

M.Pharm.
Part-I 2010
Part-II 2011

Prospectus No. 101432

संत गाडगे बाबा अमरावती विद्यापीठ
SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा
(FACULTY OF MEDICINE)

अभ्यासक्रमिका
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PROSPECTUS

OF

MASTER OF PHARMACY (PHARMACOLOGY)
EXAMINATIONS PART-I, 2010 & PART-II, 2011



2009

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Registrar

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SANT GADGE BABA AMRAVATI UNIVERSITY
SPECIAL NOTE FOR INFORMATION OF THE STUDENTS

(1) Notwithstanding anything to the contrary, it is notified for general information and guidance of all concerned that a person, who has passed the qualifying examination and is eligible for admission only to the corresponding next higher examination as an ex-student or an external candidate, shall be examined in accordance with the syllabus of such next higher examination in force at the time of such examination in such subjects, papers or combination of papers in which students from University Departments or Colleges are to be examined by the University.

(2) Be it known to all the students desirous to take examination/s for which this prospectus has been prescribed should, if found necessary for any other information regarding examinations etc. refer the University Ordinance Booklet the various conditions/provisions pertaining to examinations as prescribed in the following Ordinances-

Ordinance No. 1	:	Enrolment of Students.
Ordinance No.2	:	Admission of Students
Ordinance No. 4	:	National Cadet Corps
Ordinance No. 6	:	Examination in General (relevant extracts)
Ordinance No. 18/2001	:	An Ordinance to provide grace marks for passing in a Head of passing and Improvement of Division (Higher Class) and getting Distinction in the subject and condonation of defficiency of marks in a subject in all the faculties prescribed by the Statute NO.18, Ordinance 2001.
Ordinance No.9	:	Conduct of Examinations (Relevant extracts)
Ordinance No.10	:	Providing for Exemptions and Compartments
Ordinance No. 19	:	Admission of Candidates to Degrees

Ordinance No.109	:	Recording of a change of name of a University Student in the records of the University
Ordinance No.6 of 2008	:	Improvement of Division/Grade.
Ordinance No.19/2001	:	An Ordinance for Central Assessment Programme, Scheme of Evaluation and Moderation of answerbooks and preparation of results of the examinations, conducted by the University, Ordinance 2001.

J.S.Deshpande

Registrar

Sant Gadge Baba Amravati University

**SYLLABUS PRESCRIBED FOR
THE EXAMINATION OF THE DEGREE OF
MASTER OF PHARMACY
IN PHARMACOLOGY**

I. FIRST EXAMINATION

CP-1 : BIOSTATISTICS AND RESEARCH METHODOLOGY.

SECTION-A

The following topics in the subject covered by Sanford Bolton in Pharmaceutical Statistics-Practical and Clinical Applications, Marcel Dekker, Inc., New York, 1990, will be dealt with:

Basic Definitions and concepts, Data Graphics, The Binomial and Normal probability Distributions, Sampling, Estimation and Hypothesis Testing, Sample size and power, Linear Regression and Correlation, Analysis of variance, Factorial Designs, Transformations and outliers, Experimental Design in Clinical Trials, Quality Control, Validation, Consumer Testing, Nonparametric Methods and Optimization Techniques.

COMPUTER APPLICATIONS IN PHARMACY :

Introduction to computers, Programming languages, flow charting and system analysis-A review, Applications of LOTUS 1-2-3 and dBASE (III,IV) Strategy for building of Pharmacokinetic models, study of Computer software like AUTOAN 1, AUTOAN 2, CSTRIP, NONLIN, MACDOPE, etc., An approach to computer aided drug design.

Reference Books :

1. Buncher, C.R. and Jia-Yeong Tsay, Statistics in the Pharmaceutical Industry, Marcel Dekker Inc.
2. Peace, K.E., Biopharmaceutical Statistics for Drug Development. Marcel Dekker Inc.
3. Berry, D.A., Statistical Methodology in pharmaceutical Sciences, Marcel Dekker Inc.
4. Peace, K.E., Statistical Issue in Drug Research and Development, Marcel Dekker Inc.
5. Bergman, S.W., Statistical Methods for Pharmaceutical Research and planning, Marcel Dekker Inc.
6. Daniel, W.W., Biostatistics.
7. Fassett, W.E. and Christensen, D.B., Computer Applications in Pharmacy.

8. Gilbert, C and Williams, L., The ABC's of 1-2-3, B.P.B. Publications.
9. Simpson, Introduction to dBASE III +; B.P.B. Publications.
10. Naiman, An Introduction to Wordstar; B.P.B. Publications.

CP-1

SECTION-B

I Research

1. Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) - Objective of research-
2. Literature Survey- Use of Library, books & journals-Medline-Internet, getting patents and reprints of articles as sources for literature survey.
3. Selecting a problem and preparing research proposal for different types of research mentioned above.
4. Methods and tools used in Research.
 - Qualitative studies, Quantitative Studies
 - Simple data organisation, Descriptive data analysis
 - limitations and sources of Error
 - Inquiries in form of Questionnaire, Opinionnaire or by interview.
 - Statistical Analysis of data including variance, standard deviation, student 't' test and annova, correlation data and its interpretation, computer data analysis
5. Documentation
 - "How" of Documentation
 - Techniques of Documentation
 - Importance of Documentation
 - Uses of Computer packages in Documentation
6. The Research Report/Paper writing/thesis writing
 - Different parts of the Research paper
 1. Title-Title of project with author's name
 2. Abstract-Statement of the problem, Background list in brief and purpose and scope.
 3. Key-words-

4. Methodology - Subject, Apparatus/Instrumentation, (if necessary) and procedure.
7. Results- Tables, Graphs, Figures and statistical presentation
8. Discussion - Support or non-support of hypothesis
 - practical & theoretical implications,
 - conclusions
9. Acknowledgements
10. References
11. Errata
12. Importance of spell check for Entire project.
13. Use of footnotes

II. Presentation (specially for oral)

Importance, types, different skills.

- Content of presentation, format of model.
 - Introduction and ending
- Posture, Gestures, Eye contact, facial expressions, stage fright
- Volume-pitch, speed, pause & language
- Questionnaire

III. Protection of patents and trade marks. Designs and copyrights

- The patent system in India - Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents.
- Advantages
- The science in law. Turimetrics (Introduction)
- What may be patented
- Who may apply for patent
- Preparation of patent proposal
- Registration of patents in foreign countries and vice-versa

IV. Cost Analysis of the Project

- Cost incurred on Raw Material
- Cost incurred on Procedure

- Cost incurred on Instrumentation
- Cost incurred on Clinical trials

V. Sources for procurement of Research Grants

VI Industrial-Institution Interaction

- Industrial projects- Their feasibility reports

Books

1. Research in Education - John V. Best James V. Kahn
2. Presentation skills - Michael Halton - Indian Society for Institute Education.
3. A Practical Introduction to copy right - Gavin Mcfarlane
4. Thesis projects in Science and Engineering - Richard M.Davis
5. Scientists in legal system - Ann labor science
6. Thesis and Assignment writing - Jonathan Anderson
7. Writing a technical paper - Donald Menzel
8. Effective Business Report writing - Leland Brown
9. Protection of Industrial property rights- Purushottam Das and Gokul Das
10. Spelling for the millions - Edna Furrness
11. Preparing for publication - King Edwards Hospital fund for London
12. Information technology - The Hindu speaks
13. Documentation - Genesis & Development 3792
14. Manual for evaluation of Industrial projects - United Nations
15. Manual for the preparation of Industrial feasibility studies

CP-2 : PRODUCT DEVELOPMENT AND FORMULATION**INTRODUCTION OF NEW DRUGS:**

Steps involved in the development of a new drug, obstacles to its evaluation, limitations of screening procedures, animal toxicity tests. Extrapolation of laboratory data to man, placebo, New drug application as per WHO norms and proforma. Requirement and guidelines on clinical trials for import and manufacture of new drugs in India.

PREFORMULATION STUDIES :

Investigation of physical and chemical problems inherent in the development of new formulations.

PHYSICAL PROPERTIES :

Organoleptic properties, microscopy, intrinsic solubility and dissolution rate; powder flow and compression, properties and physical stability.

CHEMICAL PROPERTIES :

Chemical properties : Purity, physico-chemical parameters affecting absorption, solid state and solution-phase stability and compatibility with excipients. Formulation additives : Studies on all excipients to be incorporated in the development of liquid orals, solid dosage forms. Stability data : Advanced studies on stability and development of stability data on different formulations.

PROCESS VALIDATION :

Development of validation data on different formulations, Quality assurance and GMP : A Detailed study of current good manufacturing practices in manufacturing, processing, packaging and holding of drug.

Product development approach on following formulations :

LIQUID ORALS :

Cough and multivitamin syrup, antiflatulant and laxative emulsions, antacid and antidiarrhoeal suspensions.

TOICALS :

Antibiotic ointment, analgesic gels.

TABLETE :

Common cold, multivitamin, chewable antacid, soluble aspirin and dispersible/kid tablets.

STERILE DOSAGE FORMS :

B-complex injection, antibiotic eye and ear drops, antihistaminic nasal drops.

Reference Books :

1. Gennaro, Remingtons Pharmaceutical Sciences, Mack Publishing Co.
2. Lachman, Theory and practice of Industrial pharmacy, Lea and Febiger.
3. Ansel., Pharmaceutical Dosage Forms & Drug Delivery Systems, Lea & Febiger.
4. Banker, Modern Pharmaceutics, Marcel Dekker Inc.
5. Racz, Drug Formulation, John Wiley and Sons.
6. Aulton, Pharmaceutics : The Science of Dosage Forms Design, ELBS, London
7. Wells, Pharmaceutical preformulation: The physico-chemical properties of Drug Substance, Ellis Horwood Ltd.
8. Florence, Atwood, physico-chemical Principles of pharmacy, Chapman and Hall NY.
9. Welling and Tuckerman, Good Manufacturing practices : A plan for Total Quality Control, Bhalani Publishing House, Bombay.
10. Connors, Chemical stability of pharmaceuticals : A Handbook for pharmacists, Wiley Inter-Science.
11. Carstensen, Drug Stability : Principles and practices, Marcel Dekker Inc.

PL-1 ADVANCED PHYSIOLOGY**Advanced Physiology of the following :**

- 1) Selected topics in cell and molecular biology, genetic control of protein synthesis, cell reproduction, membrane physiology.
- 2) Nervous system: central nervous system, motor and sensory system
- 3) Cardiovascular system
- 4) Blood and immune system
- 5) Respiratory system: mechanism of respiration, regulation of respiration

- 6) Excretory system: Body fluids, urine formation, regulation of fluid osmolality, ion and acid-base regulation
- 7) Gastro-intestinal system: Gastrointestinal function, digestion
- 8) Endocrine system: endocrine glands, their secretions and role, neuroendocrine regulation.
- 9) Temperature regulation and fever.
- 10) Reproductive system: reproduction and related hormonal functions, pregnancy

Reference Books:

1. Vander A, Sherman. J, H, and Luciano, D. Human Physiology. The Mechanisms of Body Function, Tata Ms Graw Hill publishing Co., New Delhi.
2. Evans. C.L Principles of Human Physiology. J. and A. Churchill Ltd. London.
3. Schottellus. B.A, and Schottelius D.D., T, B. of Physiology. Toppan ci, Ltd Tokyo
4. Guyton, L.C., T.B. of Medical physiology. Saunders Co., London.
5. Best. C.H. and Taylor .N.B. The Physiological Basic of Medical Practice, The Williams and Wilkins Co. Baltimore.
6. Jensen. D. The Principles of Physiology, Appleton –Century Crofts, New York
7. Harkishansing Kapoor. Pathophysiology.
8. Ganong W.F., Review of Medical Physiology, Prentis Hall International.
9. Concise Medical Physiology by S.K.Choudhari
10. Tortora G.J., “Principles of Anatomy & Physiology”, Harper and Row Publishers N.Y.

PL-2 ADVANCED PHARMACOLOGY

Objective of the course is to provide recent advanced knowledge of pharmacological basis of therapeutics of the following categories of the drug

- 01) Drugs acting on the peripheral nervous system.
- 02) Drugs acting on the central nervous system.
- 03) Drugs acting on the cardiovascular system.

- 04) Drugs acting on the respiratory system.
- 05) Drugs acting on the excretory system.
- 06) Drugs acting on the reproductive system.
- 07) Drugs acting on the gastrointestinal system.
- 08) Drugs acting on the endocrine system.
- 09) Autacoids and their antagonists.
- 10) Drugs acting on blood and blood forming organs, Anticoagulants Thrombolytic and antiplatelet drugs.

REFERENCE BOOKS

- 1) Goodman & Gilman's, The pharmacological Basis of Therapeutics, Pergamen Press New york
- 2) James Crossland, Lewis pharmacology, Churchill livingstone London
- 3) R. Rondanelli, Clinical pharmacology of drug Interactions, Piccin Italy
- 4) Ivan H. stockley Drug Interactions Blackwell Scientific Publications london
- 5) R.S. Elackwell and A.S. Tavill Biochemical Aspects of Human Diseases Blackwell Scientific Publications, London
- 6) Davidson's Principles and practice of Medicine, CLBS, London
- 7) Lemuel B Wingard Jr. & Gheodore M. Brody, Human pharmacology- Medical to Clinical , Mosby, Year Book London.
- 8) Eric T. Herfindall, Dick R. Courly and Linds Loyd Hart, Clinical Pharmacy and Therapeutics, Williams Landon
- 9) Graems S. Avery, Drug Treatment, Adis Press. Sydney
- 10) D.C. Graliane –Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug Therapy. Oxford University Press, New York.
- 11) P. turner, Recent Advances in Clinical Pharmacology., Vols.1-4

PL-3 BIOLOGICAL EVALUATION METHODS AND TOXICOLOGY

1) LABORATORY ANIMALS:

- a. Commonly used laboratory, transgenic and other genetically prone animal models (viz., nude mice, SH rats etc).

- b. Techniques of blood collection, anesthesia and euthanasia of experimental animals.
- c. Various routes of drug administration.
- d. Maintenance and breeding of laboratory animals.
- e. Regulations and ethical requirements.

2) PRINCIPLES OF BIOLOGICAL STANDARDIZATION:

- a. Statistical treatment of model problems in evaluation of drugs.
- b. Methods of biological assay, principles of biological assays with examples.
- c. development of new bioassay.

3) IMMUNOASSAY:

- a. General principles of immunoassay: Theoretical basis, optimization of immunoassay, heterogeneous Immunoassay system, homogeneous immunoassay systems.
- b. Production of Immunoassay reagents. Introduction, receptors or binders, unlabelled ligands calibrators, labeled ligands and receptors, separation techniques, buffers.
- c. Immunoassay methods evaluation: Protocol outline, objectives and preparation, evaluation of precision, standard tracer, sensitivity, evaluation of accuracy, antibody characteristics monitoring, reaction conditions, clinical evaluation

4) Preclinical evaluation of following category of drugs:

- a. Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotic, nootropics, antiparkinsonian agents, anticonvulsants, CNS stimulants.
- b. Analgesic, antipyretics, anti-inflammatory agents, local anesthetics.
- c. Cardiac glycosides, anti-arrhythmic, antihypertensive, anti-atherosclerotics.
- d. Anti ulcer agents, laxatives
- e. Bronchodilators, antitussives
- f. Diuretics
- g. Histamine antagonists
- h. Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
- i. Anti-thyroid agents, Hypoglycemic, anti fertility agents, androgens.

TOXICOLOGY

Toxicity tests, LD₅₀, ED₅₀ determination, Acute, Subacute, and Chronic toxicity studies, tests for undue toxicity of drugs, General principles of Toxicology, Elementary knowledge of systemic toxicology, Toxicology of central nervous system, peripheral nervous system, liver, kidney ,respiratory system, haematopoietic system, reproductive system.

Radiation and radioactive material, pesticides, metals, solvents, Vapors, Air Pollutants, food additives, Toxins of animal origin, prevention and treatment of poisoning of drugs and heavy metals.

REFERENCE BOOKS :

- 1) Drug Discovery and Evaluation by Vogel HG.
- 2) Biological standardization H.H. Buru, D J finny and L.G. Goodnin Oxford University Press, London, N. Y. Toronto.
- 3) Screening Methods in pharmacology Vols I and II : A. Turner Academic Press
- 4) Evaluation of Drug Activities pharmacometrics. Vols I and II : Lawrence and Bacharach A P., London
- 5) Experiments on Isolated Organs : Livingstone.

PL-4 SELECTED TOPICS IN PHARMACOLOGY

1. New trends and concepts in pharmacology
2. Molecular aspects of drugs action: Receptors, ion channels, enzymes, and carrier proteins, mechanism of signal transduction.
3. Neurosteroids, Neuropeptides and Nitric oxide.
4. Recent advances in relation to the following receptors: Purinergic, Dopaminergic, GABAergic, Excitatory Amino Acids (EAA), Serotonergic and Opioids.
5. Chemotherapy: General mechanism of action of antimicrobial, development of microbial resistance, Recent advances in the chemotherapy of bacterial, viral, fungal, protozoal and parasitic infections. Chemotherapy of Neoplastic diseases.
6. Immunostimulants and Immunosuppressants.
7. Drug addiction and abuse.
8. Clinical Research :-
 - i) New drug discovery process and clinical evaluation of New drugs. Terminologies, organization, phases of clinical research, ethics and protocols of clinical trials.

- ii) Principles of therapeutic drug monitoring.

REFERENCE BOOKS

1. Katzung, B. G.; Basic and Clinical Pharmacology, Lange Medical Publisher, USA
2. Barar, F. S. K., Essential of Pharmacotherapeutics; S. Chand and Company, New Delhi
3. Melmon, K.L., and Morelli; Clinical Pharmacology : Basic Principle of therapeutic, Mc Millan, NewYork.
4. Rang, H.P., Dale, M. N. Pharmacology, Churchill Livingston, UK
5. Clinical Pharmacy and Therapeutics by Roger-Walker.
6. Clinical Pharmacy and Therapeutics by Smith.
7. Herfindal E.T. and Hirschman J.L., Clinical Pharmacy and Therapeutics, Williams and Wilkins.
8. Drug treatment by Avery.
9. Widdop : Therapeutic Drug Monitoring.
10. Simkim, Principles of Therapeutics drug monitoring.

PL-5 PRACTICALS IN PHARMACOLOGY

A. Experiments on isolated preparations.

1. To record concentration response curve (CRC) of different drugs using different isolated preparation of laboratory animals.
2. To calculate PA₂ value for different drugs using corresponding agonist employing different isolated preparation of laboratory animals.
3. To estimate strength of an unknown sample of Acetylcholine by three point bioassay using rectus abdominus muscle preparation.
4. To estimate strength of an unknown sample of Acetylcholine by four point bioassay using rectus abdominus muscle preparation.
5. Bioassay designs using various isolated preparations histamine, oxytocin and intact preparations (vasopressin and insulin)

B. Experiments on intact preparations.

1. To study different routes of administration of drugs in laboratory animals.
2. To study the effect of hepatic microsomal enzyme induction on the

duration of action of pentobarbital sodium.

3. To study the effect of pentobarbital on righting reflex in laboratory animals.
4. To study the analgesic effect of drugs using tail flick method in laboratory animals.
5. To study the analgesic effect of drugs using hot plate method in laboratory animals.
6. To study the analgesic effect of drugs acetic acid induced writhing in laboratory animals.
7. To study the anti-inflammatory effect of drugs against carrageenan-induced Rat paw oedema.
8. To study the anticonvulsant effect of drugs against pentylenetetrazole-induced convulsions in laboratory animals.
9. To study the anticonvulsant effect of drugs against maximal electroshock-induced convulsions in laboratory animals.
10. To study the anxiolytic effect of drugs using elevated plus-maze apparatus in laboratory animals.
11. To study the anxiolytic effect of drugs using social interaction behavior in laboratory animals.
12. To study the local anesthetic effect of drugs using foot withdrawal reflex in laboratory animals.
13. To study the inotropic and chronotropic effect of drugs on frog heart.
14. To study the effect of drugs on normal and hypodynamic frog heart.
15. To determine the acute toxicity of a given drugs. (To calculate LD₅₀)
16. Blind screening of drugs.
17. To study the depressant action of drugs using actophotometer.
18. To study muscle relaxant property of drugs using Rotarod apparatus.
19. To study anti-allergic action of drugs using histamine chamber.
20. To study effect of drugs on memory using pole climbing apparatus.

PL6 : Dissertation and Viva-voce

Every student for the degree of master of pharmacy shall be required to undertake a project involving Methodical/Scientific Research under the supervision of an approved guide and submit three copies of the report on the project, duly certified by the supervisor to the Head of the Department, Principal. The work shall be conducted in accordance with the provision of para 13 of the ordinance.

PL7 : Seminar

The candidate shall deliver seminars during the session, on selected topics of current research interest as in the journals in the field of his specialisation. Viva-voce examination shall consist of the candidate during such seminars and his overall proficiency in the principles and practice of pharmaceutical sciences.
