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# BIOAVAILABILITY AND BIOEQUIVALENCE

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### Step by step approach for level A correlation: A case study of diclofenac sodium extended release tablets

Generic drugs are copies of innovator drugs that have exactly the same dosage, intended use, adverse effects, route of administration, risks, safety, and strength as the original drug. Since, the extensive preclinical and clinical studies were conducted by the innovator; these studies are not required for the generic products. The generic product must demonstrate the bioequivalence to the innovator product. Bioequivalence is also needed in case of post approval changes in pharmaceutical formulations, manufacturing process, batch size, excipients, which is going to be a costly and time consuming affair for a pharmaceutical company. Recent time brought a paradigm shift in the approach of both industry and regulators with respect to biowaiver leading to avoidance of unnecessary exposure of drugs to healthy subjects and huge investment of resources to prove the obvious, specifically, for generic players it is very critical to develop copycat product with very limited resources. In this regard, the concept and application of the *in vitro-in vivo* correlation (IVIVC) is the major focus in pharmaceutical product development in order to reduce time and efforts. This workshop will focus on step by step procedure to establish Level A correlation using a diclofenac sodium extended release tablet case study using simple Microsoft Excel software. With time permits Level B and C correlations will also be demonstrated.

#### Biography

Aliasgar Shahiwala is currently serving as a Professor in Department of Pharmaceutics and Program Director-Postgraduate studies at Dubai Pharmacy College, Dubai. Prof. Shahiwala received his masters and doctorate in pharmaceutics and pharmaceutical technology from The Maharaja Sayajirao University of Baroda, India with high research output in the area of novel drug delivery. His Postdoctoral Research at Northeastern University, USA was specifically focused on applications of nanotechnology in the field of drug delivery and drug targeting. Prof. Shahiwala published several international publications in high impact peer reviewed journals, four book chapters with internationally renowned publishers and one patent. He is also an editor of two books with international publishers. Prof. Shahiwala's research credentials have established him as a reviewer, a member of editorial board, a speaker and an invited author for various pharmaceutical scientific journals and conferences. Prof. Shahiwala also has more than 3 years of rich research experience in Formulation & Development Division of large scale manufacturers of Pharmaceuticals in India as an added technical expertise in his field.

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