

Enrollment Form Format

Name:

Branch of Health Sciences:

Name of the College and Address:

I would like to enroll / be informed about course

By Post / E-mail / SMS

Mobile No:

E-Mail ID:

Postal Address

Signature of the participant:

Forwarded by Head of the Institution

Signature and seal



**KLE ACADEMY OF HIGHER EDUCATION  
AND RESEARCH  
BENGALURU**

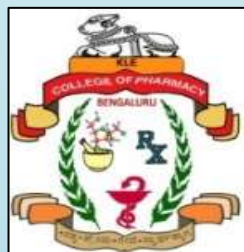


Reaccredited 'A+' Grade  
by NAAC  
Placed in category 'A' by MHRD, Govt. of  
India

**Value Added  
Courseon**

**FUNDAMENTAL OF  
PRECLINICAL STUDIES And  
SCIENTIFIC WRITING 2024**

Organized by



**KLE College of Pharmacy,  
BENGALURU  
(NAAC & NBA Accredited)  
2<sup>nd</sup> Block, Rajajinagar,  
Bengaluru - 560010, Karnataka**

**KLE Society** (Karnataka Lingayat Education Society) was started in 1916 by a group of young dedicated teachers and patrons. This Society aims to empower people through education and is well recognized for its quality education and health care services. Today, KLE Society manages around 293+ institutions with 1.38+ lakh student strength, and 18000+ employees offering world-class education in Healthcare, Pharmacy and paramedical sciences, Engineering, Management, Law and Agriculture. The educational services include School, Pre-University, Graduate and Post Graduate education **KLE Academy of Higher Education and Research** is sponsored by KLE Society was established in Belagavi in 2006 to highlight the Society's commitment to healthcare and Science education. KAHER is recognized by University Grants Commission (UGC), reaccredited "A+" grade by NAAC and placed in category "A" by MHRD, Govt. of India. KAHER provides internationally accepted education and healthcare practices, with impetus on research. University takes immense pride in its top-class faculty, curriculum and well-equipped infrastructure. The institutions of Medicine, Dentistry, Physiotherapy, Nursing, Pharmacy and Ayurveda are under the ambit of this university.

**KLE College of Pharmacy**, Bengaluru was the first private institution in Bangalore to offer a professional Diploma course in Pharmacy in 1976. The college introduced B. Pharm degree course in 1992 and post-Graduation in 2003, Doctoral Degree from 2005 and Pharm.D. from 2014. B. Pharm degree course was reaccredited in 2021 for 6 years by NBA, New Delhi.

### About the course:

Preclinical research includes In vitro, In vivo, Ex vivo, and in silico studies to obtain basic information about the safety and biological efficacy of a drug candidate. Preclinical research helps to identify potential organ toxicities, investigate dose response relationship and safety margins with respect to planned clinical doses. To bridge the gap in the existing syllabus, this value-added course was proposed and it mainly focus on important theoretical and practical aspects of preclinical research, which also includes analysis, compilation and reporting of scientific data. It helps to acquire knowledge of drug discovery and scientific writing and communication.

### Objective:

- Preclinical research aims at providing information about safety and efficacy of a drug candidate before testing it in humans.
- Provide a basic understanding of In vitro, In vivo, Ex vivo, and in silico studies
- Provide a laboratory hand on practice and gain knowledge of In vitro assay (anti-oxidant property and enzyme inhibition assay) and estimation of biochemical parameters.
- Provide guidelines for protocol and manuscript writing

### Resource persons:

- Faculty of Department of of Pharmacology and Toxicology, KLE College of Pharmacy, Bengaluru

### Chief Patron

**Dr. Prabhakar B. Kore,**  
Hon. Chancellor, KLE University, Belagavi

### Patron

**Dr. Nitin Gangane**  
Hon. Vice-Chancellor  
KLE Academy of Higher Education and  
Research (Deemed to be University)

### Chief Coordinator

**Dr. Rajamma A.J**  
Principal,  
KLE College of Pharmacy, Bengaluru

### Program Coordinators

**Dr. Hariprasad M.G.**  
Head of the Department of Pharmacology and  
Toxicology  
KLE College of Pharmacy, Bengaluru  
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### Mr. Rajashekar s chavan

Assistant Professor Department of  
Pharmacology and Toxicology  
KLE College of Pharmacy,  
Bengaluru  
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Mobile:9739338050,8904968759

- Specialized resource persons from  
**Topics:**

- **Introduction to In vitro, In vivo, Ex vivo, and in silico studies**
- **Neuropsychiatric disorders and its biomarkers.**
- **Metabolic disorders and its biomarkers**
- **Alternate to animal models.**
- **Protocol design and writing**
- **Scientific writing (Manuscript writing)**

### Career Prospects:

- **Preclinical research and development**
- **Drug Metabolism and Pharmacokinetics Research scientist**
- **Research Associate (pre-clinical pharmacology and Toxicology)**
- **Scientific data analyst**
- **Project specialist**
- **Scientific writer**

### Eligibility:

Students of B Pharmacy, PharmD, BAMS, UG-Ayurveda, MSc Clinical Research and other allied sciences of health science institutes who have genuine interest in Toxicological studies and Safety Pharmacology.

### Final grading and evaluation

On the basis of formative, summative and continuous mode assessment which includes submission assignment, report and presentation.

Schedule: June-August 2024

Classes: 2 Hrs. per week Please contact the Program Coordinators for further details:

**CERTIFICATE COURSE IN FUNDAMENTALS OF PRECLINICAL  
STUDIES AND SCIENTIFIC WRITING  
CONDUCTED AT**

**KLE COLLEGE OF PHARMACY, BENGALURU**

(Certified By KLE Academy of Higher Education and Research)

**Course Name:** Fundamentals of Preclinical studies and Scientific Writing

Preclinical research includes *In vitro*, *In vivo*, *Ex vivo*, and *In silico* studies to obtain basic information about the safety and biological efficacy of a drug candidate. Preclinical research helps to identify potential organ toxicities, investigate dose response relationship and safety margins with respect to planned clinical doses.

To bridge the gap in the existing syllabus, this value added course was proposed and it mainly focus on important theoretical and practical aspects of preclinical research, which also includes analysis, compilation and reporting of scientific data. It helps to acquire knowledge of drug discovery and scientific writing and communication.

KLE College of Pharmacy, Bengaluru, offers the Certificate course in Fundamental of Preclinical studies, empowering the candidates with all necessary theoretical and practical knowledge of the course content.

**Objectives:**

- ✓ Preclinical research aim at providing information about safety and efficacy of a drug candidate before testing it in humans.
- ✓ Provide a basic understanding of *In vitro*, *In vivo*, *Ex vivo*, and *In silico* studies
- ✓ Provide a laboratory hands on practice and gain knowledge of *In vitro* assay (anti-oxidant property and enzyme inhibition assay) and estimation of biochemical parameters.
- ✓ Provide guidelines for protocol and manuscript writing

**Course outcome:**

- ✓ Understand principles of preclinical research
- ✓ Describe pathophysiological features of Neuropsychiatric disorders, metabolic disorders and identification of their biomarkers.
- ✓ Illustrate Alternate to animals (*In silico*, *In vitro*)
- ✓ Appraise frame work of protocol and manuscript writing
- ✓ Understand and correlate practical skills of preclinical *In vitro* studies

<b>Eligibility</b>	<b>Duration</b>	<b>Programme Convener</b>	<b>Programme coordinator</b>
B.Pharm (During 3 <sup>rd</sup> Yr or 4 <sup>th</sup> Yr) /	3 months certification course	<b>Dr. Rajamma AJ</b> Principal, KLECOP.	<b>Dr. Hariprasad M.G.</b> Professor & HOD, KLECOP, Bengaluru <b>Mr. Rajashekar S chavan</b> Asst.Prof, KLECOP, Bengaluru

**Here are a few potential preclinical studies career opportunities:**

- Preclinical research and development
- Drug Metabolism and Pharmacokinetics Research scientist
- Research Associate (pre-clinical pharmacology and Toxicology)
- Scientific data analyst
- Project specialist
- Scientific writer

**Course content:**

1. Introduction to *In vitro*, *In vivo*, *Ex vivo*, and *In silico* studies
2. Neuropsychiatric disorders and its biomarkers.
3. Metabolic disorders and its biomarkers
4. Alternate to animal models.
5. Protocol design and writing
6. Scientific writing(Manuscript writing)

Module	Contents	hrs
<b>MODULE 1</b> Theory	• Introduction to <i>In vitro</i> , <i>In vivo</i> , <i>Ex vivo</i> , and <i>In silico</i> studies	04
<b>MODULE 2</b> Theory	• Neuropsychiatric disorders and their biomarkers	06
<b>MODULE 3</b> Theory	• Metabolic disorders and their biomarkers	06
<b>MODULE 4</b> Theory	• <b>Alternate to animals</b> <i>In silico</i> approach (virtual Screening) <i>In vitro</i> (Cell line studies)	04
<b>MODULE 5</b> Theory	• <b>Protocol design and writing</b> Introduction, Aim and objective, Methodology, Ethical consideration, Research outcome, References	04
<b>MODULE 6</b> Theory	• <b>Scientific writing</b> Writing and communication of Review article and Research article	04
<b>MODULE 7</b> Practical	• <b><i>In vitro</i> Assay:</b> Acetylcholinesterase activity Assay and Antioxidants, LPO Assay	06
<b>MODULE 8</b> Practical	• <b><i>In vitro</i> Assay:</b> a. Enzyme inhibition studies (Lipase, alpha amylase and alpha glucosidase inhibition) b. Biochemical estimation: Lipid profile, Liver function tests, renal function tests, OGTT and selected biomarkers of metabolic disorders.	06
****Note	➤ <b>Where ever applicable, ethical clearance will be obtained</b> ➤ <b>Wherever applicable, <i>Gallus domesticus</i> will be used</b>	