

Bio-Relevant and Bioequivalence Studies: An Overview

Suryakanta Swain* and Nerella Nagadivya

Department of Pharmaceutics, Roland Institute of Pharmaceutical Sciences, India

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Structure of the Editorial

Statistical studies include the study of bio relevant media which are biologically relevant and reflect what's actually inside our bodies. These medias mimic the body fluids such as bile salts, lethicin, bile juice etc which are absent in conventional test media. Most of the drugs are consumed orally so, they must possess excellent dissolution rate and adsorption properties in the human gastro intestinal tract (GIT). But the problem associated with conventional test media is that, they don't mimic the highly variable and dynamic environment of the human GIT. To overcome this above problem bio relevant medias have come into action. Testing the drugs in them can help us to predict how an oral drug is likely to dissolve and release in vivo far more accurately and its performance in patients. There are many benefits through bio relevant studies such as effective formulation development in pharmaceutical industries, to match the in vitro dissolution profile of the test product with the innovator in context with generic industries, only a few experiments would be conducted on animals and better medicines are designed and formulated for patients. For conducting bio relevant studies we need suitable bio relevant media which can be easily prepared in seconds by simply adding the Sif powder with that of the prepared buffer solution. The Sif powder is cost effective as well as time saving and most importantly reproducible one. It originally

makes three different kinds of bio relevant medias; fassif, fessif and fassgf. It's a patented complex of bile salts (sodium taurocholate) and lethicin (phospholipids) in 4:1 molar ratio based on Professor Jennifer Dressman's original formulation. Both bioequivalent and bio relevant studies are quite useful for formulation of better drug systems by determining its pharmacological response outside the body which is similar to human viscera. It is ready to lend a hand in the characterization of complex drug substances and products, expanding biopharmaceutics, classification of systemic biowaivers, statistical methods for drug profile comparisons, novel pharmacodynamic study designs and food and drug interactions etc. more importantly, it will expand the range of products for which generic versions are available meanwhile maintaining high standards of quality, safety and efficacy.

Bioequivalence means two pharmaceutical products are said to be bioequivalent if their bioavailability are equal, dose is same, route of administration is same, therapeutic effect with respect to both safety and efficacy is equal meeting same comparable standards. According to FAD the definition of bioequivalence is the absence of significant difference in rate and extent to which API or active moiety in pharmaceutical equivalent becomes available at the site of drug action when administered in similar conditions. This is a technique which involves the different pharmacokinetics parameters like C_{max} , T_{max} , T_{log} and AUC etc. If pharmacokinetic studies are not feasible then, pharmacodynamic criteria for studying drug comes into picture. Study of bioequivalence is necessary to observe the adsorption of drug into the GIT, which can be achieved by in vitro (dissolution or assay) and in vivo (study of pharmacokinetic properties or assay) methods. It further ensures the switch ability of patient's medication. Apart from these, bioequivalent study deals with the parametric and non parametric statistical techniques to test the drugs. The possible distinction between the branded and generic products is evaluated through bioequivalence approach.

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*Corresponding author: Suryakanta Swain, Department of Pharmaceutics, Roland Institute of Pharmaceutical Sciences, Berhampur-760 010, Odisha, India, Tel: +91-9438038643; Fax: +91-680-2404112; E-mail: swain_suryakant@yahoo.co.in

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