

## Non Clinical Studies in Development of New Drug Delivery Technologies; Are they Predictive or Indicative?

Bijay Kumar Padhi  
Unichem Laboratories Limited, INDIA



### 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 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<sub>0-15min</sub>), (AUC<sub>0-30min</sub>), (AUC<sub>0-60min</sub>) etc] , AUC from baseline through T<sub>max</sub> of reference products (AUC<sub>0-RefT<sub>max</sub></sub>), relative percentage of AUC<sub>0-T</sub> with respect to reference exposure values and C<sub>max</sub> were evaluated to rank order various formulation approaches. Translation of preclinical pharmacokinetic parameters and dosage form performance in humans also discussed. Pharmacokinetics studies in appropriate animal models provides useful insights for further formulation development and help in minimizing both development time and risks.

in formulation and drug delivery. He is the inventor for 5 USA granted patents, 1 Australian patent and more than 20 patent pending applications. He has authored more than 11 research publications in reputed journals

### Speaker Publications:

1. Aerosol Performance of Large Respirable Particles of Amikacin Sulfate Produced by Spray and Freeze Drying Techniques; Current Drug Delivery/Volume 6/Issue1
2. Development of Spray Dried Liposomal Dry Powder Inhaler of Dapsone; AAPS PharmSciTech/Volume 9/Issue1
3. Nano-liposomal dry powder inhaler of tacrolimus: Preparation, characterization, and pulmonary pharmacokinetics; International Journal of Nanomedicine/Volume 2/Issue4
4. Nano-Liposomal Dry Powder Inhaler of Amiloride Hydrochloride; Journal of Nanoscience and Nanotechnology/Volume 6/Issue9
5. Clobetasol propionate solid lipid nanoparticles cream for effective treatment of eczema: Formulation and clinical implications; Indian journal of experimental biology/Volume 43/Issue3

[19th Annual Congress on Pharmaceutics & Drug Delivery Systems](#) June 18-19, 2020 Webinar

### Abstract Citation:

Bijay Kumar Padhi, Non Clinical Studies in Development of New Drug Delivery Technologies; Are they Predictive or Indicative?, Euro Pharmaceutics 2020, 19th Annual Congress on Pharmaceutics & Drug Delivery Systems June 18-19, 2020 Webinar

(<https://pharmaceutics.annualcongress.com/abstract/2020/non-clinical-studies-in-development-of-new-drug-delivery-technologies-are-they-predictive-or-indicative>)



### 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