

Topic of Seminar

'REVERSE ENGINEERING OF ORAL SOLID AND LIQUID FORMULATIONS'

Deformulation is the technical term for reverse engineering a product's formulation parameters. A sound reverse-engineering strategy encompasses the decoding of the reference listed drug product's (RLD's) quantitative formula, the solid-state characterization of the API and the manufacturing process. This is achieved by separation, identification and quantitation of ingredients in a pharmaceutical formulation. Customized extractions and specialized instrumental techniques are used to identify and quantify the components in the formulation. Reverse engineering of pharmaceutical formulations is required for a variety of reasons including Intellectual property, analytical, stability, safety and development of generic formulations.

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. Analytical techniques used in deformulation analyses also 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. Case studies of reverse engineering a solid and liquid pharmaceutical formulation
3. Role of analytical and instrumental techniques in reverse engineering of pharmaceutical formulations
4. Role of dissolution in matching innovator product performance.
5. API particle size distribution in oral solids.

Speakers

Eminent personalities from academia, regulatory agencies, and highly experienced personnel from pharmaceutical industry 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 10.00 am. An additional fee of Rs. 500/- will be charged for on-site registration.



SMPIC

SEMINAR

ON

'REVERSE ENGINEERING OF ORAL SOLID AND LIQUID FORMULATIONS'



S.A.S. NAGAR

29th June, 2017

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 26th June, 2017

*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

Department of Pharmaceuticals, Government of India, announced the setting up of a dedicated centre for Small and Medium Pharmaceutical Industries (SMPs) at Pharmaceutical Advisory Forum (PAF) on 23rd April 2008. This Centre called as SMPIC, offers practical trainings on analytical instruments like HPLC, GC, FTIR etc. Another important activity of SMPIC is to conduct seminars on issues of relevance to the Pharma industry like GLP, GMP & regulatory affairs. Till date 29 seminars, with total attendance of around 1100, have been conducted. All these activities have been designed in consultation with SMPs. This dedicated centre aims at creating a synergy between the industry and academia.

How to reach NIPER

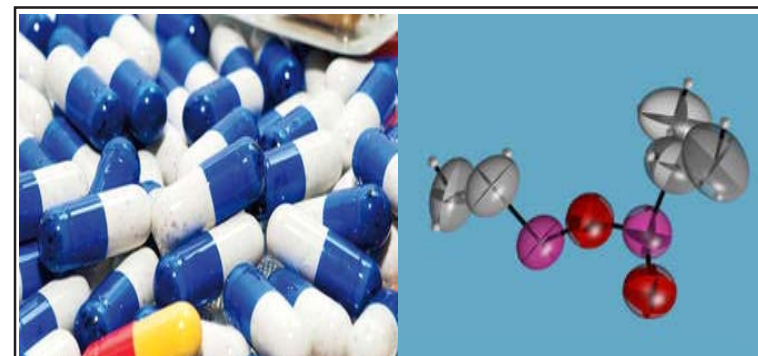
NIPER, S.A.S. Nagar (Mohali) is situated near Chandigarh, that is well connected by air, rail and road. NIPER is about 11 km from Chandigarh International Airport, 14 km from Chandigarh Railway Station, 10 km from ISBT, Sector-17, Chandigarh and 5 km from ISBT, Sector-43, Chandigarh.

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