CHPE06 PRE-FORMULATION STUDIES INCLUDING STABILITY STUDIES

COURSE OBJECTIVES:

1. Impart knowledge about Pre-formulation studies to be conducted in the new dosage form design
2. Promote understanding of the studies involved in the assessment of rate and extent of drug that reaches into systemic circulation.
3. Provide awareness on ICH guidelines for bioavailability and bioequivalence studies.
4. Divulge information on assessing the stability of formulations as per ICH guide lines

COURSE OUTCOMES:

After successful completion of the course, the students are able to

1. Understand and carry out Pre-formulation studies for the successful development of dosage form.
2. Apply the knowledge of various factors influencing the absorption and evaluate drug release by dissolution studies.
3. Choose appropriate study design involved in the bioavailability and bioequivalence.
4. Utilize the knowledge of ICH guidelines for conducting stability & photo-stability studies.

UNIT I [CO:1] **(12)**

Introduction: Pre-formulation studies & Itâ€™s Objectives and goals, Multidisciplinary development of a drug candidate, Principal areas of Pre-formulation research, Essential information helpful in designing the Pre-formulation evaluation of a new drug.

Bulk Characterization: Crystallinity & Polymorphism, Hygroscopicity, Analytical Instruments: Scanning Electron Microscopy (SEM), Thermal Analysis and Gas Chromatography, Fine particle characterization, Bulk density and powder flow properties.

UNIT II [CO:2] **(12)**

Drug Solubility: methods for enhancement of solubility. Drug absorption. Drug transport mechanisms, factors and kinetics involved. Physico- chemical and biological factors involved in Drug absorption.

Drug Dissolution: Drug Dissolution: Mechanisms, Factors and Kinetics of dissolution, Dissolution rate - Significance, Methods for enhancement of dissolution rate.

UNIT III [CO:3] **(12)**

Bioavailability: Concept, definition, objectives of bioavailability study, Measurement of Bioavailability as per ICH Guide lines.

Bioequivalence: Bioequivalence: Concept, definitions, study designs for bioequivalence studies, Study protocol and analysis of data as per ICH Guide lines.

UNIT IV [CO:4] **(12)**

Stability Testing: Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations, strategies for prolonging shelf life.

Effect of packaging materials on dosage form stability. Basic principles of ICH for stability testing of new drug substance and formulations. Photo Stability and oxidative stability.

LEARNING RESOURCES:

TEXT BOOK(s):

1. Industrial pharmacy by Libermann & Lachman, 4th Edition.

2. The science and practice of pharmaceutical dosage forms by ME Alton 2nd Edition
3. BioPharmaceutics and Pharmacokinetics, D.M. Bramankar and Sunil B. Jaiswal.

REFERENCE BOOK(s):

1. BioPharmaceutics and Pharmacokinetics, D.M. Bramankar and Sunil B. Jaiswal, 3rd Edition Pharmaceutical Sciences by Remingtons, 21st Edition
2. Modern pharmaceutics by Banker & Rhodes, 12th Edition.