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Harmonization in BABE studies: Regulatory aspects

Bioavailability and Bioequivalence studies play a major role in the drug development especially for both new drug products and their generic equivalents. Several approaches to assess Bioequivalence and each regulatory authority has its own regulations for conducting BA/BE studies before approving generic products for marketing. Thus, there is a greater need to harmonize the regulatory environment globally for bioequivalence assessment practically so that the drug product marketed in different parts and regions of the world. The assessment of BE of different drug products is based on the fundamental assumption that two products are equivalent when the rate and extent of absorption of the test/generic drug does not show a significant difference from the rate and extent of absorption of the reference/brand drug under similar experimental conditions. The approach of one size-to fit -all has begun to dissipate in recent years authorities from Europe, Canada, and United States, narrower BE limits have been proposed for drugs with narrow therapeutic windows. WHO has made remarkable progress in drug interchangeability. Apart from ICH, European and Asian organizations are actively involved in harmonization efforts for assessing of BE and improving the quality of pharmaceutical products globally. Global harmonization for regulatory requirements may be promoted by a better understanding of mentioned various approaches for bioequivalence assessment from different regulatory authorities to guarantee the safety and efficacy of the drugs and there by protecting the end users and consumers.

Biography

Mr T S Jaishankar - He is the Managing Director of Quest Life Sciences (P) Ltd, Member - Advisory Board in the journal of clinical studies UK, Member - Advisory board in Pharmabiz publication, Chairman of Chemech laboratories and CIPI chairman of Confederation of Indian Pharmaceutical industry. He has published several articles in the clinical trials in leading pharmaceutical magazines and he has given several talks on clinical research in reputed research institutes and academic organizations especially on BABE studies and Good Clinical Practice.

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