OPEN ACCESS Freely available online

Journal of Bioequivalence & Bioavailability

Editorial

A Brief Overview on Evidence to Measure Bio Equivalence

Titus S Ibekwe*

Department of Otorhinolaryngology, University of Abuja Teaching Hospital, Gwagwalada, Nigeria

DESCRIPTION

Bio Equivalence may be determined by one of the few direct or indirect methods. The choice of method depends on the purpose of the research, the analytical method available, and the type of drug product. The Bio Equivalence test should be performed using the most appropriate method available for the use of a particular product. A popular category of Bio Equivalence studies (for weight loss planning) is blood pressure research, end-point pharmacy research, and clinical point-end research. When the absorption of the drug is sufficient to measure the concentration of the drug in the blood (or other appropriate biological fluid or tissue) and the systematic absorption is consistent with the action of the drug, then a blood test (or other biological or tissue fluid) should Bio Equivalence perform. Blood pressure tests are usually chosen above all others as the most critical measure of Bio Equivalence.

Dosage and dose intake of a biological fluid cannot Bio Equivalence achieved or are not related to the action of the drug, a pharmacologic storage area (i.e., drug-induced physiologic changes associated with the approved indicators) may Bio Equivalence present. Finally, in the preferred sequence, if the concentration of the drug in the blood (or fluid or tissue) is unbalanced or incorrect, and no suitable pharmacologic effects can Bio Equivalence employed, then clinical end-of-life research may Bio Equivalence performed, comparing the (normal) test product to the product (pioneer) and control. Bio Availability can Bio Equivalence measured or Bio Equivalence expressed in several *in vivo* and *in vitro* methods.

The FDA may require *in vivo* or *in vitro* testing, or both, to measure the Bio Availability of a drug product or to establish a Bio Equivalence for certain drug products. Information about Bio Equivalence requirements for certain products is included in the current FDA publication program "Approved Drug Enforcement Testing Products" and any current supplement in the publication. The choice of method used to meet the requirements for *in vivo* or *in vitro* testing depends on the purpose of the research, the analytical methods available, and the type of drug product. The following *in vivo* and *in vitro* methods, with a declining system of accuracy, sensitivity, and duplication, are acceptable in determining the Bio Availability or Bio Equivalence of a drug product and *In vivo* testing in humans in which the active ingredient or component is active, and, if appropriate, the active metabolite (metabolites), whole blood, plasma, serum, or other biological fluid to Bio Equivalence measured as a function of time. This method is especially applicable to dosage forms aimed at transferring a functional component to the blood for systemic distribution or *in vitro* testing associated with predicting human Bio Availability *in vivo* or *in vivo* experiments in individuals where the urine component is active, and, if appropriate , the active metabolite is measured as a time function. Periodic measurements should generally measure as short as possible so that the completion rate is accurate.

This method is not suitable when urination is not an important means of elimination and *in vivo* testing in humans where the appropriate pharmacological effect of the active component and where appropriate its active metabolite, is measured as a time function if that effect is not measured with sufficient accuracy, sensitivity, and reproduction. This method is used only when appropriate methods are not available to measure the fullness of the component, and, where appropriate, it's active metabolite, in biological fluids or in extruded products but a method is available to measure the appropriate acute pharmacological effect. Bio Equivalence particularly effective in counteracting the ill effects of diarrhea and well-controlled clinical trials that establish the safety and efficacy of a drug product for Bio Availability measurement purposes, or appropriately designed clinical trials, for Bio Equivalence demonstration purposes.

This method is more accurate, sensitive, and Bio Equivalence Reason for Testing and Principles which can be repeated from the usual methods of measuring Bio Availability or showing Bio Equivalence. With dosage forms intended to supply the active component to the blood for systematic distribution, this method may Bio Equivalence

Correspondence to: Titus S Ibekwe, Department of Otorhinolaryngology, University of Abuja Teaching Hospital, Gwagwalada, Nigeria, E-mail: ibekja@gmail.com

Received date: December 1, 2021; **Accepted date:** December 15, 2021; **Published date:** December 22, 2021

Citation: Ibekwe TS (2021) A Brief Overview on Evidence to Measure Bio Equivalence. J Bioequiv Availab. S6:e001.

considered acceptable to allow the use of one of the above-mentioned alternatives. Bio Equivalence considered accurate enough in measuring Bio Availability or showing Bio Equivalence of dosage forms intended to bring the active component into place, e.g., skin, eye, and mucous membrane preparations, oral dosage forms not intended for absorption. Any other means deemed sufficient by the FDA to measure Bio Availability or establish Bio Equivalence. The FDA may require in vivo testing of product people at any time if the agency has evidence that the product and may not produce therapeutic effects compared to drug dosage or other intended use in exchange and it may not be the same as medication or other targeted alternatives.