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BCS-Based biowaivers: Which drugs are eligible?

Anita Nair

Merck KGaA, Germany

Interchangeability of pharmaceutically equivalent multisource drug products can be evaluated by bioequivalence studies. Generally pharmacokinetic, pharmacodynamic or clinical studies involving human subjects are used for bioequivalence evaluation. However, improved understanding of the biopharmaceutical and clinical parameters of drug products has helped pharmaceutical scientists to utilize *in vitro* dissolution testing as a method to evaluate bioequivalence in lieu of *in vivo* bioequivalence studies. The term “biowaiver” is used to describe the use of surrogate *in vitro* method to waive the need for *in vivo* assessment. The concept of biowaiver is based on the Biopharmaceutics Classification System (BCS) and evaluates the biopharmaceutical and clinical parameters of the active pharmaceutical ingredient and the drug product along with the risks associated with the decision of bioequivalence based on *in vitro* method. Biowaiver approach provides the advantage of circumventing expensive and time consuming *in vivo* human studies thus reducing the time to bring multisource drug product into the market.

Biography

Anita Nair is a Pharmacist and has a Masters degree from the University of Mumbai, India. She completed her PhD in Pharmaceutical Technology from Goethe University, Frankfurt where she worked extensively on biowaiver concept of drug products and published several biowaiver monographs. She is presently heading the solubility and physico-chemical characterization department at Merck in Germany.

anita.nair@merckgroup.com