SANDIP FOUNDATION

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SANDIP INSTITUTE OF PHARMACEUTICAL SCIENCES

SANDIP FOUNDATION'S SIPS SANDIP INSTITUTE OF PHARMACEUTICAL SCIENCES

NAAC Accredited

COURSES OFFERED

ANIMAL HANDLING & PRECLINICAL STUDIES

2024-2025

ADD ON / VALUE ADDED CERTIFICATE COURSES

Our Animal Handling and Preclinical Studies program provides pharmacy students with the flexibility to enhance their academic experience by enrolling each academic year, with the option to take one module per semester. This approach allows students to deepen their expertise in animal research, expand their practical skills, and align their learning with their career goals. The program is designed to offer a comprehensive and adaptable educational experience in preclinical research.

COURSE OBJECTIVES

- Equip pharmacy students with comprehensive knowledge and practical skills in animal handling, preclinical study design, dose calculations, and toxicity studies.
- Ensure students understand and apply ethical considerations, regulatory requirements, and best practices in preclinical research.
- Prepare students for effective and responsible conduct of pharmaceutical research by fostering critical thinking and problem-solving abilities.
- Provide hands-on training and real-world scenarios to enhance the students' practical experience and confidence in preclinical studies.

COURSE OUTCOMES

- Demonstrate proficiency in handling and restraining common laboratory animals, minimizing stress and discomfort during procedures.
- Design and develop preclinical study protocols, including formulating study objectives, endpoints, control groups, and writing comprehensive protocols that meet regulatory guidelines.
- Perform accurate dose calculations and conduct various toxicity studies, such as acute, subacute, and chronic, while evaluating and interpreting toxicity endpoints.
- Understand and apply ethical principles and regulatory requirements.

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Campus: Mahiravani, Trimbak Road, Tal & Dist. Nashik–422213, Maharashtra, India.

COURSE MODULE

ANIMAL HANDLING AND PRECLINICAL STUDIES

Chapter	Topic	Hours	Resource Person
1	**INTRODUCTION TO ANIMAL HANDLING** Importance of animal handling in pharmaceutical research Ethical considerations, welfare regulations, and use of PPE Techniques for handling and restraining mice, rats, and rabbits Practical training sessions with supervised hands-on experience	06	Mrs. A. Pavani Gayathri
2	**PRECLINICAL STUDY DESIGN AND PROTOCOLS** Definition, importance, and stages of preclinical studies in drug development Regulatory requirements and guidelines Designing preclinical studies: objectives, endpoints, control groups, and statistical considerations Developing and writing study protocols, including ethical considerations and approval processes	06	Dr. Sarika Maruti Kamble
3	**DOSE CALCULATIONS AND TOXICITY STUDIES** Principles of dose calculation for different routes of administration Determining appropriate doses for efficacy and safety Conducting acute, subacute, and chronic toxicity studies Evaluating toxicity endpoints and interpreting results	06	Dr. Srinivas Nandyala
4	**LABORATORY TECHNIQUES IN PRECLINICAL STUDIES** Common techniques: blood collection, drug administration routes, monitoring physiological parameters Advanced techniques: Imaging, histopathology, and molecular biology techniques Practical sessions with hands-on training in basic techniques and demonstrations of advanced methods Data collection, statistical analysis, and presentation of preclinical study results	06	Dr. Sarika Maruti Kamble & Mrs. A. Pavani Gayathri
5	**ETHICAL CONSIDERATIONS AND REGULATORY AFFAIRS** Ethical guidelines and the 3Rs (Replacement, Reduction, Refinement) Best practices: humane endpoints, euthanasia, record-keeping Regulatory framework: key agencies (FDA, EMA), regulations, and guidelines Documentation: SOPs, study reports, regulatory submissions	06	Dr. Aman Suresh Tharayil

CHIEF PATRON

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Prof. Pramod Karole
Academic Facilitator
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REGISTRATION DETAILS

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