



International Conference & Exhibition Bioequivalence and Bioavailability 2010

doi:10.4172/0975-0851.1000002

TITLE

BIOEQUIVALENCE TESTING- INDUSTRY PERSPECTIVE

R.T. Bapuji

Aurobindo Pharma Research Center,
Hyderabad, India

Generic drugs are cost effective alternatives for the brand name drugs and the savings are estimated in the average \$8 to \$10 billion a year. Over the years the prescription of generic drugs has increased from 19 % to 60-70 % (1984: 19% & 2009- 60-70 %). A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, route of administration, indication and to be bioequivalent with the innovator. Bioequivalence testing is very important for regulatory filing. This data forms the important component for ANDA submissions.

The generics have to be developed and tested in human subjects by following stringent GCP/GLP standards. From time to time various regulatory guidances were issued to bring more clarity and uniformity for conducting BA/BE studies. For example FDA is issuing product specific BE guidance's to bring a uniform standard. In the European Union, no such specific guidance except a general one. There are some issues constantly faced by the industry for proper conduct of the BA/BE studies.

The presentation describes current regulatory requirements from various regulatory agencies and its impact on industry while designing a bioequivalence study and also highlights some of the common areas which need to be addresses or commented upon. It is the time for industry to partner with regulatories to make bioequivalence studies and intern development of generic drugs more cost effective.