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Bioavailability and bioequivalence studies and researches in Nepal: The challenges and opportunities

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ccording to Nepalese Medicine Registration Guidance 2016, comparative in vivo bioequivalence study is necessary for oral products, locally applied; but systemically acting products, non-oral immediate release forms with systemic action, modified release products, transdermal products and those products which have narrow therapeutic index, low bioavailability, nonlinear kinetics and poor dissolution profile. BABE-study and research in Nepal was first started in 2005 by Department of Pharmacy, Kathmandu University with establishment of Bioavailability and Bioequivalence Study Center (only one in the country) in collaboration with Nepal Pharmaceutical Lab (Pvt.) Ltd. After the establishment of this center, some bioavailability and bioequivalence studies and researches were carried in collaboration with Nepal Pharmaceutical Lab (Pvt.) Ltd. and Kathmandu University Teaching Hospital. Some of these studies were of Ofloxacin Immediate Release Tablet (2008), Sodium Valproate and Valproic Acid Tablet (2010) and Ofloxacin Gastro Retentive Controlled Release Tablet (2011) in healthy human volunteers (2011). In these studies, bioanalytical method development and sample analysis were done in the Bioavailability and Bioequivalence Study Center whereas clinical part was done in Kathmandu University Teaching Hospital. The ethical approval of these studies was granted by the ethical review board (ERB) of Nepal Health Research Council. In Nepal only, few pharmaceuticals have done the BABE-studies as per the decision of DDA due to limited resources and experts, high cost involved in design of BABE-study bioanalytical laboratory, not mandatory for domestic generic products, weak monitoring of authorities, noncompliance with US FDA, WHO and others regulatory authorities' requirements. Whereas, due to cheap manpower, easy availability of huge number of native heterogenous Caucasian volunteers and weak legal and regulatory barriers Nepal could be potential center for global pharmaceuticals for BABE-studies and researches.

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