



SEVEN HILLS COLLEGE OF PHARMACY [AUTONOMOUS]

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



VAC Value Added Courses

VALUE ADDED COURSE ON CHIRAL METHOD DEVELOPMENT AND VALIDATION, DATA MANAGEMENT & HANDS ON TRAINING ON ANALYTICAL INSTRUMENTS

Organized by

Department of Pharmaceutical Analysis

ELIGIBILITY: M PHARM 1st & 2nd YEAR STUDENTS

All the students enrolled in this course will be provided with a certificate

HYBRID MODE

03-06-2023 to

09-06-2023



Patron

Dr. M. Niranjan Babu,

Professor & Principal,
Seven Hills College of Pharmacy,
Tirupati

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.



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 and solid working Principles of best practices (method development, operation, and troubleshooting) of HPLC.
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. Chiral chromatography in drug discovery and confirmation of enantiomeric drug purity, food science, and environmental analysis.
5. Data integrity (DI) reaffirms the pharmaceutical industry's commitment to manufacture drugs that are safe, effective and fulfil quality standards.

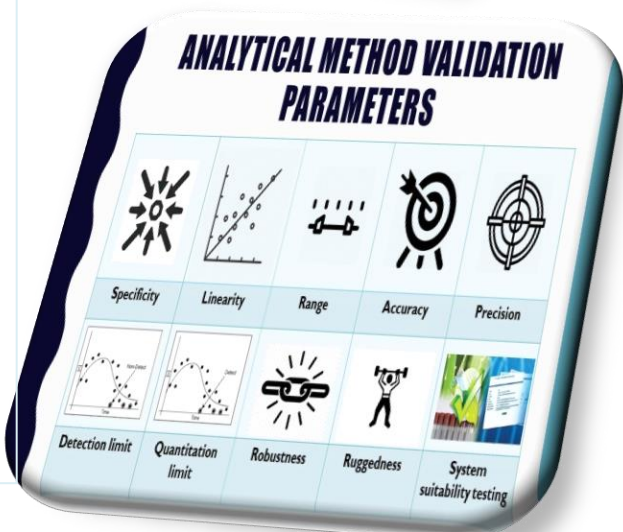
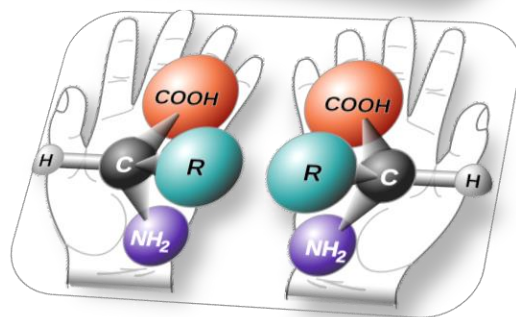
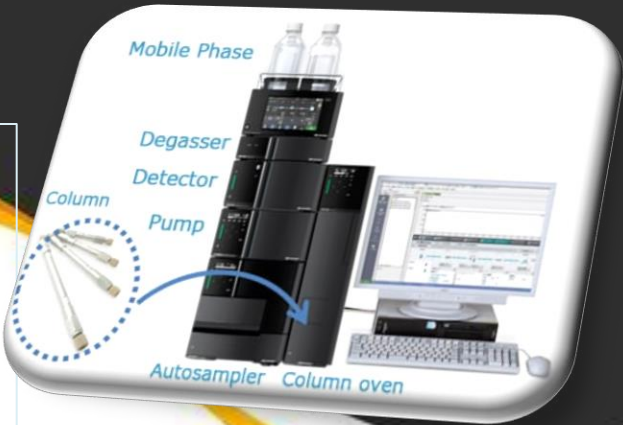
WHAT YOU LEARN

- Fundamentals of HPLC method development and Easier approaches, Overview of method validation and transfer.
- The ICH M10 guideline provides recommendations on the validation of bioanalytical assays for chemical and biological drugs and their metabolites in biological matrices
- An overview of applications of Bioanalysis in Pharmacokinetic Studies, Bioavailability Studies.
- DMPK studies can help evaluate the potential for drug-drug interactions (DDIs), and adverse effects.
- The separation of enantiomers of chiral compounds by chromatographic methods and related techniques.

WHO SHOULD ATTEND

Research Scholars, Post Graduate Students and B Pharmacy IV year Students who want to get an updated overview of fundamentals and best practices of method development, troubleshooting and diversified HPLC applications.

A basic understanding with hands-on experience in analytical instruments is assumed.



Key Speakers



Dr. GOWRAMMA. B
Associate Professor
Dept of Ph Chemistry
JSS College of Pharmacy,
Ooty, The Nilgiris, Tamil
Nadu.



Dr. B. BABU
Associate Professor
Head Drug Testing Lab
JSS College of Pharmacy,
Ooty, The Nilgiris, Tamil
Nadu.



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

Day-1 SESSION-1: Saturday 03-06-2023 (6 Hrs)

Topic: Fundamentals of HPLC Method Development and Validation & Easier approaches

Speaker-1: Mrs. B. Sivagami, Associate Professor, Dept of Pharmaceutical Analysis, Seven Hills College of Pharmacy, Tirupati

Day-2 SESSION-2: Monday 05-06-2023 (6 Hrs)

Topic: Data Integrity in Pharma Industry

Speaker-2: Dr. B. BABU, Associate Professor, Department of Pharmaceutical Analysis, JSS Academy of Higher Education and Research, Ooty, The Nilgiris, Tamil Nādu.

Day-3 SESSION-3: Tuesday 06-06-2023 (6 Hrs)

Topic: Calibration of HPLC & Troubleshooting strategies

Speaker-3: Mrs. B. Sivagami, Associate Professor, Dept of Pharmaceutical Analysis, Seven Hills College of Pharmacy, Tirupati

Day-4 SESSION-4: Wednesday 07-06-2023 (6 Hrs)

Topic: Chiral HPLC Column Selection & Screening, Tips and Tricks for Chiral HPLC

Speaker-4 Dr. GOWRAMMA. B, Associate Professor, Department of Pharmaceutical Chemistry, JSS Academy of Higher Education and Research, Ooty, The Nilgiris, Tamil Nādu.

Day-5 & 6 SESSION-5 & 6: Thursday & Friday 08-06-2023 & 09-06-2023 (12 Hrs) Practical Session: Hands on training on Analytical Instruments

Mrs. B. Sivagami, Associate Professor, Dept of Pharmaceutical Analysis, Seven Hills College of Pharmacy, Tirupati

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COURSE SYLLABUS

DURATION 36 HRS

COURSE NAME: VALUE ADDED COURSE ON CHIRAL METHOD DEVELOPMENT AND VALIDATION, DATA MANAGEMENT & HANDS ON TRAINING ON ANALYTICAL INSTRUMENTS

COURSE OBJECTIVES

- To provide basic understanding on sophisticated Instruments like UV-Visible Spectrophotometry, FTIR & HPLC
- Imparting training on procedures in handling sophisticated analytical Instruments
- Training on data keeping and routine maintenance of analytical instruments

COURSE OUTCOME

- To explain the theoretical aspects of key analytical techniques and instruments
- 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

Fundamentals of HPLC method development, physicochemical properties of drug molecules, setting up HPLC conditions, preparation of sample solution, Overview of method validation according to ICH guidelines such as accuracy, precision, linearity, LOD & LOQ, Robustness etc.

MODULE-2

Data integrity (DI) reaffirms the pharmaceutical industry's commitment to manufacture drugs that are safe, effective and fulfil quality standards.

MODULE-3

Calibration of HPLC components which include Calibration of pump, calibration of injector, calibration of Detector and potential issues surrounding HPLC and Troubleshooting strategies.

MODULE-4

Chiral chromatography in drug discovery and confirmation of enantiomeric drug purity, food science, and environmental analysis. The separation of enantiomers of chiral compounds by chromatographic methods and related techniques.

MODULE-5

A basic understanding with hands-on experience on analytical instruments such as RP-HPLC and Gas Chromatography.

REFERENCES

1. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol. I & II.
2. Skoog, Principles of Instrumental Analysis.
3. Chatwal & Anand, Instrumental Methods of Analysis.

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