Topic of Seminar

Role of BA- BE Studies in Drug Development: A Regulatory Perspective

(Event jointly organized by IPA and SMPIC-NIPER)

Bioavailability (BA) is a measurement of the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. Similarly, Bioequivalence (BE) is defined as the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Bioequivalence based on plasma drug concentration has become the most frequently used and successful biomarker of safety and efficacy of a drug. BA studies can furnish pharmacokinetic information related to drug absorption, distribution and elimination in vivo. In contrast, BE studies are primarily utilized for formulation comparisons.

The concepts of bioavailability (BA) and bioequivalence (BE) have gained much importance because of their application to new brand-name drugs, as well as to generic drugs. This information is important in the drug development and for regulatory approval of pharmaceutical products. In clinical development of New Chemical Entities (NCEs), these studies necessitate to be performed when the formulation of the pharmaceutical dosage form has been changed. In vivo pharmacokinetic data can be used as surrogate parameters for in vivo solubility and permeability data.

Bioequivalence testing is playing a vital role in generic drug development. But to make a generic drug enter in to a regulated market a company has to meet the stringent criteria in the same way as innovative drugs. There are some issues constantly faced by the industry for proper conduct of the BA/BE studies. There are continuing efforts by regulatory authorities and the scientific community, both nationally and internationally, to understand and develop more efficient and scientifically valid approaches to the assessment of BE of various dosage forms.

In the recent Ministry of Health and Family Welfare has mandated the submission of BE data for BCS Class II and IV category of drugs prior to the grant of license.

The present seminar shall emphasize the necessity of BA- BE studies, current regulatory requirements from various regulatory agencies and its impact on industry while designing a bioequivalence study. The target audience includes personnel from the industry and researchers within the academic community.

The following are some of the topics that shall be deliberated in the seminar:

1. BA-BE studies - Global prospects
2. An overview and necessity of BA-BE studies
3. International Regulations and guidelines for conduct of BA-BE studies
4. Indian regulations and recent amendments for conduct of BA-BE studies
5. BA-BE studies and FDCs
6. Challenges and solutions for BA-BE studies. Procedure for DCGI approvals

Speakers

Eminent personalities from academia, regulatory and highly experienced personnel from pharmaceutical industry shall deliver the lectures. A panel discussion on queries from participants shall also be held.

Registration Fee

Rs. 3000 /- per delegate, Rs. 2000/- for members registered with SMPIC, NIPER and Rs. 800/- for students. The fee includes course material in the form of CD, lunch, refreshments, tea /coffee and excludes accommodation charges.

On-site Registration

The on-site registration desk will be open on the day of seminar from 9.00 am to 9.30 am. An additional fee of Rs. 500/- will be charged for on-site registration.

SMPIC

SEMINAR ON

S.A.S. NAGAR

ROLE OF BA- BE STUDIES IN DRUG DEVELOPMENT: A REGULATORY PERSPECTIVE

(EVENT JOINTLY ORGANIZED BY IPA AND SMPIC-NIPER)

23rd February, 2018

SMALL AND MEDIUM PHARMACEUTICAL INDUSTRY CENTRE
National Institute of Pharmaceutical Education and Research (NIPER)
Sector-67, Near PCA Stadium, S.A.S. Nagar-160062. (Punjab)
Phone: 0172-2292032, Fax: 0172-2214692, email:smpic@niper.ac.in

Registration Form

Name Prof./Dr./Mr./Ms .....

Designation .....

Institute/Organization .....

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Address .....

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Mobile No. .....

E-mail .....

Amount Paid for Registration .....

DD No. & Date .....

Registration Fee

Delegates	Rs. 3000/-
SMPIC Members	Rs. 2000/-
*Students	Rs. 800/-

The last date for Registration is 20th February, 2018 An extra Rs. 500/- for on-site Registration
**Students are required to attach id Proof DD in favour of Director, NIPER, Payable at Mohali should be sent along with dully filled form.*

About IPA

The Indian Pharmaceutical Association (IPA) is the oldest premier association of pharmaceutical professionals in India, with a member base of over 13,000, spread across the length and breadth of the nation. IPA operates in India through 20 state branches and more than 46 local branches. The members represent various facets of pharmaceutical profession viz., industry, regulatory, community and hospital pharmacy practices and education. As a member of the Drug Technical Advisory Board, India, IPA is actively involved in advising the government on matters of professional importance. IPA is affiliated with international pharma associations like FIP, FAPA, CPA, AAPS, AAiPS and is working with international bodies such as WHO and WHPA for carrying out various collaborative professional activities that include organizing training programmes for professionals from industry, academics, regulatory and practice. IPA makes representations to the authorities on matters of professional interest and works constantly towards upgrading the standards of pharmacy professional services offered by the pharmacists. IPA's major objective is to position pharmacists as one of the important healthcare providers in our country.

About SMPIC

NIPER had successfully conducted 53 training programs under the World Bank sponsored "Capacity Building Project" in the years 2004 to 2008. These were meant for the technical staff from government testing laboratories, regulatory bodies, private testing laboratories and analytical as well as production staff from Small and Medium Pharmaceutical Industries (SMPIs). Department of Pharmaceuticals, Government of India, announced the setting up of a dedicated centre for SMPIs at Pharmaceutical Advisory Forum (PAF) on 23rd April 2008. This Centre offers practical trainings on analytical instruments and conducts seminars on issues of relevance to the Pharma industry like GLP, GMP & regulatory affairs. All these activities have been designed in consultation with SMPIs. This dedicated centre aims at creating synergy between industry and academia.

How to reach NIPER

NIPER, S.A.S. Nagar (Mohali) is situated near Chandigarh, that is well connected by air, rail and road. NIPER is about 11 km from Chandigarh International Airport, 14 km from Chandigarh Railway Station, 10 km from ISBT, Sector-17, Chandigarh and 5 km from ISBT, Sector-43, Chandigarh.

INDIAN PHARMACEUTICAL ASSOCIATION

DELHI STATE BRANCH

SMALL AND MEDIUM PHARMACEUTICAL INDUSTRY CENTRE

SMPIC

Seminar

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NIPER

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