Workshop on bioavailability and bioequivalence (13th – 14th October 2012) at Maliba Pharmacy College, Bardoli

A two-day national workshop "Practical approach to bioavailability and bioequivalence" was held on 13th – 14th October 2012 at Maliba Pharmacy College, Uka Tarsadia University, Bardoli, Surat. More than 270 delegates from various colleges in Gujarat and Maharashtra took part in the workshop. A poster session relevant to the theme was also conducted on the first evening. Twenty posters in all were displayed and were evaluated.

Discussions focused on best practices leveraging biopharmaceutics, formulation and clinical data to identify drug development challenges in yielding a successfully performing product. Quality by design (QBD) and product development paradigms were also emphasized upon.

Delivering his keynote address, *"Intricate drug delivery system for BA-BE study"* **Dr. P.R. Vavia, Academic Dean, Institute of Chemical Technology, Mumbai** addressed unique bioavailablilty issues pertaining to novel drug delivery systems (NDDS) and how the information gained form this study would be exploited in deciding the formulation strategy. A brief overview of factors that affect dosage form behavior & drug release/absorption pattern amongst NDDS to achieve desired effect & patient compliance were also delved upon.

Dr. Prakash Patel and Dr Gunjan Shah of Veeda Clinical Research, spoke on *"Pharmacokinetics, BA-BE determination & current issues"* and *"Bioequivalence Regulatory Perspective"* respectively. The talks in nutshell were centered upon bioavailabity problems associated with high intrasubject variability, its study design and a comparative review of regulatory status of various countries in this regard.

Dr. Nailesh Patel of Synchron Research Services Pvt. Ltd. gave an insight into strategies to achieve specific pharmacokinetic and pharmacodynamic issues like biowaivers and biosimilars and their study design in his topic *"Design, documentation and reporting of BA & BE study".*

Dr. Shailesh Shah, Dean, Research and Post-graduate studies, Uka Tarsadia University, clarified the issues related to QC samples, determination of matrix effect, stability considerations, internal standards and also issues raised with respect to stability and reproducibility of incurred samples in his talk *"Development of bioanalytical methods for BE studies".*

Dr. Ganesh Divekar of Sun Pharma Advanced Research Co. Ltd. conducted the session on *"Bioequivalence and bioavailability study of oncology drugs"* and gave a background of different FDA routes for pharmacokinetics and BA-BE studies of generic drugs and their development with the help of case studies.

Concluding the session **Dr. M. C. Gohel, Dean, Pharmacy, Ahmedabad University** elaborated on *"Use of design of experiment in the establishment of IVIVC"*. He emphasized the need for

designing BE study design to be tailored to drug product's characteristics and physiological factors that may affect bioavailability.

Overall the workshop was well attended and ended with a feeling of optimism about future of BA-BE studies in the country. But it was also felt that amount of work being done at the institutional level needs a lot to be desired and needs a real boost from academic community.