SEVEN HILLS COLLEGE OF PHARMACY
[AUTONOMOUS]

Venkatramapuram, Ramachandrapuram (Mandal), Tirupati (Dist),
TIRUPATI - 517 561, A.P, INDIA

HYBRID MODE
14-07-2023 to 21-07-2023

VALUE ADDED COURSE ON INTEGRATED ANALYTICAL QUALITY BY DESIGN APPROACH FOR THE BIOANALYTICAL METHOD DEVELOPMENT & VALIDATION

Organized by

Department of Pharmaceutical Analysis

ELIGIBILITY: M PHARM 1st & 2nd YEAR STUDENTS

RESOURCE PERSONS

Dr. M. Sivaselvakumar,
Associate Professor,
Centre for Molecular Medicine & Therapeutics,
PSG Institute of Medical Sciences and Research, Coimbatore, TN

Dr. S. Rajan,
Head
ADME PK Laboratory,
Styrax Pharma Innovation Research,
Hyderabad, Telangana

Dr. Karri V V S Narayana Reddy,
Assistant Professor,
Department of pharmaceutics,
Research Coordinator,
JSS college of pharmacy,
Rockland's, ooty,
The Nilgiris. Tamilnadu-643001.

ABOUT THE INSTITUTION

Seven Hills College of Pharmacy(SHCP) was started in 2007 as an institution exclusively specialized in Pharmacy Education by Global Vision Educational & Welfare Society (Reg.No.296/2005), a non-profit organization registered under the Registration of Societies Act with the Registrar of Societies, Balaji Registration District. The College has been carefully launched & nurtured by its founders & visionaries Shri M. Venkatrama Raju & Shri Prof. Dr. M. Niranjan Babu, who have been learned educationists themselves.

Courses Offered by the Institution

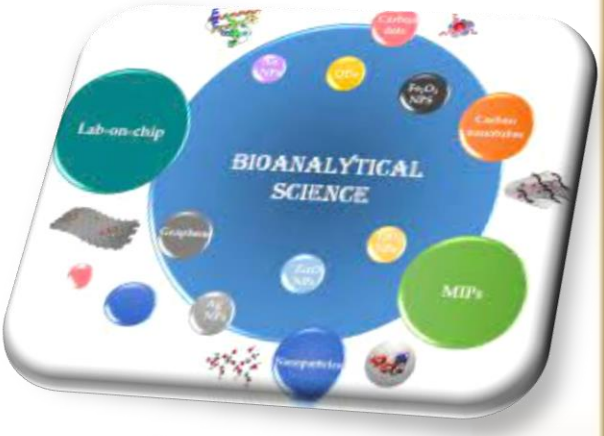
B Pharmacy, Pharm D, M Pharmacy (Pharmacology, Pharmaceutics & Pharmaceutical Analysis) and Ph. D. in Pharmaceutical Sciences.

Patron
Dr. M. Niranjan Babu,
Professor & Principal,
Seven Hills College of Pharmacy,
Tirupati

Promoted by:
GLOBAL VISION EDUCATIONAL & WELFARE SOCIETY, TIRUPATI

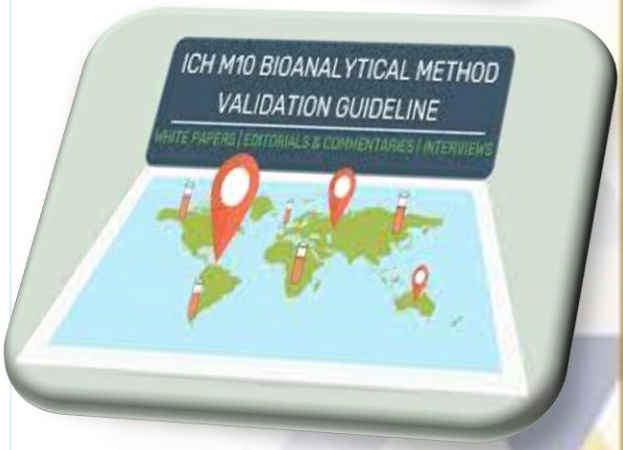
ABOUT THE DEPARTMENT

The Department of Pharmaceutical analysis Seven Hills College of Pharmacy aims to focus on the development of analytical methods using new combinations of established instrumentation and approaches. The department is involved in teaching and training post graduate students, in the subjects of analytical sciences pertaining to qualitative and quantitative estimation of natural and synthetic compounds in various matrices by application of spectroscopy, chromatography and analytical methods. It involves basic research in identity, purity, content and stability of starting materials, excipients and active pharmaceutical ingredients.



ABOUT THE COURSE

1. This value added course will provide basic knowledge and a clearer understanding on Bioanalysis in Drug Discovery and development.
2. The M10 guideline represents a harmonisation and update of the regulatory requirements for bioanalytical method validations and for the application of bioanalytical methods.
3. DMPK studies in drug discovery for optimizing the drug-like properties of compounds or drug molecules.
4. QbD and AQbD In Pharmaceutical Development, Current approach and its limitations.



WHAT YOU LEARN

- An overview of applications of Bioanalysis in Pharmacokinetic Studies, Bioavailability Studies.
- The ICH M10 guideline provides recommendations on the validation of bioanalytical assays for chemical and biological drugs and their metabolites in biological matrices
- DMPK studies can help evaluate the potential for drug-drug interactions (DDIs), and adverse effects.
- QbD and AQbD In Pharmaceutical Product Development, Current approach and its Applications.

WHO SHOULD ATTEND

Research Scholars, Post Graduate Students and B Pharmacy IV year Students who want to get an updated overview of applications of Bioanalysis in Pharmacokinetic Studies, Bioavailability Studies Bioanalytical method development ICH Q 10 guidelines, Drug Metabolism and Pharmacokinetic Studies (DMPK) & Quality by Design approach in Pharmaceutical Produc Development.

Day-1 SESSION-1: 14/07/2023 (4 Hrs)
Topic: Quality by Design (QBD) in Pharmaceuticals
Speaker-1 Dr. Karri V V S Narayana Reddy, Assistant Professor, Department of pharmaceutics, Research Coordinator, JSS college of pharmacy, Rockland's, ooty, The Nilgiris. Tamilnadu-643001.

Day-2 SESSION-2: 15/07/2023 (4 Hrs)
Topic:Drug Metabolism and Pharmacokinetic Studies (DMPK)
Speaker-2: Dr. S. Rajan, Head, ADME PK Laboratory, Styrax Pharma Innovation Research, Hyderabad, Telangana

Day-3 SESSION-3: 17/07/2023 (4 Hrs)
Topic: Bioanalytical Method Validation & ICH Q 10 Guidelines
Speaker-3:Dr. M. Sivaselvakumar, Associate Professor,
Centre for Molecular Medicine & Therapeutics, PSG Institute of Medical Sciences and Research, Coimbatore, TN.

Day-4 SESSION-4: 18/07/2023 (4 Hrs)
Topic: Bioanalytical Method Development and Validation
Speaker-4: Mrs. B. Sivagami, Associate Professor, Dept of Pharmaceutical Analysis, Seven Hills College of Pharmacy, Tirupati

Day-5 SESSION-5: 19/07/2023 (4 Hrs)
Topic: Bioanalytical Method Development and Validation
Speaker: Mrs. B. Sivagami, Associate Professor, Dept of Pharmaceutical Analysis, Seven Hills College of Pharmacy, Tirupati

Day-6 SESSION-6: 20/07/2023 (4 Hrs)
Topic: Analytical and bioanalytical method development and validation in Pharmacokinetic Studies & Bioavailability Studies.
Speaker-5: Dr. G. Satheesh Kumar, Professor, Dept of Pharmaceutical Chemistry, Seven Hills College of Pharmacy, Tirupati

Day-7 SESSION-7: 21/07/2023 (4 Hrs)
Topic: Analytical and bioanalytical method development and validation in Pharmacokinetic Studies & Bioavailability Studies.
Speaker: Dr. G. Satheesh Kumar, Professor, Dept of Pharmaceutical Chemistry, Seven Hills College of Pharmacy, Tirupati

Coordinator
Mrs. B. Sivagami, M Pharm (Ph.D)
Associate Professor,
Dept. of Pharmaceutical Analysis
Seven Hills College of Pharmacy
Tirupati

Organizing Committee
Mrs. D. Meena, Assistant Professor
Mr. Deepak Sai Ram, Assistant Professor
Mr. V. Pavan Kumar, Associate Professor
Mr. R. Chandrasekar, Associate Professor

COURSE SYLLABUS **DURATION 28 HRS**

COURSE NAME: VALUE ADDED COURSE ON INTEGRATED ANALYTICAL QUALITY BY DESIGN APPROACH FOR THE BIOANALYTICAL METHOD DEVELOPMENT & VALIDATION

COURSE OBJECTIVES

- To provide basic knowledge on bioanalytical method development and validation
- Imparting basic understanding on bioanalysis, pharmacokinetic and bioavailability studies
- The Q 10 guideline is intended to provide recommendations for the validation of bioanalytical methods for chemical and biological drug quantification and their application in the analysis of study samples.
- Understand and apply QbD terminology including the principles of a science- and risk-based approach, the importance of product and process understanding and requirements.

COURSE OUTCOME

- To explain the theoretical aspects of bioanalytical method development and validation
- To undertake correct sample preparation and characterization prior to analysis by the chosen techniques or instruments
- Design an analytical work flow to acquire data and achieve the research objectives of their projects
- Process data from chosen instruments and demonstrate understanding of the limitations and quality of the data

MODULE-1

Analytical and bioanalytical method development and validation in Pharmacokinetic Studies & Bioavailability Studies.

MODULE-2

The M10 guideline represents a harmonisation and update of the regulatory requirements for bioanalytical method validations and for the application of bioanalytical methods.

MODULE-3

DMPK studies in drug discovery for optimizing the drug-like properties of compounds or drug molecules.

MODULE-4

Advantages, Elements of QbD, and Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization

MODULE-5

Process Analytical Technology: Introduction, Scope, Background, PAT Framework, PAT Tools, Risk-Based Approach, Integrated Systems Approach, Real Time Release, Strategy For Implementation, Regulatory Approach, Examples of PAT Implementation

REFERENCES

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m10-bioanalytical-method-validation-step-5_en.pdf

S. Cyrus Khojasteh, Harvey Wong, Discovery DMPK Quick Guide to Data Interpretation and integration Book 2022

Chemolab Lebrun, Development of a new predictive modeling technique to find with confidence equivalence zone and design space of chromatographic analytical methods, Chemometrics and Intelligent Laboratory Systems; 2008; 91(1): 4-16.

Sarwar Beg, Md Hasnain Pharmaceutical Quality by Design Principles and Applications 1st Edition - March 27, 2019

Walkiria S. Schlindwein, Mark Gibson Pharmaceutical Quality by Design: A Practical Approach 2018

Zoom Link

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