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Pharmaceutical absorption modeling - A new approach in formulation development

Z. Jane Li
Boehringer Ingelheim Pharmaceuticals, USA

One of the keys in developing a viable drug product (DP) is to achieve the desired performance profile such as target bioavailability and/or bioequivalence. Pharmaceutical (dosage form) Absorption Modeling is a new approach to integrate API, dissolution testing and *in vivo* performance for formulation selection in achieving the target performance profile. Gastro Plus has been a modeling tool to simulate selected formulation factors and a new tool, dynamic dissolution and permeation model is under development to enhance features in simulating the API and formulation variables to develop a bio-relevant dissolution testing method for formulation selection and prediction of *in vivo* performance. Modeling of pharmaceutical absorption enables development and selection of formulations which will be science-based and performance driven to attain a greater confidence in the clinical trial outcome and reduce the time and cost in DP development. In this seminar, Pharmaceutical Absorption Modeling will be introduced and case studies will be given to illustrate its application to guide in drug product development.

Biography

Z. Jane Li is a Sr. Research Fellow at Boehringer Ingelheim Pharmaceuticals in Ridgefield, Connecticut, US. She has earned her Ph.D. in Pharmaceutics from University of Minnesota and had over 20 years experience in pharmaceutical R&D. Her research interests and expertise include solid-state pharmaceuticals (polymorphs, salt/cocrystals), biopharmaceutics, process induced phase transformation and material characterization. She has published more than 30 publications in research papers and patents, and is recognized as an expert in solid-state pharmaceuticals.

jane.li@boehringer-ingelheim.com