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Dissolution testing for generic drugs: An FDA perspective

Om Anand

CDER-Food and Drug Administration, USA

In vitro dissolution testing is an important tool used for development and approval of generic dosage forms. The objective of this presentation is to summarize how dissolution testing is used for the approval of safe and effective generic drug products in the United States (US). Dissolution testing is routinely used for stability and quality control purposes for both oral and non-oral dosage forms. The dissolution method should be developed using an appropriate validated method depending on the dosage form. There are several ways in which dissolution testing plays a pivotal role in regulatory decision-making. It may be used to waive *in vivo* bioequivalence (BE) study requirements, as BE documentation for Scale Up and Post Approval Changes (SUPAC), and to predict the potential for a modified-release (MR) drug product to dose-dump if co-administered with alcoholic beverages. Thus, *in vitro* dissolution testing plays a major role in FDA's efforts to reduce the regulatory burden and unnecessary human studies in generic drug development without sacrificing the quality of the drug products.

Biography

Om Anand, Ph.D., Division of Bioequivalence, OGD, CDER, FDA: Rockville, MD. Dr. Anand is a reviewer and dissolution focal point at Division of Bioequivalence-2, Office of Generic Drugs, CDER, FDA at Rockville, Maryland. He received his Bachelor in Pharmacy from the University of Delhi, India in 1997, and a Master in Pharmacy in 2000 from the Punjabi University Patiala, Punjab, India. He received his Doctorate in Pharmaceutical Sciences from the University of Tennessee, USA, in 2008. His Ph.D. research involved formulation and development of biodegradable injectable gels loaded with insulin. From 2000 to 2003, he worked in pharmaceutical industry as a formulation scientist and developed wide variety of modified-release solid oral dosage forms. Research interests have included Pharmacokinetics, Biopharmaceutics and in-vitro dissolution of poorly soluble drugs and in-vitro and in-vivo correlations. He has published several articles and has two patents on his name.