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Biowaiver approaches for generic drug products in the US: Case studies

The bioequivalence (BE) evaluation is a critical component of the Abbreviated New Drug Application (ANDA) review process. For systemically acting generic oral dosage forms, the BE is often demonstrated through *in vivo* pharmacokinetic studies by comparing the rate and extent of absorption of active ingredient or moeity from generic drug product with that of the corresponding reference listed drug product. Per criteria set forth in 21 CFR § 320.22, the United States Food and Drug Administration (U.S. FDA) may grant waiver of *in vivo* BE study requirements (biowaiver) for generic drug products, if *in vivo* bioavailability or bioequivalence of the drug product is self-evident. The biowaivers may also be granted for solid oral dosages and other dosage forms administered via a different route of administration (e.g. azacitidine injectable suspension, acyclovir topical ointment), using *in vitro* tests to assess bioequivlaence. This presentation will discuss about recently implemented *in vitro* BE approaches for different dosage forms, waiver of *in vivo* BE studies for non biostudy strengths, and biowaivers in the presence of an established *in-vitro in-vivo* correlation (IVIVC) along with the case studies from ANDA submissions.

Biography

Paramjeet Kaur is a Senior Reviewer at the Division of Bioequivalence II, Office of Generic Drugs, CDER, FDA. She reviews the bioequivalence studies, *in vitro* dissolution data, and bioanalytical method validations submitted in support of approval of generic drug applications. She has also written several bioequivalence study design recommendations for specific drug products. She received her Bachelor in Pharmacy from the Banaras Hindu University, India, and Doctorate in Industrial Pharmacy from St. John's University, USA. Her current research interests include pharmacokinetics, use of pharmacokinetic modeling and simulation to predict bioequivalence, and *in-vitro in-vivo* correlations.

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