



Novel approaches of bioavailability and bioequivalence studies

Barbara M. Davit

Center for Drug Evaluation and Research,
US-FDA, USA

The US-FDA's regulations define bioequivalence as the lack of a significant difference in the rate and extent to which a drug becomes available at the site of action when administered at the same dose under similar conditions in an appropriately designed study. For systemically active drugs, bioequivalence between a test and reference product is generally determined in an *in vivo* bioequivalence study in which drug rate and extent of absorption are determined from plasma pharmacokinetic profiles. However, bioequivalence evaluation is more challenging for drug products intended for local activity, such as drugs to treat diseases of the gastrointestinal (GI) tract. This presentation will address the use of studies with pharmacodynamic, clinical, and / or *in vitro* endpoints to determine bioequivalence of locally-acting GI drug products. Several case studies will be presented to illustrate the application of these various novel bioequivalence approaches.

Biography

Dr. Barbara Davit completed her Ph.D from the University of California, Davis, and postdoctoral studies from the California Primate Research Center. Dr. Davit also holds a law degree from George Mason University School of Law. Dr. Davit is currently the Acting Director of the Division of Bioequivalence 2 in the Office of Generic Drugs, CDER, US-FDA. Her Division of 40 scientists reviews bioequivalence studies for generic versions of neuropharmacological drugs, antiviral and antibiotic drugs, cardiovascular drugs, analgesics, and locally-acting drugs to treat GI diseases. She has published over 25 peer-reviewed articles and given over 100 invited presentations.