

Regulatory needs in bioavailability and bioequivalence studies of pharmaceuticals

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Bioavailability (BA) and bioequivalence (BE) studies play a vital role in providing information in a set of data that helps to ensure the availability of safe and effective medicine to the patients. They are frequently expressed as the exposure measures in the study to determine plasma concentration time curve and maximum concentration. They generally help in the drug development process for both new drug products and their generic equivalents. In both the cases these studies are important as their post approval process changes from time to time depending upon the drug content. The purpose of this article is to enforce on the various current regulatory issues to measure BA and they by to establish BE based on the drafts and guidelines which are the major concerns for Food and Drug Administration. So the major outcomes will focus on the background, general concepts, test procedures, criteria for comparisons, additional topics and future directions in the study pattern of BABE. The data provided will lead to national and international efforts to determine the appropriate procedures and their assessment in the BABE studies. Thus this article will also review the regulatory science of bioavailability and bioequivalence and provides FDA's recommendations for drug sponsors who intend to establish bioavailability and/or demonstrate bioequivalence for their pharmaceutical products during the developmental process or after approval.

Biography

Dr. Chakraborty G.S. has completed his Ph.D from Hamdard University. He holds first position and distinction in his Post Graduation Studies from Tamil Nadu Dr MGR Medical University, Chennai. He is working as Associate Professor and Head of the Department in Pharmacognosy in the Dept. of Pharm. Technology, NIET. He has also completed his Post Graduation Diploma in Clinical Research from Delhi. He has published more than 80 research papers in reputed journals and presented 90 research articles in conferences of national and international repute. He is also serving as editorial board member of reputed journals.

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