STES's Sinhgad Institute of Pharmaceutical Sciences, Lonavala

SINHGAD TECHNICAL EDUCATION SOCIETY (STES), was established in the year 1993 under the able and dynamic leadership of Prof. M. N. Navale with an objective of providing quality education in the field of Pharmacy, Engineering, Management, Computer, Architecture, Law, Arts, Science, Commerce and school education from Kindergarten onwards. There are 85 Institutes under the aegis of the Society offering full-fledged education at 13 Educational Campuses.

Sinhgad Institute of Pharmaceutical Sciences (SIPS) is a rapidly growing institute imparting quality pharmacy education. The institute is situated at Lonavala, a place with an excellent panoramic view, lush green landscape and natural bounty. SIPS firmly believes in its strength and try to remain at the forefront of Pharmaceutical education, Research and training by constantly maintaining excellence, stimulating evolutionary progress , developing skill and intellectual ability to meet new global challenges. Coherent team of adroit teaching staff is constantly helping the students to achieve an extra edge in this fiercely competitive world.

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Professor, SIPS, Lonavala

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Hospitality
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Sameer Lakade 9421821533

Registration for the Workshops

- The number of participants will be limited to maximum 50 on first come first serve basis.
- Send the duly filled registration form till 25th February 2012 to rjdias75@gmail.com
- The registration fees include Seminar kit, Lunch, Refreshments, Dinner & Certificate.
- Cancellation will not be accepted but substitutions may be entertained.
- Registration fee per delegate: Rs. 300 for National level workshop & Rs. 200 for State level workshop.
- Confirmation of registration shall be conveyed by e-mail. (Please provide valid e-mail ID)
- Outstation delegates will be provided accommodation on request at SIPS, Lonavala campus if intimated along with the registration form.

Neha Creations: (020) 2430 8240

Sinhgad Technical Education Society's
Sinhgad Institute of Pharmaceutical Sciences
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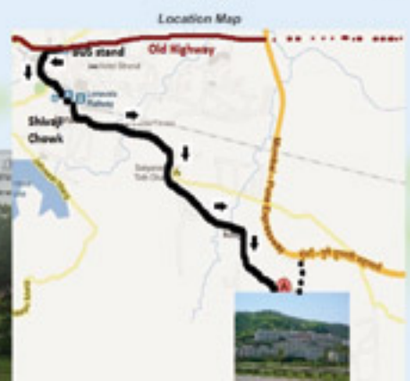
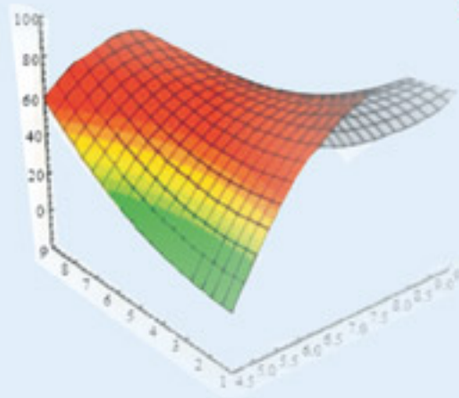


University of Pune Sponsored Workshops at

Sinhgad Technical Education Society's
Sinhgad Institute of Pharmaceutical Sciences (SIPS)
Kusgaon (Bk.), Lonavala – 410401

Three days National Workshop
Applications of Statistics in Designing Pharmaceutical Experiments
(2nd – 4th March 2012)



Two days State Level Workshop
Industrial Applications of In-Vitro In-Vivo Correlation (IVIVC)
(10th & 11th March 2012)

Three days National Workshop

Applications of Statistics in Designing Pharmaceutical Experiments

(2nd – 4th March 2012)

Scope:

Statistical methods are becoming increasingly important for the pharmaceutical industry. The FDA and other regulatory and standard-setting organizations are moving swiftly to establish Quality by Design (QbD) guidance relevant to the needs of pharmaceutical manufacturing. The FDA suggests the use of design of experiments (DoE) because "it provides a structured, organized method for determining the relationship between factors affecting a process and the response of that process."

While it is possible to perform DoE with general statistical software, most users in the pharmaceutical should know the basics involved in using these softwares and a suitable design for their experiments.

This workshop will focus on number of key concepts in designing of pharmaceutical experiments so that the systematic approach in performing & optimizing the experiments will be effectively done by the participants, which will best meet their needs.

Objectives:

Through lectures and practice sessions, the workshop is designed to allow the participants to:

- Develop an overall understanding of the basic statistics & its applications to pharmacy.
- Learn various principles involved in designing of pharmaceutical experiments.
- Understand various designs & optimization based on case studies.
- Gain hands on experience in designing various pharmaceutical experiments.
- Work and interchange ideas with faculty and other participants.

Who should attend:

This workshop presents an in-depth study of designing pharmaceutical experiments and its optimization. The workshop is useful for all M.Pharm & PhD students, Teachers, Researchers, and Industry personnel who need an introduction to designing of the experiments

Topics

- Keynote Address on "Design of Experiments"
- Review of Basic Statistics
- Experimental Designs: An Overview
- Factorial Designs
- Response Surface Methods
- Artificial Neural Networks in Pharmacy field
- Screening of Prototype Formulation
- Mixture Designs
- Solving Problems in Formulation using DOE
- Design, Synthesis & Discovery of Novel Anti-Cancer Clinical Candidate
- Application of DOE: Case Study
- Designing Clinical Trials
- Demo of Systat Software

Faculty:

Dr. Subrata Rath
Indian Statistical Institute, Pune
Dr. A. P. Pawar
Poona College of Pharmacy, Pune
Dr. Mangal Nagarsenker
Bombay College of Pharmacy, Mumbai
Dr. S. P. Boldhane
Abbott Healthcare Pvt. Ltd., Mumbai
Dr. S. S. Bhagwat
Institute of Chemical Technology, Mumbai
Dr. Preety Gupta
Dr. Reddy's Laboratories, Hyderabad
Dr. M. R. Bhalekar
AISSMS College of Pharmacy, Pune
Dr. Manish Grover
Abbot Healthcare Pvt. Ltd., Mumbai
Dr. Debjani Paul
Piramal Life Sciences, Mumbai
Dr. Sanjay Kumar
Piramal Life Sciences, Mumbai
Dr. Preeti Dali
IPCA Ltd., Mumbai
Dr. Suresh Bowalekar
PharmaNet Clinical Services, Mumbai
Mr. Madhav Kulkarni
Dow Chemical International Pvt. Ltd., Pune

Two days State Level Workshop

Industrial Applications of In-Vitro In-Vivo Correlation (IVIVC)

(10th & 11th March 2012)

Scope:

A key goal in pharmaceutical development of dosage forms is a good understanding of the in vitro and in vivo performance of the dosage forms. One of the challenges of biopharmaceutics research is correlating in vitro drug release information of various drug formulations to the in vivo drug profiles (IVIVC). Thus the need for a tool to reliably correlate in vitro and in vivo drug release data has exceedingly increased. Such a tool shortens the drug development period, economizes the resources and leads to improved product quality. Increased activity in developing IVIVCs indicates the value of IVIVCs to the pharmaceutical industry. IVIVC can be used in the development of new pharmaceuticals to reduce the number of human studies during the formulation development, as the main objective of an IVIVC is to serve as a surrogate for in vivo bioavailability and to support biowaivers. It supports and/or validates the use of dissolution methods and specification settings. This is because the IVIVC includes in vivo relevance to in vitro dissolution specifications. It can also assist in quality control for certain scale-up and post-approval changes (SUPAC). With the proliferation of modified-release products, it becomes necessary to examine the concept of IVIVC in greater depth. Investigations of IVIVC are increasingly becoming an integral part of extended release drug development. There must be some in vitro means of assuring that each batch of the same product will perform identically in vivo. This workshop will cover all those aspects representing the FDA guidance, development, evaluation, and validation of an IVIVC to grant biowaivers, and to set dissolution specifications for oral dosage forms, application of BCS in IVIVC development and concept of mapping. The importance of dissolution media and methodology and pharmacokinetic studies in the context of IVIVC will also be highlighted.

Who should attend:

This workshop presents an in-depth study of in vitro in vivo correlation and USFDA guidelines for biowaivers apart from dissolution studies. The workshop is useful for all M.Pharm & PhD students, Teachers, Researchers, and Industry personnel who need an introduction to IVIVC.

Objectives:

Through lectures and practice sessions, the workshop is designed to allow the participants to:

- Identify the needs and various methods used for IVIVC
- Understand various levels of correlation & BCS Classification
- Understand USFDA regulatory guidelines & biowaivers for IVIVC
- Apply concept of IVIVC to immediate & extended release products
- Know various softwares available for IVIVC.

Topics

- Introduction to Dissolution Science
- Development of Dissolution Method for Immediate Release Dosage Forms
- Development of Dissolution Method for Poorly Soluble Drugs
- Development of Dissolution Method for Novel Dosage Forms
- Introduction to IVIVC
- In vitro Parameters for IVIVC
- In vivo Parameters for IVIVC
- IVIVC & Dissolution Specifications: Industrial Perspective

Faculty:

Dr. S. P. Boldhane
Abbott Healthcare Pvt. Ltd., Mumbai
Dr. A. R. Khan
Maulana Azad College, Aurangabad
Dr. V. K. Mourya
Govt. College of Pharmacy, Amravati
Dr. S. B. Bhise
Sinhgad Institute of Pharmaceutical Sciences, Lonavala
Dr. Rajkumar Malayandi
FDC Ltd., Mumbai
Mr. Srinivas Reddy
Abbot Healthcare Pvt. Ltd., Mumbai
Mr. Amol Kulkarni
Alkem Ltd., Mumbai
Miss Preeti Dali
Ipca Pvt Ltd., Mumbai