KLE COLLEGE OF PHARMACY, BENGALURU

A CONSTITUENT UNIT OF KLE ACADEMY OF HIGHER EDUCATION & RESEARCH, BELAGAVI

VALUE ADDED COURSE

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

KLE College of Pharmacy, Bengaluru, offers the Certificate course in Analytical Method Development and Validation, empowering the candidates with all necessary theoretical and practical knowledge of the course content.

Course Duration

3 Months

Eligibility : B. Pharmacy 4th year

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(Constituent unit of KLE Academy of Higher Education and Research)

VALUE ADDED COURSE

COURSE SYLLABUS: **DURATION: 30 hours**

COURSE NAME: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

KLE College of Pharmacy, Bengaluru, offers the Certificate course in Analytical Method Development and Validation, empowering the candidates with all necessary theoretical and practical knowledge of the course content.

Course Objectives:

1. To ensure the use of calibrated analytical instruments in Method Development.
2. To identify the steps involved in Calibration of Analytical Instruments
3. To enhance skill in Method Development.
4. To study the ICH Guidelines for Method Validation.

Course Outcomes:

Upon completion of the value added course, the student will be able to

CO1: Understand the importance of calibration of analytical instruments.

CO2: Appreciate the significance of method development and validation in drug development.

CO3: Develop an analytical method for estimation of drugs and their combinations.

CO4: Overcome the troubles encountered during the process.

Eligibility	Duration	Programme Convener	Programme coordinator
B. Pharmacy (During their 4th year)	3 months certification course	**Dr. Vanita Somasekhar** Professor & HOD, Department of Pharm. Analysis, KLECOP, Bengaluru	**Dr. P. V. Murali Krishna** Associate Professor, Department of Pharm. Analysis, KLECOP, Bengaluru

COURSE CONTENT

MODULE-1 : SIGNIFICANCE OF CALIBRATION **06 hours**

Sl. No.	Topics	Hours
1	Calibration of Glassware	2 Hrs
2	Calibration of pH Meter	
3	Calibration of UV-Visible Spectrophotometer	
4	Potential issues surrounding the analytical instruments and trouble-shooting strategies	
5	Calibration of HPLC	1 Hr
6	Calibration of Dissolution Apparatus	1 Hr
7	Practical exposure to calibration of analytical instruments	2 Hrs

MODULE-2 : ANALYTICAL METHOD DEVELOPMENT **05 hours**

Sl. No.	Topics	Hours
1	Purpose, Steps for development of method, Characterization of analyte standard, Method requirements	2 Hrs
2	Literature review on prior methodology, Choosing a method, instrument set up, Optimization	1 Hr
3	Documentation, Evaluation of developed method, Demonstration of quantities in real samples.	2 Hrs

MODULE-3 : STEPS INVOLVED IN METHOD DEVELOPMENT **05 hours**

Sl. No.	Topics	Hours
1	Understanding physiochemical properties of drug molecules	1 Hr
2	Setting up HPLC conditions, Preparation of sample solutions, Method Optimization.	1 Hr
3	Practical Case Studies	1 Hr
4	Preparation of Buffer Solutions	2 Hrs

MODULE-4 : PREPARATIVE HPLC **03 hours**

Sl. No.	Topics	Hours
1	Developing HPLC Separation including effect of sample size, Optimizing separations & gradient separations	3 Hrs

MODULE-5 : QUANTITATION **03 hours**

Sl. No.	Topics	Hours
1	Measurement of Signals Quantitation Methods Sources of errors in Quantitation	3 Hrs

MODULE-6 : METHOD VALIDATION AS PER ICH GUIDELINES **04 hours**

Sl. No.	Topics	Hours
1	System suitability, Accuracy, Linearity, Detection limit, Quantification Limit, Specificity, Robustness	2 Hrs
2	Solution stability studies, Forced Degradation studies.	2 Hrs

MODULE-7 : INTERLABORATORY CROSS OVER STUDIES **01 hour**

Sl. No.	Topic	Hours
1	Transferability studies	1 Hr

MODULE-8 HANDS-ON TRAINING **03 hours**

Sl. No.	Topic	Hours
1	**Practical Session:** Handling of HPLC, Solvent Treatment, Sample injection, software handling, input of chromatographic conditions, and evaluation of chromatograms	3 Hrs

References:

1. Practical Pharmaceutical Chemistry, 4" edition, Part 2, by Beckett and Stenlake, CBS publishers and Distributors, P. No: 157-174.
2. Instrumental method of Chemical Analysis by Chatwal Anand, Himalaya Publishing House, P.No:615-623.
3. Govt. of India, Ministry of Health and family Welfare. Vol. 2. Delhi: Publication by controller of publication; 2007. Indian Pharmacopoeia; pp: 484-554.
4. Skoog, West, Holler, Crouch. Fundamentals of Analytical Chemistry, 8 edition, 2012 (Indian Edition), Cengage learning India Pvt Ltd, New Delhi, and Pg.No:271-280.
5. ICH Topic Q2 (R1) Validation of Analytical Procedures: Text and Methodology.
6. Azim Md. Sabir, Mitra Moloy, Bhasin Parminder S. HPLC Method Development and Validation: A review. International research Journal Of Pharmacy, 2013, 4(4): 39-46.
7. G.Santhosh, G. Nagasowjanya, A.Ajitha, Y.UmaMaheswara Rao. HPLC Method Development and Validation: An Overview.2014, 4(4) :274-280.

8. Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch. Practical HPLC Method Development second edition, A Wiley-Interscience Publication.