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Research article

# Developments of bioequivalency regulations for orally administered pharmaceutical products in USA, India, and Gulf cooperation council states – Regulatory concept study

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**Key words:** Bioequivalence, Bioavailability, Pharmacokinetics, USFDA, GCC (Gulf Cooperation Council) CDSCO (Central Drug Standard Control Organization).

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**Abstract**

The concepts of bioequivalence have gained considerable importance during the last three decades because of their application to new brand-name drugs, as well as new generic drugs. Generic pharmaceutical products need to comply the same standards of quality, efficacy and safety of the innovator product. Generic product should be therapeutically equivalent and interchangeable with the reference product. Present study highlights the developments of bioequivalence regulatory requirements in USA, India and the Gulf Cooperation Council States (Saudi Arabia, Kuwait, The United Arab Emirates, Qatar, Bahrain, Oman and Yemen).

No international harmonization of regulatory requirements for bioequivalence, however, bioequivalence range and statistical analysis are to some extent harmonized, but there are differences in selection of subjects, selection of reference product, food effect, application of multiple dose study, in vitro dissolution study, etc. The growth of pharmaceutical market depends upon the drug regulatory system and drug regulatory laws. The drug regulatory system is responsible for protecting the public health by assuring the safety, efficacy and quality of human drugs and its distribution.

In generic drug approval process one of the major requirements is the bioequivalence study. In bioequivalence studies, the plasma concentration time curve is generally to assess the rate and extent of absorption. Selected pharmacokinetic parameters and preset acceptance limits allow the final decision on bioequivalence of the tested products. Present study includes recent developments and information about important aspects of bioequivalence study design and specification guidelines of each parameter.