International Conference & Exihibition on
Analytical and Bioanalytical Techniques 2010
ANANBIOANAL - 2010
Pharmaceutical R & D Summit
doi:10.4172/2155-9872.1000100

Preformulation Challenges and Advices to Obtain the Bioavailability and Bioequivalence Studies of Pharmaceuticals

Josélia Larger Manfio

Biocinese – Biopharmaceutical Studies Center, Toledo, Brazil

Actually the approval at a Bioavailability/Bioequivalence Studies is a great challenge after a development of Pharmaceuticals. In many instances, the reproach in these studies were correlated successfully to dissimilar drug blood levels caused mainly by impaired absorption. A biopharmaceutical assessment of drug substance is crucial in generic drug product development. An extensive formulation screening has gained increasing attention during the last years after it became evident that decrease the failure bioequivalence risk. Bonding, binding, isomerism and polymorphism (dissolution behavior) are important processes that influence that activity and elimination of many drugs. The identification, characterization and quantification of crystal forms are becoming increasingly important within the pharmaceutical industry. A combination of different physical analytical techniques (as differencial scanning calorimetry, for instance) is usually necessary for this task. Herein a drug categorization according to the biopharmaceutical classification system (BCS) is helpful. The drug solubility in indifferent systems and the permeability assays are very important determinations at characterization of drug substance. In light of the FDA's recent guidances, there is an increased awareness of the potential relevance of dissolution tests but also realizes the need for individualizing the method on a case by case. The evaluation of dissolution profiles changing the media to obtain a pH gradient or simulate fed and fasted conditions may be a tool for predicting bioavailability, and in some cases, replace clinical studies to determine bioequivalence. The permeability assay is considered to be the development gold standard for in vitro prediction of in vivo human intestinal permeability and bioavailability of orally administered drugs (as Caco-2 cells). Although the cost and the ethics aspects bioavailability testing in animals can be an alternative to predict the bioequivalence. 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.