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Pre-clinical strategies to predict the Bioavailability/ Bioequivalence studies

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The approval at a Bioavailability/Bioequivalence Studies is a key component in the evaluation for generic drug products. The dissimilar drug blood levels caused mainly by impaired absorption were correlated successfully to reproach in these studies. For the development of efficacious oral drug delivery systems the estimation of oral drug absorption in human based on in vitro and in vivo animal studies is of considerable importance. During the last years, an extensive formulation screening has gained increasing attention after it became evident that decrease the failure bioequivalence risk. The association of well-made characterization of drug, the relevant dissolution profile test and permeability assay gains the maximal information from which factors could have an impact on the oral bioavailability. Although the cost and the ethics aspects bioavailability testing in animals can be an alternative to predict the bioequivalence. The presentation will cover the correlation, when possible, between in vivo bioavailability data of some drugs examples classified by Biopharmaceutical Classification system (BCS) as class I, II, III and IV. Application of the animal (rat) model for the assessment of bioequivalence will be described and the predict error for relevant pharmacokinetic parameters will be discussed. Finally the presented correlations encourage the use of the rat model for the prediction of human oral bioavailability of drug in addition of biorelevant dissolution testing.

Biography

Josélia Larger Manfio has been studied his Ph.D at School of Pharmaceutical Sciences from University of São Paulo (USP). She is the director of Biocinese Biopharmaceutical Studies Center, a premier Bioequivalence Center of South Brazil. She has published more than 15 papers and serving as a reviewer member in reputed journals. In this role she leads a group of research investigators responsible for equivalence, bioequivalence and pharmacokinetics assessment of several molecules. She began her career at Prati,Donaduzzi (Brazilian Pharmaceutical Company) were she held several positions of increasing responsibility in different areas as quality control, assurance affairs, research and development, and finally served as director of Biocinese. In the Biopharmaceutical Studies Center she concluded more than 500 studies of equivalence and bioequivalence.