Punyashlok Ahilyadevi Holkar Solapur University, Solapur

NAAC Accredited-2015
'B' Grade (CGPA 2.62)

Name of the Faculty: Science & Technology

CHOICE BASED CREDIT SYSTEM

Syllabus: Pharmacy

Name of the Course: Ph. D. Course Work Paper No. 2(A)

(Syllabus to be implemented from w.e.f. June 2021)

Pharmacy Ph D Course Work

Paper- III

Drug Development Process: Overview, new drug development and regulatory approval in different countries, contents of the NDA, preclinical investigation, clinical phases of drug development, Pharmacokinetic and bioavailability-testing requirements, Concept of generic medicine, Bioequivalence study.

Pre-formulation study: Introduction, pre-formulation testing criteria, regulatory requirements. Physiochemical properties of active pharmaceutical ingredient, excipients and packaging materials.

Controlled Drug Delivery: Introduction, basic concepts, rationale of design of SR/CR drug delivery. Role of polymers in modifying drug delivery. Evaluation of drug release.

Drug Design: Approaches to drug design, traditional methods of drug discovery, rational drug design: computer-aided drug design, ligand-based drug design and, structure-based drug design. Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization: synthesis of analogs, variation of substituents, bioisosterism. Pro-drug approaches.

Basic concepts of spectroscopy (UV, IR, NMR and Mass) and chromatography (TLC, HPLC, HPTLC, GLC, preparative chromatography), interpretation of spectral data and applications in drug development.

Plant Constituents: Different techniques adopted for the extraction and isolation of phytoconstituents. Herbal Drug Standardization

Laboratory Animals: Good laboratory practice, Preclinical Screening of New Substances for the Pharmacological Activity. General principles of preclinical screening limitations of Animal Experimentation and Alternate animal Experiments, Extrapolation of in vitro Data to Preclinical and Preclinical to Humans, Toxicity Studies: Acute, sub-acute, sub-chronic, chronic toxicity. Regulatory Guidelines Guidelines for maintenance and experimentation using laboratory animals (CPCSEA, OECD, ICH, ICMR, Schedule Y). In-vitro Experimentation Techniques