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Regulatory concepts of bioequivalence studies: Comparison between different international guidelines

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Health care costs continue to increase and one important component that can be reduced substantially is drug cost. For this purpose, substitution of the expensive originator drugs with cheaper generic copies is required. This reduction in price is due to that the generic manufacturers do not have to conduct costly clinical trials to test the safety and effectiveness, but generic copies should be therapeutically equivalent to the brand innovator products. A generic product is a multisource pharmaceutical product which is intended to be interchangeable with the comparator product. It is usually manufactured without a license from the innovator company and marketed after the expiry of patent or other exclusivity rights. Bioequivalent drug products are those that show no significant difference in the rate and extent of absorption of the therapeutic ingredient. There is 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, food effect, application of multiple dose study, in vitro dissolution study, reference product or market leader and two stages or add on studies. The regulatory requirements of various countries of the world vary from each other. Therefore, it is challenging for the companies to develop a single drug which can be simultaneously submitted in all the countries for approval. This paper will highlight the different international guidelines and how they vary from each other including the Gulf Council countries g.uidelines.

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