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BA/BE Challenges to generic pharmaceutical industry

Bioequivalence testing is playing a vital role in generic drug development. BA/BE studies are important elements in support of INDs, NDAs, ANDAs, and their supplements.

To introduce a generic drug in to a regulated market Generic industry need to meet the stringent criteria in the same way as innovative drugs. One must have a clear picture on designing bioequivalence studies to face the cost challenges in BA/BE studies

This presentation reviews the different methods to establish bioavailability and/or demonstrate bioequivalence for pharmaceutical products and specific methods to establish bioequivalence and validity of these methods for regulatory acceptance of the specific products. The presentation also focuses on bioequivalence determination for products related to various therapeutic areas (Locally acting GI products, Topical products, Respiratory products-Nasal Sprays/ Inhalations, Liposomal Injectables, Ophthalmics and complex drug products like biosimilars) and their limitations and regulatory acceptance in the related areas.

It also describes BA/BE challenges particularly in case of product failures related to solid orals (highly viable products & ER dosage forms) and products related to different therapeutic areas (criticality in designing and conducting PD endpoint studies and comparative clinical studies which involves high cost & time consuming with respect to patient recruitment) and uncertainty in case of a product failure.

Biography

Dr. AT Bapuji is a Masters in Pharmaceutics from Kakatiya University and PhD in Pharmacokinetics from Jamia Hamdard(New Delhi). Dr Bapuji is having total 19 years of experience industrial experience. He is the Senior VP at Aurobindo Research Center handling clinical Pharmacology and Pharmacokinetics division for the last 7+ years. Prior to this he worked in Ranbaxy Research Center in various capacities. He is proficient in Pharmacokinetics, Bioanalysis, Biopharmaceutics and Biostatistics. To his Credit published scientific papers in international journals of repute. Currently Guiding M.Pharm and PhD students for their project work/ Doctoral work.

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