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Cuban experiences on bioavailability and bioequivalence studies of pharmaceuticals

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The topic Bioavailability/Bioequivalence (BA/BE), which is a primary driving force for the introduction of generic drugs, has been discussed for several decades. BA/BE studies are also important for the development of new drugs as API manufacturing process and formulation options keep changing during the entire drug development paradigm. The design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities over the last couple of decades. The Cuban industry produces about of 70% of pharmaceuticals (generic) included in the National List of Basic Drugs (889 pharmaceuticals). The focus of this work is to share with pharmaceutical scientists, academic researchers, regulators and key opinion leaders, the Cuban experiences on bioavailability and Bioequivalence Studies of Pharmaceuticals. Through selected examples we disclose the several stages, such as analytical method selection, information required for the protocol concerning analytical method development and validation, as well as design, conduction and statistical analysis of the studies, according to national and international regulations.

Biography

Alejandro Saul Padron Yaquis has completed his PhD at the age of 33 years from Habana University. He graduated from Russian University of Chemistry D. I. Mendeleiev. He is the Director of the Center for Pharmaceuticals Research and Development, one of the enterprises of BioCubaFarma Organization. He has published more than 25 papers in reputed journals and has been serving as Director of a Bioequivalence Unit. He has provided training and support for the conduction of BE study in other countries.

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