

M.Pharm.Semester-I to IV

Prospectus No. 20121432

संत गाडगे बाबा अमरावती विद्यापीठ  
SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा  
(FACULTY OF MEDICINE)

अभ्यासक्रमिका  
औषधिनिर्माण पदव्युत्तर परीक्षा

सत्र-१ व ३, हिवाळी-२०११ व सत्र-२ व ४, उन्हाळी-२०१२

**PROSPECTUS**

OF

MASTER OF PHARMACY (PHARMACOLOGY) EXAMINATIONS

SEMESTER-I & III, WINTER-2011

SEMESTER-II & IV, SUMMER-2012



2011

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Published by  
**Dineshkumar Joshi**  
Registrar,  
Sant Gadge Baba  
Amravati University  
Amravati - 444 602

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**M. Pharm. (Pharmacology)****Semester – II****Subject code : MPL-201****Subject : ADVANCED PHARMACOLOGY AND TOXICOLOGY****THEORY : 60 Hours (4 hrs./week)****SECTION-A**

1. Cellular and molecular mechanism for drug dependence, tolerance and resistance (illustrate with suitable examples).  
Microbial resistance to drug and their testing methods. Hypersensitivity, allergy, adverse drug reaction, anaphylaxis, idiosyncrasy and detection methods.
2. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research. Antisense genes as a research tool.
3. Endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

**SECTION-B**

4. Endogenous bioactive molecules as TNF Interleukins, Process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.
5. **Introduction to molecular biology (Bioinformatics)/ Computational Biology** Basics of DNA, RNA and protein, Structure of cell, cell reproduction, concept of gene, control of protein synthesis. Introduction to Southern Blots, Northern Blots, Western Blots, Cloning and Sub-cloning.
6. **Toxicology:**  
Preparation of protocol for safety assessment  
Biochemical basis of acute, sub-acute, chronic, ocular, dermal and skin sensitization testing.  
Biochemical basis of toxicokinetics, mutagenesis, carcinogenesis, reproductive genotoxicity and teratogenicity  
Knowledge of documentation and protocol preparation, knowledge of planning, performing, analyzing, reporting and monitoring of above toxicity.

**Reference Books**

- (1) Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London
- (2) Guyton LC, Text Book of Medical Physiology, Saunders Co., London
- (3) Best CH and Taylor NB, The Physiological Basis of Medical Practice, The Williams and Wilkins Co., Baltimore

- (4) Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
- (5) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- (6) Scientific basis of drug dependence by Hannah Steingerg
- (7) Hypersensitivity to drugs vol-I by Samter & C.W. Parker
- (8) Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (9) Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
- (10) Rang H. P. and Dale M. M. Pharmacology (Churchill Livingstone, U. K.)
- (11) Mutagenicity testing and related analytical techniques by R. W. Frei & U.A. Th. Brinkman
- (12) In vitro toxicity testing by John M. Fraizer
- (13) OECD and EPA Guidelines
- (14) Toxicology, The basic science of poison by Cassarate and Doulls McGraw Hill Medical, New York Chicago
- (15) General and Applied toxicology by Bryan Ballantyne, T. Mars & P. Turner
- (16) Safety evaluation of drugs and chemicals by W. Eugene Llyod
- (17) Review articles from published journals.

**Subject code: MPL-202****Subject : ADVANCED CLINICAL PHARMACOKINETICS****THEORY : 60 Hours (4 hrs./week)****SECTION-A**

1. Introduction, concentration time profile, plotting the data, different fluid compartment and blood flow rate compartment models
2. Protein and tissue binding, factors effecting protein binding, kinetics of protein binding determination of rate constants and different plots (direct, scatchard and reciprocal); significance of volume of distribution, implications and in vitro methodologies
3. Drug disposition, renal clearance, mechanism of clearance, clearance ratio, determination of clearance, hepatic clearance, biological half life, area under curve % drug metabolized, relationship between blood flow, intrinsic clearance, protein binding, different volume of distribution and its significance.  
Compartment modeling and their limitation: one compartment open model and multiple compartment models kinetics of i.v infusion, bolus and multiple dose regimen (including the calculations and derivatization)

**SECTION-B**

4. Drug selection, dosage regimen design, dosage adjustment in elderly,

children and obese patient. Evaluation of patient response, measurement of serum drug concentration, monitoring of dosage regimen.

5. Nonlinear pharmacokinetics, direct, linear and orbit graph methods of dosing. Nonlinear pharmacokinetic due to drug protein binding
6. **Therapeutic drug monitoring:** introduction, necessity of TDM, criteria for valid TDM, essential for effective TDM, organization of TDM service, Effectiveness of TDM

#### REFERENCE BOOKS:

1. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
2. Remington's Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
3. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
6. Biopharmaceutics; By Swarbrick.
7. Biopharmaceutics and Pharmacokinetics- A Treatise; By D.M. Brahmkar and Sunil B. Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N. Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C. Boylan. Marcel Dekker Inc, New York, 1996.

**Subject code: MPL-203**

**Subject : TOPICS IN PHARMACOLOGY**

**THEORY : 60 Hours (4 hrs. /week)**

#### SECTION-A

1. **Immunotherapy:** Immunostimulants, Immunodepressant, cytokines
2. **Autacoids and endocrine Pharmacology** Pharmacodynamic, pharmacokinetic, therapeutic of Histamine and bradykinin agonist and antagonist, drug acting through eicosanoids and platelet activating factors, thyroid and antithyroid agents, adenohipophysial hormones and related substance, insulin and oral hypoglycemic agents, endocrine pancreas, adrenocortical

hormones and their inhibitors of synthesis, agent affecting calcifications, estrogens and progesterone and their antagonist, androgens, oral contraceptive.

3. Pharmacology of Ca, Na, K, Cl channel modulators.

#### SECTION- B

4. **Chemotherapy of parasitic and microbial infections:** Biology of tuberculosis, viral infection, malaria, amobiasis, leishmaniasis, filariasis, (Including target for drug development and mechanism of drug resistance).
5. **Drug metabolism:** Biotransformation of drugs, enzyme responsible for biotransformations, microsomal and non-microsomal mechanism, factors influencing enzyme induction and inhibition. Model to study drug metabolism. Dose effect relationship.
6. **Clinical Trials:** Clinical evaluation of new drug, phases of clinical trial, ethics and protocol. Preparation of clinical trial. New drug development process and drugs registration.

#### Reference Books

- (1) Evans CL, Principles of Human Physiology, J and A Churchill Ltd. London
- (2) Guyton LC, Text Book of Medical Physiology, Saunders Co., London
- (3) Best CH and Taylor NB, The Physiological Basis of Medical Practice, The Williams and Wilkins Co., Baltimore
- (4) Vander A, Sherman JH and Luciano D. Human Physiology –The Mechanisms of Body Functions, Tata McGraw Hill Publishing Co., New Delhi.
- (5) Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- (6) Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
- (7) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- (8) Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
- (9) Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (10) Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
- (11) Rang H. P. and Dale M. M. Pharmacology (Churchill Livingstone, U. K.)
- (12) Scientific basis of drug dependence by Hannah steingerg
- (13) Discoveries in Pharmacology vol. I and II by Parnham & J. Bruibvels
- (14) Pharmacological methods, receptors & chemotherapy by Parnham & J. Bruibvels
- (15) Pharmacotherapy: A Pathophysiologic Approach- Joseph T. Dipiro et al, Appleton & Lange.
- (16) Discoveries in Pharmacology vol. I and II by Parnham & J. Bruibvels

(17) Pathologic Basis of Disease-Robinson SL, WB Saunders Publications.

**Subject code: MPL-204**

**Subject : BIOLOGICALEVALUATION(PRICLINICAL PHARMACOLOGY)**

**THEORY : 60 Hours (4 hrs. /week)**

**SECTION-A**

1. **Care, handling and breeding techniques** of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA. Proforma for performing experiments on animals. Alternatives to animal studies. Correlation between various animal models and human situations
2. **Organization of Preclinical screening** programme (Blind screening)
3. **Preclinical evaluation** of following categories of drugs.
  1. Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, anticonvulsants, local anesthetics, CNS stimulations
  2. Analgesic, anti-inflammatory & antipyretic agents,
  3. Cardiac glycosides, antiarrhythmic, antihypertensives, antitatherosclerotics,
  4. Antiulcer agents, laxatives, bronchodilators, antitussives,
  5. Diuretics.
  6. Histamine antagonists. Immunomodulators,
  7. Hypoglycemics, Cholesterol lowering agents, antifertility agents, androgens.
  8. Anti-thyroid agents, Dermatological agents, Antitumor agents.

**SECTION- B**

4. **Concept of transgenic animals**, knockout animals, nude animals, receptor binding assays, principles of immunoassay, patch clamp techniques.
5. **In vitro testing of drugs**. Animal cell lines and their uses. Limitation of in vitro testing of drugs. Correlation between invitro- and in-vivo screening methods (emphasis based on cell base assay, biochemical assay, radioligand binding assay, High throughput screening etc.)
6. **Toxicity testing of drugs/chemicals**  
Evaluation of acute, sub-acute, chronic, dermal, ocular and skin sensitization toxicity testing of drugs and chemicals.  
Invitro toxicity testing and its applications to safety evaluation of drugs and chemical,

**References recommended**

- (1) Goodman and Gilman: Pharmacological Basis of Therapeutics, Pergamon Press, New York.
- (2) Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
- (3) Turner RA, Screening Methods in Pharmacology, Academic Press, London
- (4) Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
- (5) Crossland J, Lewis's Pharmacology, Churchill Livingstone, Edinburgh
- (6) Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- (7) Bacq ZM, Capek, Fundamentals of Biochemical Pharmacology
- (8) Laurence DR, Bennett PN, Borown MJ, Clinical Pharmacology, Churchill Livingstone, New York
- (9) Vogel HG, Drug Discovery and Evaluation, Springer, Germany
- (10) Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
- (11) Mutagenicity testing and related analytical techniques by R. W. Frei & U.A.Th.Brinkman
- (12) Quantitative methods in Pharmacology by H. De Jonge
- (13) Invitro toxicity testing by John M.Fraizer
- (14) OECD and EPA Guidelines
- (15) Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, Newyork Chicago
- (16) General and Applied toxicology by Bryan Ballantyne , T. mars & P Turner
- (17) Safety evaluation of drugs and chemicals by W.Eugene Llyod
- (18) Review articles from published journals.

**Subject code: MPL-205**

**Subject : RECEPTORINPHARMACOLOGY**

**THEORY : 60 Hours (4 hrs. /week)**

**SECTION-A**

1. Molecular mechanism of drug action, Receptor binding and occupancy theory, rate theory, criteria for characterization of receptor, receptor structure, receptor transduction, receptor classification.  
Dose response relationship and different types of antagonisms  
Receptor down regulation and up regulation
2. **Study of different classes and subclasses of receptor**  
Ion channels and their modulators

G-protein couple receptor-22-  
 Tyrosine kinase link receptor  
 Neurotransmitters receptors  
 Hormone receptors  
 Opiod receptor  
 Nicotinic receptor  
 Glutamate receptor  
 Orphan receptor

### SECTION-B

3. **Presynaptic receptor for catecholamines:** Muscarinic receptor, GABA receptor, Dopaminergic receptor, adrenergic receptor, cholinergic receptor, Serotonergic receptor
4. **Second messenger receptors:** Phospholipase and phasphokinase, cyclic, Protein kinase. Signal transduction through protein tyrosine kinase, diacyl glycerol and Phosphotidyl inositol

#### Recommended references

- (1) Goodman and Gilman: Pharmacological Basis of Therapeutics, Pregamon Press, New York. (MacGraw Hill)
- (2) Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California
- (3) Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
- (4) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
- (5) Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
- (6) Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology. Avery G. S. Drug treatment (Adis Press, Sydney)
- (7) Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K.
- (8) Receptor –based drug design by paul left
- (9) Drug receptor and their effectors edited by Nigel J.M. Birdsall
- (10) Text book of receptor pharmacology by John C. Foreman, Torben Johansen
- (11) Scientific basis of drug dependence by Hannah steingerg
- (12) Receptor binding in drug research by Robert A O Brien
- (13) Receptor binding techniques edited by Mary keen Humana press
- (14) Text book of receptor pharmacology edited by John Foreman and Torben Johansen
- (15) Drug receptor by H.P. Raug
- (16) Discoveries in Pharmacology vol. I and II by Parnham & J. Bruibvels

- (17) Pharmacological methods, receptors & chemotherapy by Parnham & J. Bruibvels
- (18) Review articles from published journals.

#### Subject code : MPL-206

#### Subject : Laboratory course-I

#### PRACTICLE (4 hrs./week) (Minimum 20 practical should be conducted)

1. Calculations of pA<sub>2</sub> and pD<sub>2</sub> values using isolated tissue preparations: Suitable isolated animal tissue.
2. Bioassay of drugs: Acetylcholine, adrenaline, Histamine, Oxytocin
3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
4. Use of anesthetics and cannulation of veins, arteries and trachea.
5. Pharmacological screening for drug acting on GIT
6. Pharmacological screening of drugs for bactericidal, wormicidal, fungicidal and etc.
7. Pharmacological screening of drug acting on kidney for diuretic activity
8. Neuropharmacological screening test: CNS stimulant and CNS depressants, Anticonvulsants, Anticonvulsants, Antipsychotics, Anxiolytics.
9. LD<sub>50</sub> determination as per OECD guideline
10. Evaluation for Pyrogen testing in Pharmaceutical product

#### Reference Books:

1. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
2. Ghosh MN, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta
3. Kulkarni SK, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi
4. Seth UK, Dadkar NK, and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay
5. Nodine Siegler, Animal and Clinical Pharmacological Techniques in Drug Evaluation.
6. Turner RA, Screening Methods in Pharmacology, Academic Press, London
7. Goldsteine, Principles of Drug Action, John Wiley and Sons, New York
8. Vogel HG, Drug Discovery and Evaluation, Springer, Germany review articles from published journals.

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