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

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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. (AUC0-15min), (AUC0-30min), (AUC0-60min) etc.] , AUC from baseline through Tmax of reference products (AUC0-RefTmax), relative percentage of AUC0-T with respect to reference exposure values and Cmax 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.