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Application of pharmacokinetics and dissolution tests to the prediction of *In-Vivo* performance of an oral sustained-release pellet dosage form

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Successful generic drug development needs a holistic approach of adequate pharmacokinetic knowledge of the molecule. Prediction of pharmacokinetic behavior at the early stage of drug development could be more beneficial for mitigating unsuccessful outcome. The major obstacle in making such predictions is the inability to correlate the *In vitro* data to the *In vivo* data. Key formulation variables like polymer selection and its coating and other scale up parameters are most critical factors influencing the success of the generic formulations. The presentation is designed to provide establishing relationships between different level of Eudragit RS 30D polymer coating (5%, 6% and 7%) and the effect of batch size (120 gm vs 1.200 kg), on pharmacokinetics of BCS Class 2 Sustained Release Capsules. The data from bioavailability study was used to construct *In vitro* and *in vivo* correlation. Appropriate dissolution methods and study designs for in-vivo outcome were used to predict better IVIVC. Results demonstrated that, increase in polymer coating concentration showed delay in the release rate and decrease in obtained C_{max} and AUC values. The results evidencing that the reasonable influence of scale-up effects on bioavailability during 10 X scale-up employing similar equipment.

Thus, characterizing some of the critical formulation variables in advance will definitely reduce the number of pharmacokinetic studies using healthy human subjects and also development time and cost in R&D establishment of generic players.

Biography

Ravisekhar Kasibhatta has completed his Ph.D. from Nizam's Institute of Medical Sciences, Hyderabad, India. He is currently working as Vice President of Lupin Bioresearch Center, Pune, India a division of Lupin Ltd, India. He has published about 25 papers in reputed journals and recognized guide of Ph.D. programme in couple of universities in India in Pharmaceutical Sciences.

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