

Scheme and Syllabus

First Semester

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
C R-101	Pharmacology-101	3	1	-	40	60	100	3	4
CR -102	Clinical Research-102	3	1	-	40	60	100	3	4
CR -103	Medicine - 103	2	2	-	40	60	100	3	4
CR -104	Biostatistics -104	2	2	-	40	60	100	3	4
CR-105	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4
		10	06	8	200	300	500	--	20

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CR - 101	Pharmacology-101	3	1	-	40	60	100	3	4

Introduction to Pharmacology – Definitions and brief – (pharmacology, pharmacokinetics, pharmacodynamics, drug, pharmacotherapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts

Routes of Drug Administration – Local routes (topical, deeper tissues and arterial supply etc.), systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.)

Dosage Forms of Drug – Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices)

Sources of Drugs – Natural sources and synthetic sources

Pharmacodynamics – Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction

Factors Modifying Drug Action - Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc.

Pharmacokinetics – brief of absorption, distribution, metabolism and excretion

Autonomic nervous system - Introduction, cholinergic system, anti-cholinesterase, anticholinergic, adrenergic system, alpha blocker, beta blocker

Reference Books

1. Rang & Dale's Pharmacology, 7th Edition. By Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Publisher: Elsevier.
2. Basic and Clinical Pharmacology, 12th Edition. By Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor. Publisher: Lange.

3. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 12th Edition. Laurence Brunton, Bruce Chabner, Bjorn Knollman. Publisher: Mc Graw Hill.
4. Essentials of Medical Pharmacology, 7th edition. By K D Tripathi. Publisher Jaypee.
5. Ganong's Review of Medical Physiology, 24th Edition. Authors: Kim E. Barrett, Susan M. Barman Scott Boitano, Heddwen Brooks. Publisher: Lange.

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C R-102	Clinical Research-102	3	1	-	40	60	100	3	4

Introduction to Clinical Trials - Glossary of terms in clinical trials, history, requirements, new drug development process, need for new drug, selection of a chemical compound as a potential drug, screening of chemical compounds, translation medicine, assessment of preclinical data

Phases of clinical trials- Phase 1, Phase 2, Phase 3, Phase 4

Principles of controlled clinical trials- Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials- Requirements, regulations and feasibility. Improving patient enrolment and retention in Clinical Trials

Other Clinical Studies- Pharmacoepidemiology, pharmacovigilance, ADR monitoring, pharmacokinetic trials, quality of life studies

Legal issues in clinical trials

Drug regulations- National- good clinical practice and schedule Y

Critical evaluation of literature- Systematic review and meta analysis, evidence based medicine

Reference Books

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Shein-Chung Chow, Jen-Pei Liu. Publisher: Wiley.
3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

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RC - 103	Medicine-103	2	2	-	40	60	100	3	4

Note: brief study of the following topics with their relevant applications

Introduction to clinical medicine – Science and art of medicine, global issues in medicine, screening and prevention of diseases

Basic climatic and environmental diseases

Diabetes mellitus - Functional anatomy, physiology, presenting problems in Diabetes mellitus, management, drugs-class effect and side effects, dietary management, long term complications in brief

Hypertension - Definition, types of hypertension, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects

Coronary artery diseases - Ischemic heart disease ; definition , types, causative factors, pathophysiology, life style modifications, treatment (different classes) ,class effect and side effects in brief

Cerebrovascular diseases- Stroke; etiology, management; life style modifications, treatment (different classes), class effect and side effects in brief

Reference Books

1. Harrison's Principles of Internal Medicine, 18th Edition. Dan Longo, Anthony Fauci, Dennis Kasper, Stephen Hauser, J. Jameson, Joseph Loscalzo. Publisher: McGraw-Hill.
2. Davidson's Principles and Practice of Medicine, 22nd Edition. Brian R. Walker, Nicki R Colledge, Stuart H. Ralston, Ian Penman. Publisher: Churchill Livingstone, Elsevier.
3. Oxford Handbook of Clinical Medicine, 9th Edition. Murray Longmore, Ian Wilkinson, Andrew Baldwin, and Elizabeth Wallin. Oxford Medical Handbooks.

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CR - 104	Biostatistics-104	2	2	-	40	60	100	3	4

Introduction- Biostatistics and standard terminology

Basic knowledge about presentation of data - Type of diagram, one dimensional diagram, two dimension diagram, three dimensional, pie diagram and pictogram

Graphic representation of data - Histogram, frequency, polygon and frequency curve.

Sampling - Definition, selection of samples, merit and limitation of sampling, methods of sampling.

Measures of central tendency - Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean.

Measures of dispersion - Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation.

Definition and application - Correlation, regression, Chi-square test and t-test.

Reference Books

1. Biostatistics, 1st Edition. Sai Subramanian. Publisher: Career Publications.
2. Pharmaceutical Biostatistics, 1st Edition. Shadab Ahmed Khan, Ismaili, Ahmed and Husain. Publisher: Birla Publications.
3. Biostatistics for Pharmacy, 1st Edition. Khan and Khanum. Publisher: Ukaaz Publication.
4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

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CR - 105	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4

MS- Excel – Introduction to excel and RDBMS

Clinical Data Management – Overview, regulation, data management plan, data acquisition and CRF designing, database designing and implementation, data entry and verification and data analysis.

Soft Skills - Introduction and definition, motivation, SWOT analysis, goal setting, business etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.

Communication – Types of communication, pronunciation; consonants and vowel sounds. Grammar; noun, adjectives, use of definite and indefinite articles, tenses. Vocabulary; antonyms, synonyms, homonyms, one word substitution, common phrases and idiomatic expressions. Vocabulary power; words related to various concepts of life and activities.

Reference Books

1. Practical Computer Literacy, 3rd Edition. June Jamrich Parsons, Dan Oja. Publisher: CENGAGE Learning.