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Design, Documentation and Reporting of BA/BE Studies on Anticancer Products: Protocol Issues

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Designing of Bioequivalence (BE) study protocol for oncology generic products poses several challenges for researchers including but not limited to selection of study population, selection of individual dose for the patients, selection of appropriate study design (cross-over vis-a-vis steady state design), analysis of samples at investigator sites due to sample instability, high patient's dropout rates and regulatory scenario.

A bioequivalence study is generally conducted in healthy volunteers if the drug has shown safety profile in healthy population and is not a narrow therapeutic index drug. But the same is not ethically and medically acceptable in case of the most of anticancer drugs because of cytotoxicity in healthy population. Moreover the regulatory bodies' recommendation and criteria varies in different regions. For example, in case of bioequivalence studies of Imatinib USFDA recommends patients with gastrointestinal stromal tumors and patients in their first three months of treatment for chronic myeloid leukemia (CML) while EMA accept data of Imatinib in healthy volunteers also. This also translated into a challenge for the sponsors in finalizing the regulatory filing strategy.Titration of the exact dose of anticancer drug product based on the body surface area of the patient is a challenge as this has to be standardized in BE study.This talk will highlight the experience in the protocol issues faced in designing of bioequivalence studies of oncology products with appropriate examples and an overview of the regulatory bodies recommendation on some key oncology molecules going off-patent in upcoming years.

Biography

Mr. Vikas Kumar has completed his M.Pharm. (Pharmaceutics) at the age of 24 years from Punjabi University, Patiala. He is working as Research Scientist (Clinical Research and Medical Services) at Fresenius-Kabi Oncology Ltd, a premier generic oncology pharmaceutical organization. He has previously worked with Ranbaxy laboratories, India. He was awarded membership of American Association of Pharmaceutical Scientist (AAPS) from 2008-2009. He has participated in several conferences.

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