Hello Sir,

This is ----------, India. My Project work is based on IVIVC of a novel bronchodilator drug. So far, i have worked on its Pre-formulation Studies, BCS - Class establishment , Analytical & Bio-analytical Method Development & Pharmacokinetic study in rats . I have read several articles on IVIVC and could only learn that i need to compare plasma-conc vs time profile with the dissolution profile. But, your article published in the open drug delivery journal ,2010,4, 38-47 titled " In Vitro-In Vivo Correlation (IVIVC) and Determining Drug Concentrations In Blood From Dissolution Testing - A Simple and Practical Approach "was a deeper insight into the topic and actually illustrates how can we make use of Convolution Techniques for IVIVC Establishment.

I have some queries regarding my project , I would be highly obliged if you could take some time out of your busy schedule to answer these.

a) Pharmacokinetic- Studies are done in rats only taking rat dose. No human studies are done so far. Although i have calculated Human Equivalent Dose using formula provided by USFDA on choosing first dose for clinical trials.

You have very clearly mentioned in the article dose of the drug should not be changed.

My Question is : which dose should i choose for dissolution method development , dose given to rats or its Human Equivalent Dose (right now i do not have the provision to go for its Human Pharmacokinetic Studies)

b) Solid Dosage forms are considered as ideal for IVIVC and I have administered drug to the animal in the suspension form , Should i convert the same dose to pellet/ tablet for dissolution studies or may use suspension only (with rat or human dose)

The purpose of IVIVC here is not Bioequivalence Study but to assist in Pharmaceutical Product Development before Clinical Trials.

Hope you reply to these doubts sir !

With Regards!

