



International Conference & Exhibition Bioequivalence and Bioavailability 2010

doi:10.4172/0975-0851.1000055

TITLE

ASSURING BIOEQUIVALENCE: PILOT STUDIES OR DISSOLUTION?

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Development of generic oral solid dosage forms that are equivalent to the innovator approved formulation is a challenging task for companies. As NCE development gets more expensive and time-consuming, innovators focus not just on getting a safe and effective drugs into the market but take into account the entire life cycle of the product. In many cases, this leads to complicated formulations, regimens and delivery systems to increase the barrier to generic competition. One of the tools that can be used by generic formulators is dissolution testing as an early predictor of in vivo performance. Dissolution testing is used in the drug development phase, both for new chemical entities (NCEs) and generic products, but can also be used as a tool for evaluating product quality. Variability issues and lack of scientific understanding of critical product attributes essential for bioequivalence have led to an excessive reliance on in vivo bioequivalence testing as the final proof of product performance. The proliferation of contract research organizations (CROs) in India undertaking studies on healthy human volunteers for the testing of bioequivalence between pharmaceutical formulations is proof to this development. Easy availability of volunteers and quick turnaround of results at a low price has led to indiscriminate use of humans as surrogates for evaluating pharmaceutical formulations, instead of dissolution testing being used as a surrogate to provide indirect assurance of in vivo performance. The regulatory requirement to submit failed BE studies as part of ANDAs may have an impact on the prevalent practice.