

Topic of Seminar

'Reverse Engineering of Pharmaceutical Formulations'

Reverse Engineering also known as deformulation, is the separation, identification and quantitation of ingredients in a formulation. Reverse engineering is the decoding of an innovator product's formulation parameters. It helps determine the chemicals, substances or materials incorporated into a product. The parameters studied include quantitative composition of the innovator product, the solid-state characterization of the active pharmaceutical ingredient (API), and the manufacturing process. This is as challenging as designing a new product since complex product formulations can contain dozens of components of varying chemical nature. Most generics are oral solid dosage forms (tablets and capsules). Generics companies must be highly skilled in product and process development and achieving bioequivalence- the most critical development area. Deformulation involves customized extractions and specialized instrumental techniques to identify and quantify the components of a complex mixture. Investigations in reverse engineering are carried out with a broad scan of a sample by infrared spectroscopy (FT-IR) or mass spectrometry (GC/MS, LC/MS); however, several other complementary analytical techniques are needed to conduct a detailed deformulation analysis. These include nuclear magnetic resonance spectroscopy (NMR), energy-dispersive x-ray spectroscopy, ultraviolet/visible spectroscopy (UV/VIS), induced coupled plasma (ICP-MS), and atomic absorption spectroscopy (AA).

Reverse engineering is a useful tool for developing bioequivalent generic products. The present seminar shall

emphasize on the strategies and various techniques used in deformulation of both solid and liquid pharmaceutical formulations. 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. Role of reverse engineering in development of generic products
2. Role of dissolution in matching innovator product performance
3. Case studies of reverse engineering solid and liquid pharmaceutical formulations

Speakers

Eminent personalities from industry, regulatory (Mr Harna, Retd. Astd. Drugs Controller, Haryana) and academia (Prof. A K Bansal, Head, Deptt. of Pharmaceutics, NIPER, Mohali) shall deliver the lectures.

Registration Fee

- Rs 3000/- per delegate
- Rs 2000/- for SMPIC members
- 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 8.30 am to 9.00 am. An additional fee of Rs. 500/- will be charged for on-site registration.



SEMINAR ON

'REVERSE ENGINEERING OF PHARMACEUTICAL FORMULATIONS'

1st March, 2019

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

Address

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 26th February, 2019

*Students are required to attach ID Proof
DD in favour of Director, NIPER, Payable at Mohali should be sent along with duly filled form.

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 (SMPs). Department of Pharmaceuticals, Government of India, announced the setting up of a dedicated centre for SMPs 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 SMPs. 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.

Seminar
on



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S.A.S. NAGAR

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