

SIKKIM UNIVERSITY

SYLLABUS

FOR

PH.D. (PHARMACY)

COURSE WORK

2019

# Sikkim University

## Syllabus for Ph.D. (Pharmacy) Course Work

Semester	Paper Code	Name of the Paper	Credits	Full Marks
I	PHA-RS-C101	<i>Compulsory Subject:</i> Research Methodology	4	100
	PHA-RS-C102	<i>Compulsory Subject:</i> Preparation of Research Proposal	4	100
	PHA-RS-O103 PHA-RS-O104 PHA-RS-O105 PHA-RS-O106 PHA-RS-O107	<i>Optional Subjects: (Any One)</i> Advanced Pharmaceutics Advanced Pharmaceutical Chemistry Advanced Pharmacognosy Advanced Pharmacology Advanced Pharmaceutical Analysis & Quality Assurance	4	100
	II & III	PHA-RS-C201	Dissertation/ Project	12

## PHA-RS-C101: RESEARCH METHODOLOGY

### **I: Research Methods:**

Introduction to research; Definitions and characteristics of research; Types of research; Main components of any research work, Criteria for prioritizing problems for research. Analysis and Statement of the problem.

Research Design: Different Research Designs, Basic Principles of Experimental Designs.

Uses of literature review; Source of information; Organization of information on index cards.

Data collection; Methods of data collection; Plan for data processing and analysis.

Plagiarism and Research Ethics.

### **II: Statistical Methods:**

Probability & Sampling distribution; Estimation, Hypothesis testing & application; Correlation & regression analysis. Types of Experiment design: Student t-test, Chi-square test, Analysis of Variance (ANOVA).

### **III: Computer Applications:**

Spreadsheet tool: Features & functions, using formulae & functions, data storing, features for statistical data analysis, generating charts/graphs & other features [Tools: Microsoft Excel, Open office and similar or other advanced tools]. Presentation tool: Introduction to presentation tool, features & functions, creating presentations, customizing presentation [Tools used: Microsoft PowerPoint, Open Office or any other tool]. Thesis writing & Scientific editing tools.

### **IV: Drug Regulatory Affairs:**

Indian Patent Act 1970 and its amendments, Concepts of IPR, criteria for granting patents, and filing an Indian patent. Patent infringement. OECD guidelines and ICH guidelines.

### **Books Recommended:**

1. Montgomery, Douglas C. (2007) 5/e, Design and Analysis of Experiments (Wiley India).
2. Montgomery, Douglas C. & Runger, George C. (2007) 3/e, Applied Statistics & probability for Engineers (Wiley India).
3. Kothari C.K. (2004) 2/e, Research Methodology – Methods and Techniques (New Age International, New Delhi).
4. Krishnswamy, K.N., Shivkumar, Appa Iyer and Mathiranjani M. (2006) Management Research Methodology; Integration of Principles, Methods and Techniques (Pearson Education, New Delhi).
5. The Complete reference Office Xp- Stephan L. Nelson, Gajula Kelly (TMH).
6. Basic Computer Science and Communication Engineering – R. Rajaram (SCITECH).

## PHA-RS-C102: PREPARATION OF RESEARCH PROPOSAL

Preparation of Research Proposal is a non-lecture paper where the student has to write a detailed research proposal through review of literature in the topic of research and present the same in a seminar at the end of the semester.

## PHA-RS-O103: ADVANCED PHARMACEUTICS

- 1. Preformulation:** Introduction, organoleptic properties, purity, particle size, shape & surface area. Effects of particle size & surface area, temperature, pH, co-solvency, surfactants, molecular inclusion & solid dispersion on solubility. Crystal properties & polymorphism, stability studies & shelf life.
- 2. Polymers:** Natural and synthetic polymers with respect to their pharmaceutical applications.
- 3. Controlled Drug Delivery:** Concept and design of oral, buccal, bone, vesicular and transdermal drug delivery systems.
- 4. Compartment Modeling in Pharmacokinetics:** Significance of different pharmacokinetic parameters, Non-linear pharmacokinetic and reasons thereof.
- 5. Bioavailability and Bioequivalence Studies:** Concepts of bioavailability and bioequivalence, design and interpretation of results.

### Books Recommended:

1. Chien, Y.W. 1992. Novel Drug Delivery Systems. New York: Marcel Dekker, Inc. ...
2. Robinson, J.R., Lee V.H.L. 1992. Controlled Drug Delivery Systems. New York: Marcel Dekker, Inc.
3. Mathiowitz, E. 1999. Encyclopedia of controlled delivery. New York/ Chichester/ Weinheim: Wiley Interscience Publication, John Wiley and Sons, Inc.,
4. Banker and Rhodes. 1990. Modern Pharmaceutics. New York: Marcel Dekker, Inc.
5. Lachman, Lieberman, Kanig J.L. 1987. Theory and Practice of Industrial Pharmacy. Bombay: Varghese Publishing House.
6. Gibaldi, M. Text book of Bio-Pharmaceutics and clinical Pharmacokinetics (3<sup>rd</sup> ed.) Philadelphia: Lea & Febiger.
7. Berry, I.R., Robert, A. 1993. Pharmaceutical process validation (Drugs and Pharmaceuticals Series) (2<sup>nd</sup> ed) New York: Marcel Dekker Inc.
8. Gilbert R. and Banker 1990. Modern Pharmaceutics (2<sup>nd</sup> ed.), New York: Marcel Dekker Inc.
9. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing Company, Eastern Pennsylvania.
10. Remington's Pharmaceutical Sciences, by Alfonso and Gennaro, 19<sup>th</sup> edition 1995 Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

## PHA-RS-O104: ADVANCED PHARMACEUTICAL CHEMISTRY

1. Modern concept and principles of drug design, analog design, receptors and enzymes as drug targets and their characterization, drug-target interactions, modern virtual and physical tools for lead compound identification and optimization: molecular modeling, virtual docking, combinatorial synthesis and high-throughput screening.
2. Modern synthetic methods: Microwave assisted organic synthesis – concepts, applications and case studies. Solid-phase organic synthesis – concepts and applications. Transition metal catalyzed reactions and coupling reagents and their applications. Reaction mechanisms: Aldol condensation, Cannizzaro reaction, Hoffmann degradation, Perkin's reaction, Birch reduction, Diazotization, Mitsunobu, Stille, Suzuki, Heck, Buchwald-Hartwig amination
3. Synthesis, mode of action, structure-activity relationships of newer drugs and agents belonging to the following categories: COX-2 inhibitors, anti-histamines (H1, H2 & H3), oral hypoglycemics, anticonvulsants, fluoroquinolone antibiotics, anticancer & anti-HIV drugs.
4. Mode of actions of (a) Steroids: Sex hormones; (b) Glycosides (c) Antibiotics: New generation cephalosporins and macrolides.

### Books Recommended:

1. Burger's Medicinal Chemistry (6<sup>th</sup> Ed.). Vol-I & II. The Basis of Medicinal Chemistry. John Wiley
2. Block, J.H., Beale, J.M. 2004. Wilson & Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry (11<sup>th</sup> Ed.). Lippincott Williams & Wilkins
3. Evaluation of Herbal Medicinal Products - Perspectives of Quality, Safety and Efficacy" Pulok K. Mukherjee, Peter J. Houghton, Pharma. Press, Royal Pharmaceutical Society of Great Britain, 2009.
4. Quality Control on Herbal Drugs- Pulok K. Mukherjee, Eastern Publishers (Business Horizons Ltd.) New Delhi 2002.
5. Peech and Tracey, Modern Methods of Plant Analysis.
6. Miller, Jan Nostrant Rein Hold. Pytochemistry Vol-I and II
7. Recent Advances in Pytochemistry – Vol:I-IV, Scikel Runeckles.
8. Chemistry of Natural Products Vol-I onwards IWPAC
9. Nakanishi, G., Natural Products Chemistry.
10. Martin, Y.C. Introduction to Quantitative Drug Design.

## PHA-RS-O105: ADVANCED PHARMACOGNOSY

- 1. Extraction and Isolation techniques:** Introduction, Principle and Applications of different extraction & isolation methods viz Soxhlet extraction, microwave extraction, supercritical fluid extraction etc.
- 2. Recent development in the research on Natural medicinal products:** Isolation and Pharmacological studies of different class of Phytoconstituents (Alkaloids, Glycosides, Steroids, and Saponins etc).
- 3. Application of chromatographic techniques and spectroscopic techniques:** Application of chromatographic techniques such as column, paper, TLC, HPTLC, GLC, HPLC in the isolation and purification of phyto-pharmaceuticals. Applications of spectroscopic techniques like UV, IR, NMR and Mass spectroscopy for structural elucidation of phyto-pharmaceuticals.
- 4. Methods of biological evaluation of plant drugs for the following pharmacological categories:** Antidiabetics, hepatoprotectives, antioxidants, anti-inflammatory and analgesics.
- 5. Standardization of herbal drugs:** Determination of pesticide residue, Determination of Micro-organisms, Determination of Arsenic and heavy metals
- 6. Herbal Drug Regulatory affairs**  
Role and importance of national and international regulatory bodies in assessment of quality of herbal drugs and formulations.
- 7. Tissue Culture Techniques:** Types, Techniques and Application of Callus, Suspension, and organ culture, Hairy root culture and their application, Protoplast culture and Protoplast fusion.

### Books Recommended:

1. Brain, K.R. & T.D. Turner, T.D. 1998. The Practical Evaluation of Phytopharmaceuticals. Bristol: Wright Scietechnical.
2. Kalia, A.N. Industrial Pharmacognosy.
3. Agarwal, S.S. Herbal Drug technology.
4. Choudhury, R.D. 1996. Herbal Drug Industry. New Delhi: Eastern Publisher.
5. Anonymous. 1998, 2000. Indian Herbal Pharmacopoeia. RRL, IDMA.
6. Rajpal, V. 2002. Standardisation of botanical. New Delhi: Eastern Publishers.
7. Verpoortee, R & P.K. 2003. GMP for botanicals - regulatory and quality issues on phytomedicines. New Delhi: Business Horizons.
8. Mukherjee, P.K. 2002. Quality Control of Herbal Drugs. New Delhi: Business Horizons.
9. Tyler, V.E & Brady, R. 1981. Textbook of Pharmacognosy. Philadelphia: Lea and Febiger.
10. Peech and Tracey, Modern Methods of Plant Analysis.

## PHA-RS-0106: ADVANCED PHARMACOLOGY

1. Introduction to new approaches in drug discovery, drug development process- Preclinical, clinical trials with special emphasis on types, design, phases-0, I, II, III, IV. Ethical consideration, drug toxicity, ADR, drug interaction.
2. Detailed study of guidelines for maintenance, breeding techniques and experimentation using laboratory animals: CPCSEA, ICH, GLP, ICMR.
3. Fundamentals of molecular mechanism of drug action: Pharmacokinetic, pharmacodynamic-drug receptor interaction, receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, phosphatidyl inositol, ion channels and their modulators. Experimental tools for studying molecular mechanism such as bioassay (including Meta analysis).
4. Drugs acting on nervous system: Chemical mediators (ACH, NA, nitric oxide, amino acid transmitters, dopamine, histamine). Cholinergic transmission, adrenergic transmission and drugs acting on CNS disorder like neurodegenerative disorder, antipsychotic, antidepressant, antiepileptic and opioid analgesic.
5. Drugs affecting major organ system: Heart, atherosclerosis and lipoprotein metabolism, haemopoietic system.
6. Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory, analgesic, anti-diabetic, hepatoprotective, nootropic and anti-cancer activities.
7. Introduction to Pharmacogenomics, proteomics and array technology. Alternatives to animal experimentation: Animal cell lines and their uses, radioligand binding assay, ELISA, stem cell research etc.

### Books Recommended:

1. Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman. 2011. The Pharmacological basis of therapeutics. 12th ed. McGraw-Hill.
2. H.P. Rang M.M, Dale, J.M. Ritter & P.K. Moore. 2011. Rang and Dale's Pharmacology. 7<sup>th</sup> ed. Elsevier.
3. H. Gerhard Vogel, W.H. Vogel. 2002. Drug discovery and evaluation. 2<sup>nd</sup> ed. Springer.
4. Bertram G. Katzung, Susan B. 2012. *Basic & Clinical Pharmacology*. 12<sup>th</sup> ed. McGraw-Hill.
5. Dan L. Longo, Anthony S. Fauci, Dennis L. Kasper and Stephen L. Hauser. 2011. *Harrison's Principles of Internal Medicine*. 18<sup>th</sup> ed. McGraw-Hill.
6. Joseph T. DiPiro, Robert L. Talbert, Gary C. Yee, Gary R. 2014. *Pharmacotherapy: A Pathophysiologic Approach*. 9<sup>th</sup> ed. McGraw-Hill.
7. Michael Lieberman, Rick E. Ricer. 2013. BRS Biochemistry, Molecular Biology, and Genetics. 6<sup>th</sup> ed. Lippincott Williams and Wilkins.

## PHA-RS-O107: ADVANCED PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE

1. **Analytical method validation:** Spectroscopic methods (UV, FTIR, NMR), HPLC and GC methods, statistical analysis and significance in analytical methods.
2. **Analysis of drugs and excipients:** Analysis of drugs and excipients in the solid state. Introduction, particle size analysis, importance of particle size in various dosage forms, methods of particle size analysis, X-ray powder diffraction.
3. **Principles and procedures involved in the use of the following reagents in pharmaceutical Analysis:** MBTH (3-methyl-2-benzothiazone) reagent, FC (Folin Ciocalteu) reagent, Ninhydrine reagent, Bratton-Marshall reagent.
4. **Pyrogens:** Production, chemistry and properties of bacterial pyrogens and endotoxins. Pyrogens testing. Interpretation of data comparison with other official pyrogen tests.
5. **Sterility testing-methodology and interpretation.**
6. **Microbial assays of antibiotic and vitamins.**
7. **Quality Assurance:** GMP, GLP, ISO 9000, TQM.

### Books Recommended:

1. Ghosh S.K. Introduction to ISO 9000 and Total quality management. Calcutta: Oxford Publishing House.
2. Shah, D.H. QA Manual, 1<sup>st</sup> edition, 2000, Business Horizons.
3. Controller of Publications, Govt. of India: Indian Pharmacopoeia 1996., Vol-I and II.
4. The international pharmacopoeia Vol-1.2.3.4; 3<sup>rd</sup> edition, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
5. Hobarth Williard. Instrumental Methods of Analysis. 6<sup>th</sup> Edition, CBS Publishers, New Delhi, 2002.
6. Skoog, West. Pharmaceutical Analysis.
7. A.I. Vogel. Text Book of Quantitative Chemical Analysis. ELBS Longman. London.
8. Instrumental Methods of Analysis by Gurdeep Chatwal.
9. Kemp, W. Spectroscopy
10. Kenneth, A. Connors. 1982. Text Book of Pharma. Analysis. (3<sup>rd</sup> Ed.) New York: John Wiley & Sons.