



Non clinical studies in development of new drug delivery technologies; are they predictive or indicative?

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Abstract:

Increasing demand in new and complex delivery technologies for differentiated formulations urges to identify early indicative or predictive non clinical methods. Predicting in-vivo performance of dosage forms is critical to the development of new drug delivery approaches. Physiological factors that influence in-vivo performance of formulations include gastrointestinal condition, mechanical stress, effects of food, enzymatic or pH related degradation of drug and its excipients, in-vivo drug release profile and the direct influence of some excipients on drug metabolism and transport etc. Practicality of non-clinical studies during product development is discussed with case studies on novel oral lipid based formulations, nasal sprays and long acting depot formulations. Absorption studies in animal models are discussed on early stage formulations. Primary pharmacokinetic parameters of interests; partial AUCs [e.g. (AUC_{0-15min}), (AUC_{0-30min}), (AUC_{0-60min}) etc.] , AUC from baseline through T_{max} of reference products (AUC_{0-RefTmax}), relative percentage of AUC_{0-T} with respect to reference exposure values and C_{max} were evaluated to rank order various formulation approaches. Translation of preclinical pharmacokinetic parameters and dosage form performance in humans are also discussed. Pharmacokinetics studies in appropriate animal models provide useful insights for further formulation development and help in minimizing both development-time and risks.



Biography:

Bijay Kumar Padhi has completed his PhD from The M.S. University of Baroda, INDIA on Pharmaceutics and Drug Delivery. He is the Associate Vice President and Head Formulation R&D at Unichem Laboratories Limited, INDIA. He has more than 18 years of industrial and research experience in formulation and drug delivery. He is the inventor for 5 USA granted patents, 1 Australian patent and more than 20 patent pending applications.

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Citation: Bijay Kumar Padhi; Non clinical studies in development of new drug delivery technologies; are they predictive or indicative?; Webinar on Pharmaceutical Sciences, November 30,2020, Rome, Itly.