

Aditya nagar, Surampalem, Andhra Pradesh 533437



A Certificate course on "Method development and validation by HPLC"

Eligibility: III B.Pharm

Students who are interested to join the certificate course should contact the respective coordinator



Coordinator: P. Satya Mounika Asst. Professor, Aditya College of Pharmacy



Resource Person: N.Divya Asst. Professor, Aditya College of Pharmacy



Convener: Dr.K.Ravishankar Principal, Aditya College of Pharmacy



Patron: Dr.N. Satish Reddy Vice-Chairman, Aditya Educational Institutions



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





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(ADITYA NAGAR, ADB ROAD, SURAMPALEM 533 437, E.G.Dt, Ph.9949876664, 08852-200005)

Website: www.acop.edu.in, Email: office@acop.edu.in

COURSE SYLLABUS

DURATION: 30Hrs

COURSE NAME: METHOD DEVELOPMENT AND VALIDATION BY HPLC

Course Objective:

- To identify the steps involved in method development.
- To study the ICH guidelines for method validation
- To enhance skill in method development and validation.

Course Outcome:

- To understand the importance of method development and validation by HPLC in drug development.
- To understand procedures for method development and validation.
- To overcome the troubles during the process.

DAY 1: 21-01-2021 (6Hrs)

MODULE I:

HPLC – introduction, principle, instrumentation, applications. Chromatographic parameters.

DAY 2: 28-01-2021 (6Hrs)

MODULE II:

Analytical Method Development- Purpose, Steps for development of method, Characterization of analyte standard, method requirements, literature review on prior methodology, choosing a method, Instrumental Set up. Optimization, Documentation, Evaluation of developed method, demonstration of quantities in real samples.



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DAY 3: 04-02-2021 (6Hrs)

MODULE III:

Steps involved in Method Development- understanding physicochemical properties of drug molecules, Setting up HPLC conditions, Preparation of sample solutions for method development, method optimization, method validation.

DAY 4: 11-02-2021 (6Hrs)

MODULE IV:

Method validation-components – System Suitability, Accuracy, Precision, Linearity, Detection Limit, Quantification Limit, Specificity, Robustness, Solution Stability studies, Forced Degradation Studies.

DAY 5: 18-02-2021 (6Hrs)

MODULE V:

Practical Session- handling of HPLC, sample injection, software handling, input of chromatographic conditions, evaluation of chromatograms.

REFERNCES:

- 1. Practical Pharmaceutical Chemistry, 4th 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 bhy controller of publication; 2007. Indain Pharmacopoeia; pp. 484-554.



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- 4. Skoog, West, Holler, Crouch. Fundamentals of Analytical Chemistry, 8th edition, 2012 (Indian Edition), Cengage learning India Pvt Ltd, New Delhi, Pg.No:271-280.
- 5. ICh Topic Q2 (R1) Validation of Analytical Procedures: Text and Methodology.
- 6. Azim Md. Sabir, MitraMoloy, BhasinParminder 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.

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Approved by AICTE & PCI - NEW DELHI, Affiliated to JNTUK KAKINADA (Formerly known as Sri Sai Aditya Institute of Pharmaceutical Sciences & Research)

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Website: www.acop.edu.in

CERTIFICATE COURSE SUMMARY 2020-21

COURSE CODE AND NAME

CMDV and Method development and validation by

HPLC

COURSE DURATION

30Hrs

BRANCH AND YEAR OFFERED:

III B.Pharmacy

COURSE INSTRUCTORS

N.Divya, Assistant professor

COURSE OUTCOME

The student would be able to understand the importance of method development and validation by HPLC in drug development, procedures for method development and validation, and overcome the troubles during the process.

COURSE TYPE

Self framed course

ASSESSMENT MODE

ATTENDANCE

30 Hours

NO.OF PARTICIPANTS

105

SCHEME OF EXAM

MCQ Offline

DATE OF EXAM

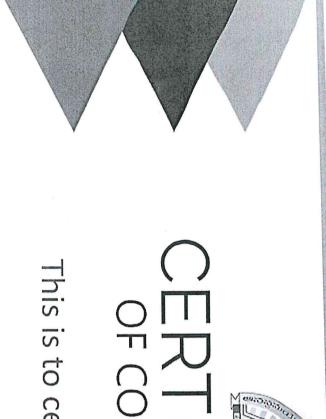
22-02-2021

PS. Moune la Course coordinator

SURAMPALEM RAPALEM RAP

Principal
PRINCIPAL
Aditya College of Pharmacous
SURAMPALEM-533 43





OF COMPLETION

This is to certify that Mr./Ms

"Method Development and Validation of HPLC." bearing roll number held in Aditya College of Pharmacy, Surampalem completed the Value-added course entitled from 21st January to 18th February 2021 has successfully

N. Sale Jady



Aditya College Of Pharmacy
SURAMPHIENUGAA (3 MOUM)

Director & Principal

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