

Program and Course Structure

School of Medical Science and Research

MSc (Medical Pharmacology)

Session:2020-22

1. Standard Structure of the Program at University Level

1.1 Vision, Mission and Core Values of the University

Vision of the University

To serve the society by being a global University of higher learning in pursuit of academic excellence, innovation and nurturing entrepreneurship.

Mission of the University

1. Transformative educational experience
2. Enrichment by educational initiatives that encourage global outlook
3. Develop research, support disruptive innovations and accelerate entrepreneurship
4. Seeking beyond boundaries

Core Values

- Integrity
- Leadership
- Diversity
- Community

1.2 Vision and Mission of the School

Vision of the School

To serve the society by being a premier institute that promotes a comprehensive approach to human health through excellence in academics, research and clinical care

Mission of the School

- Provide a transformative educational experience in Medical Science
- Develop skills and competencies to create global leaders in clinical care
- Promote innovative and collaborative research through intellectual and technological advancement
- Establish a center for excellence in preventive, promotive and curative health care

Core Values

- Integrity
- Leadership
- Ethics
- Community Health

1.3 Program Educational Objectives (PEO)

1.3.1 Writing Program Educational Objectives (PEO)

Program Objectives

At the end of the MSc training program in Pharmacology, the student should acquire competencies in the following areas:

PEO1. Acquisition of knowledge

The student should be able to explain clearly concepts and principles of Pharmacology and therapeutics. The student should also be able to explain the drug development processes. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial procedures

PEO2.Teaching and training

The student should be able to effectively teach undergraduate students in medicine (MBBS) and allied health science courses (Dentistry and Nursing) so they become competent healthcare professionals and able to contribute to training of postgraduate trainees.

PEO3. Research

The student should be able to carry out a research project (both basic and clinical) from planning to publication and be able to pursue academic interests and continue life-long learning to become more experienced in all the above areas and to eventually be able to guide postgraduates in their thesis work

1.3.2 Map PEOs with Mission Statements:

PEO Statements	School Mission 1	School Mission 2	School Mission 3	School Mission 4
PEO1. The student should be able to explain clearly concepts and principles of Pharmacology and therapeutics. The student should also be able to explain the drug development processes. S/he should be able to explain Drugs and Cosmetics Act, in addition to clinical trial	3	3	3	3

procedures				
PEO2. The student should be able to effectively teach undergraduate students in medicine (MBBS) and allied health science courses (Dentistry and Nursing) so they become competent healthcare professionals and able to contribute to training of postgraduate trainees.	3	3	2	3
PEO3. The student should be able to carry out a research project (both basic and clinical) from planning to publication and be able to pursue academic interests and continue life-long learning to become more experienced in all the above areas and to eventually be able to guide postgraduates in their thesis work	3	3	3	3

1.3.3 Program Outcomes (PO's)

1. Cognitive domain

PO1. Describe and apply pharmacological principles to explain the mechanism/s of the effects of drugs used in diagnosis, prevention and treatment of diseases of all systems of human body.

PO2. Explain pharmacodynamics and pharmacokinetics of drugs.

PO3. Acquire knowledge on pharmacogenetics and pharmacogenomics

PO4. Acquire knowledge on principles of Pharmacoeconomics, pharmacoepidemiology, including drug utilization studies.

PO5. Acquire knowledge on essential medicines and pharmacovigilance

PO6. Acquire knowledge and apply the principle of biostatistics in the evaluation and interpretation of drug safety and efficacy studies

PO7. Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery

PO8. Demonstrate knowledge of basics of research methodology, develop a research protocol, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and disseminate these results and to have the potential ability to pursue further specializations and eventually be competent to guide students.

PO9. Describe the principles of teaching - learning technology towards application and take interactive classroom lectures, modules for problem based learning (PBL), case discussions, small group discussions, seminars, Journal club and research presentations

PO10. Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.

PO11. Demonstrate knowledge of principles of Instrumentation.

PO12. Demonstrate knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology.

PO13. Acquire knowledge on generic drugs and generic prescription.

PO14. Acquire knowledge on rational use of drugs and prescription auditing

PO15. Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance

PO16. Acquire knowledge on animal toxicity studies

PO17. Acquire knowledge on common poisoning

PO18. Acquire knowledge

- a. On the legal and ethical issues involved in drug development and research.
- b. and understanding of the various principles & guidelines (GCP, CPCSEA, ICH-GCP etc.) both applicable to pre-clinical & clinical research.

PO19. Acquire knowledge in Biostatistics including use of statistical software's :

Affective domain

PO20. Communicate effectively with pharmacological reasoning with students, peers, staff and faculty,

PO21. Demonstrate ethical behavior and integrity in one's work.

PO22. Acquire skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.

Psychomotor domain

PO23. Able to predict efficacy and adverse effects associated with use of drugs, along with causality assessment.

PO24. Perform major *in vivo* and *in vitro* animal experiments.

PO25. Observe and understand basic principles of working of important advanced techniques, like High Performance Liquid Chromatography (HPLC).

PO26. Demonstrate standard operating procedures of various methods and techniques used in clinical trials and research.

PO27. Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.

PO28. Be able to analyze and evaluate a research paper

1.3.4 Mapping of Program Outcome Vs Program Educational Objectives

	PEO1	PEO2	PEO3
PO1	3	3	3
PO2	3	3	3
PO3	3	3	3
PO4	3	3	3
PO5	3	3	3
PO6	3	3	3
PO7	3	3	3
PO8	3	3	3
PO9	3	3	3
PO10	2	2	3
PO11	3	3	3
PO12	3	3	3
PO13	3	3	3
PO14	3	3	3
PO15	3	3	3
PO16	3	3	3
PO17	3	3	3
PO18	3	3	3
PO19	2	2	3
PO20	3	2	3
PO21	3	2	3
PO22	3	3	3
PO23	3	3	3
PO24	3	3	3
PO25	3	3	3
PO26	3	3	3

PO27	3	3	3
PO28	3	2	3

School: SMSR		Batch: 2019-20
Program: MSc MEDICAL PHARMACOLOGY		Current Academic Year: 2019-20
1	Programme Code	SMS0702

Department of Pharmacology

School of Medical Sciences & Research

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Date:-7/02/2019

Curriculum

M.Sc. in Pharmacology

Goals

The overall goal of the course is to develop expertise in the field of Pharmacology. A process of rational thinking and coherent action will be inculcated in an individual so that he/she shall be competent to pursue various activities as demanded by the profession, as a Pharmacologist and to orient the learners towards research in the field of Pharmacology

Objectives

To achieve this goal, the following objectives must be fulfilled. At the end of course in Pharmacology, the trained specialist shall be able to

1. Acquire sound knowledge of general pharmacological principles, systemic pharmacology and rational use of drugs.
2. Perform common experimental techniques required for evaluation of new drug with competence.
3. Carry out screening of drugs for pharmacological and toxicological profile.
4. Critically review and comment on research papers.
5. Monitor adverse drug reactions, therapeutic drug monitoring, and able to provide drug information service.
6. Preparation of protocols to conduct experimental studies in animals and human drug trials independently.

7. Plan and conduct lecture, practical demonstration, and tutorial classes for students.
8. Plan and carry out both laboratory and clinical research with adherence to scientific methodology and GLP/GCP guidelines
9. Be aware of legal and ethical aspects of drug evaluation.
10. Communicate the findings, results and conclusions of scientific research, both verbally and in writings.
11. Be aware of regulatory procedures needed to be carried out prior to the marketing of a new drug in India.
12. Develop the ability for continued self-learning so as to update the knowledge of recent advances in the field of Pharmacology and allied fields.

Learning Methods

The following self learning sessions for the students will be held

- Post graduate lectures to update knowledge in various aspects of pharmacology.
- Therapeutic club: To critically analyze the day to day development in therapeutics and new drug development
- Journal club: To familiarize with research methodologies and critical appraisal of results.
- Seminars: To update newer developments in pharmacology/emerging trends/ novel mechanisms of drug action .
- Practical exercises: Once in a week, under the supervision of a faculty, with/without the help of animals, various principles/ mode of drug action/ screening of drugs/ drug analysis using various techniques should be performed to develop practical skills to conduct similar experiments in future.

Thesis/ Dissertation

Each PG student will carry out research work under the supervision of a faculty member of the Pharmacology Department. The thesis will be submitted to Sharda University and will be refereed by suitable experts in the field. The acceptance of the thesis/dissertation by the University will be a prerequisite for the candidate to be allowed to appear in the final examination.

Thesis/Dissertation Objectives

1. To make the post graduate student aware about every aspect of research including finding research topic, searching literature, research methodology, statistics, analysis of results, scientific writing and ethical aspects involved.
2. The topic or project taken need not necessarily bring out /explore something very novel, very big or breakthrough in medical science. the main aim is to train post graduate student for taking up such challenges in the future and learn maximum about the research methodology during their curriculum.

Thesis/Dissertation topic, along with protocol of work, is to be submitted to the university within one year of registration. The study is to be cleared by the institutional ethics committee. [Topics not be repeated for three years].

Seven Copies of completed dissertation with appropriate certificates should be submitted at the end of fifth semester.

Four examiners will examine these dissertations and report acceptance or otherwise.

Course Details

Duration of the course -36 months

Assessment

M.Sc. Examination

Final Examination

Theory examination

There will be four question papers of 3-hour duration, each of 100 marks.

There will be **four question papers** of 3-hour duration, **each of 100 marks**.

Paper- I

General pharmacological principles and clinical pharmacology

Paper-II

Systemic pharmacology, chemotherapy and therapeutics

Paper-III

Experimental pharmacology, screening of drugs, research methodology and biostatistics

Paper-IV

Recent advances in pharmacology

History of Pharmacology

Practical examination (2 days)

1. Experimental pharmacology exercise on intact animal including handling.
2. Experimental pharmacology exercise on isolated organ.
3. Chemical pharmacology exercise.
4. Clinical pharmacology exercise.

Oral Examination

1. Thesis presentation and discussion
2. General viva voce
3. Microteaching session

Course Content

Paper-I (Theory)

General Pharmacology

Pharmacokinetics :Absorption, Distribution , Biotransformation and Elimination

Basics of pharmacokinetics, calculation of pharmacokinetic estimates (C-max, Tmax, T1/2, AUC(0-n),AUC(0- ∞), (Vd, Ke, Ka etc.) Compartment models used in pharmacokinetics (oral and intravenous).

Compartment fitting (one comp & two comp). Pharmacodynamic /pharmacokinetic (PK/PD) correlation.

Practical skills: Calculation of Pharmacokinetic estimates from given concentration vs time data.

Drug Delivery Systems

Pharmacodynamics:Mechanisms of Drug Action, Drug Receptors, Interactions, antagonism ,Therapeutic index.

Toxicology

Drug toxicity, LD 50, AD50, TD50, Monitoring of ADRs, Antidotes in the management of poisoning. Applied analytical toxicology and toxicovigilance.

Molecular Pharmacology .

Gene expression, Pharmacogenomics, Proteomics, techniques involved in studying receptor dynamics.PCR, Northern blot, Southern blot and Western blot. Protein purification. Mono, poly clonal antibodies.Molecular biology in receptor identification. Antisense oligonucleotides, molecular targets of drug action.

Pharmacogenetics

Drug regulations

Drugs and Cosmetics Act, Drug Price Control order, Application for Investigational New Drug (IND),

Application for New Drug Discovery (NDD) according to Indian Control Authority & USFDA guidelines.

Conducting bio-equivalence studies. Ethical considerations in utilizing human subjects for drug discovery process. Helsinki's declaration. ICH-GCP Guidelines. Ethical guidelines in utilising animals for experimental purposes.

Practical skills: Draft an IND and NDD application for the approval of a numbered compound

Pharmacoepidemiology

Pharmacoeconomics

Pharmacovigilance

Therapeutic audit

Drug development process

Methods involved in the development of new drugs. Preclinical toxicological studies.

Calculation of LD50 & ED50

Acute, subacute and chronic toxicity studies. Irwin profile test, Pre-clinical pharmacokinetic and dynamic studies. Lipinski's rule for drug like molecule, High

throughput screening (invitro and invivo) for pre-clinical pharmacokinetic and pharmacodynamic studies.

Clinical Trials

Types of clinical trials, clinical trial for a new investigational drug in India.

Methods involved in the assessment of drugs in human volunteers and bio-equivalence studies. Key points in drafting protocol for a large scale multicentric drug trial in India. Practical skills: Draft a protocol to conduct phase II clinical trial for a newly discovered drug.

Therapeutic drug monitoring

Basic principles of TDM. Therapeutic index. Trough level monitoring and dosage adjustments.

Drug delivery systems: sustained release, enteric coated formulations and liposome etc.

History & Recent Advances in Pharmacology

Paper-II (Theory)

Systemic Pharmacology

Autonomic nervous System:

- Neurotransmission
- Cholinergic transmission
- Muscarinic and nicotinic receptor and subtypes
- Adrenergic receptors and subtypes
- Muscarinic receptors agonists and antagonist
- Anti-cholinergic agents
- Drugs acting on Autonomic Ganglia
- Adrenergic agonists and antagonist

Peripheral nervous System:

- Drugs acting on neuromuscular junction
- Local anesthetics

Central nervous system:

- Neurotransmission and central nervous system
- General anesthetics

Therapeutic gases.

Hypnotics and Sedatives:

- Anti-Anxiety
- Anti-psychotics and anti-maniac drugs
- Anti-depressant drugs
- Drug used in the treatment of epilepsy
- Drugs used in the treatment of Neurodegenerative disorders (Parkinson's disease, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis) and therapy of migraine
- Opioid analgesics and antagonists

Drug addiction and drug abuse -Tobacco and Alcohol

Cardiovascular system:

Diuretics and ADH antagonists

Drugs affecting renal renin-angiotensin system

Calcium channel blockers

Drug treatment of hypertension

Drug treatment of myocardial ischemia

Drug treatment of congestive cardiac failure

Anti-arrhythmic drugs

Lipid lowering agents

Drug therapy of shock

Gastro intestinal system

Drug treatment of peptic ulcer and gastro-esophageal reflux disease.

Antacids

Anti- Diarrheal drugs

Laxatives and purgatives.

Drug used in the treatment of disorder of bowel motility and water flux, inflammatory Bowel Disease.

Anti-emetic drugs

Endocrines, Autacoids, Hormones

Pituitary hormones

Corticosteroids

Insulin and oral hypoglycaemic agents

Thyroid and parathyroid hormones and antagonists

5HT agonist and antagonists

Prostaglandins

Estrogens and Anti-Estrogens

Progestin and Anti-progestins

Androgens and Anti-androgens

Estrogen and progesterone receptor modulators

Female and male contraception

Tocolytic agents

Histamine & Anti-histamine

Hematopoietic System

Iron and Iron salts

Erythropoietics

Myeloid Growth factors (CSFs)

Thrombopoietics growth factors

Vitamin_{B12}, Folic acid, and treatment of megaloblastic anemia.

Oral and parenteral anti-coagulants

Fibrinolytic agents

Anti-platelets drugs

Procoagulants

Analgesic, Anti-pyretic & Anti-Inflammatory agent, Treatment of Rheumatoid arthritis and Gout

Pharmacotherapy of Bronchial Asthma and COAD.

Lipid Derived Autocoids:- Eicosanoids and Platelet Activating factor

Immunosuppressant and immunomodulators.

Drug management of osteoporosis

Antimicrobial Chemotherapy

General consideration and principal of antibiotics therapy
Sulfonamides quinolones, and agents for UTI
Penicillins, cephalosporins and other B-Lactam antibiotics.
Protein synthesis inhibitors (Aminoglycosides, Tetracyclines, Macrolides).
Miscellaneous anti-bacterial agents
Chemotherapy of tuberculosis, MAC disease, and leprosy.
Anti-fungal agents
Anti-viral agents
Anti-retroviral agent and treatment of HIV infection.

Chemotherapy of parasitic infection

Protozoal infection.
Chemotherapy of malaria
Chemotherapy of helminthic infection

Chemotherapy of neoplastic diseases:

Anti-neoplastic agents

Misc. topics

Dermatological Pharmacology

Ocular pharmacology
Chelating agents
Diagnostic agents
Complementary and Alternative Medicine (CAM)

Paper III**Experimental Pharmacology and Biostatistics**

Drug Discovery Process: - Principles and strategy used in new drug discovery, regulation, laboratory animal care and additional requirements, Drug Development.

Bioassay

Basic principles
Types of bioassay
Experimental models and statistical designs employed in biological standardization
Preclinical and clinical models employed and screening models for new drugs
Screening of :Analgesic and anti-pyretic, Anti-inflammatory agent , Anti-anxiety agents, Anti-depressants, Anti-diabetics, Anti-convulsants ,Local anesthetics,

Anti-arrhythmic drugs, Anti-hypertensive agent, Anti-anginal drugs, Drugs use in treatment of congestive of cardiac failure, Screening of Anti-Diabetics , Screening of anti epileptic drugs

Isolation of compounds from herbal sources

Basic constituents of plants (chemical classification). Isolation of active constituent from plant materials. Percolation and maceration. Qualitative constituent characterisation techniques. Utilisation of HPTLC for the constituent analysis. Estimation of marker compound in biological fluid after crude plant material administration.

Biostatistics

Calculation of basic statistical parameters (mean, median, mode, standard deviation, standard error etc.). Null hypothesis, parametric and non parametric tests (Student 't' test, Wilcoxon, ANOVA etc.). Meta-analysis.

Practical skills: Calculation for statistical significance in the given data for Student paired and unpaired

't' test. Applying ANOVA to the given set of concentration vs time data of two drug formulations to comment about their bio-equivalence.

Introduction of Bio-statistics, graphical representation (histogram line diagram) data collection, measure of central tendency, dispersion sample size, coefficient of variation, relative errors, probit . Definition and probability, by using Binomial distribution and normal distribution continuous data distribution logistic analysis . Correlation and regression, rank- correlation, method of least square curve fitting. Introduction of multiple correlation, Test of significance type I & II errors, level of significance t-test, Z-z-test, χ^2 -test (chi-square), and significance for correlation coefficient .

Practical:

Experimental Pharmacological Practical:

On Isolated tissues

Bioassay of histamine

Bioassay of 5-HT, Angiotensin, Oxytocin, Acetylcholine, Adrenaline

Intact animals

i Bioassay of Diuretics (Rat)

ii. Rat BP

iii. Langendroff's Preparation

Effect of various drugs on dog blood pressure respiration and other parameters and also detections and unknown drugs (Demonstration).

Effect of anti-inflammatory agents on carrageenan induced rat paw edema.

Evaluation of analgesic activity of morphine using tail flick latency test. Evaluation of cardiotonic drug on isolated rabbit heart (Langendroff isolated heart preparation).

Demonstration of Dale's vasomotor reversal and nicotinic effect of acetylcholine on dog blood pressure. Effect of autonomic drugs on rabbit intestine. Demonstration of bronchodilation on guinea pig tracheal chain. Effect of sedatives on rodents (rotarod test). Four point assay of

histamine and acetylcholine on guinea pig ileum. Four point assay of 5HT on rat uterus. Estimation of PA2 value of atropine. Identification of unknown by evaluating its action on dog haemodynamic parameters. Assay of acetylcholine using rat fundus. Estimation of pressor agents on rat blood pressure.

Chemical Pharmacology

Extraction of active principle, from medicinal plants.

Qualitative testing, titrimetric analysis. Beer and Lambert's law. Basis and working principle of colorimeter, ultraviolet, atomic absorption spectrometers, Fluorescence spectroscopy, NMR and Mass Spectroscopy.

Basics of Chromatography. Partition, adsorption and ion exchange chromatography. Column chromatography, thin layer chromatography, paper chromatography, immunoabsorbant chromatography, high performance thin layer chromatography, high performance liquid chromatography and gas Chromatography. Radio immunoassay. Processing of biological materials for drug analysis. Calculations in drug analysis. Good laboratory practice. Validation of analytical procedure. Practical skills: Spectrophotometric & fluorimetric estimations of drugs in biological fluids.

Recommended Reading

Journals

- Annual review in Pharmacology Annual Review in Medicine
- British Journal of Clinical Pharmacology
- British Journal of Pharmacology
- Clinical Pharmacology & Therapeutics
- Drugs
- ICMR bulletin
 - Indian Journal of Experimental Biology
 - Indian Journal of Pharmacology
 - Lancet
 - New England Journal of Medicine
 - Pharmacological Reviews
 - Trends in Pharmacological Sciences
 - WHO Reports & Bulletin
 - Indian Journal of Medical Research

Books

1. Goodman & Gilman's The Pharmacological Basis of Therapeutics. Hardman JG & Limbird LE (Ed), Publisher: McGraw-Hill, New York.
2. Basic & Clinical Pharmacology. Katzung BG (Ed), Publisher: Prentice hall International Ltd., London.
3. Avery's Drug Treatment. TM Speight & NHG Holford (Eds), Adis International.
4. Principles of Drug Action. The Basis of Pharmacology. WB Pratt & P Taylor (Eds), Churchill Livingstone, Edinburgh.
5. Pharmacology & Pharmacotherapeutics. Satoskar RS, Bhandarkar SD (Ed), Publisher: Popular Prakashan, Bombay.
6. Principles of Pharmacology. Sharma HL & Sharma KK (Ed), Publisher: Paras Medical Publishers. New Delhi.
7. Clinical Pharmacology. Bennet PN, Brown MJ (Ed). Publisher: Churchill Livingstone
8. A Textbook of Clinical Pharmacology. Roger HJ, Spector RG, Trounce JR (Ed),

Publisher: Hodder and Stoughton Publishers.

9. Harrison's Principles of Internal Medicine. AS Fauci, JB Martin, E Braunwald, DL Kasper, KJ Isselbacher, SL Hauser, JD Wilson, DL Longo (Eds), McGraw Hill, New York.

10. Guides to Good Prescribing. TPGM de vries, RH Henning, HV Hogerzeil, DA Fresle, Who Geneva.

11. Critical appraisal of epidemiological studies and clinical trials- Mark Elwood. Oxford Press.

12. Pharmacology. Rang HP, Dale M, Ritter JM. Edinburgh, Churchill Livingstone, 1999.

13. Essentials of Medical Pharmacology, Tripathi KD, Jaypee Brothers Medical Publishers, New Delhi

14. Martindale The Complete Drug Reference, Sweetman SC. Pharmaceutical Press; London.

15. Indian Pharmacopoeia

Evaluation of Drugs

1. Drug Discovery and Evaluation-Pharmacological Assays. H. Gerhard Vogel, Springer-Verlag, Berlin

2. Selected Topics in Experimental Pharmacology. UK Sheth, NK Dadkar & UG Kamat. Kothari Book Depot, Mumbai.

3. Fundamentals of Experimental Pharmacology. MN Ghosh (Ed), Scientific Book Agency, Calcutta.