: Room 2406 (Lift 17/18)

Abstract

As more generic drug products become available in the marketplace, it is of great concern whether a number of generic drug products of the same brand-name drug can be used safely and interchangeably. Drug interchangeability can be classified as drug prescribability or drug switchability. Drug prescribability is defined as the physician's choice for prescribing an appropriate drug product for his/her new patients between a brand-name drug product and a number of generic drug products of the brand-name product which have been shown to be bioequivalent to the brand-name drug product. Drug switchability is related to the switch from a drug product to an alternative drug product within the same subject whose concentration of the drug product has been titrated to a steady, efficacious, and safe level. In 1997, US FDA adopted several concepts of BE, so-called average bioequivalence (ABE), population bioequivalence (PBE) as drug prescribability, Individual bioequivalence (IBE) as drug switchability and released the guidance of BE study in 2001. Statistical meanings of those BE concepts models are reviewed and current issues about those concepts and assessment methods discussed.

❖ All interested are welcome! ❖

For details, please contact ISMT Department.