

Final B.Pharmacy Exam.2010
(Four Year Integrated Course)

Prospectus No.10147

संत गाडगे बाबा अमरावती विद्यापीठ

SANT GADGE BABA AMRAVATI UNIVERSITY

(FACULTY OF MEDICINE)

PROSPECTUS

OF

THE FINAL EXAMINATION FOR THE DEGREE OF

BACHELOR OF PHARMACY, 2010.

(FOUR YEAR INTEGRATED COURSE)



2009

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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 examination 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 : Examinations in General (relevent 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 (relevent 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**B.PHARM FINAL YEAR****IV.T.1****COMMUNITY PHARMACY****THEORY (50 hours)**

1. Introduction to the concept of community pharmacy, its activities and professional responsibilities, professionals in trade versus traders in profession.
2. Organization and structure of retail and wholesale pharmacy, factors to be considered for location of retail pharmacy, legal and infrastructure requirements for establishing retail pharmacy, maintenance of records of retail and wholesale pharmacy.
3. Community pharmacy management - finance, personnel, infrastructure, materials, computers and drug information resources.
4. Polypharmacy and its implications.
5. Role of community pharmacist in health care system as per WHO guidelines.
6. Community pharmacies in primary health care services : Family planning, first aid, communicable diseases, non communicable diseases.
7. Community pharmacist as health educator and role of community pharmacist in population control, first aid and prevention of communicable diseases like AIDS, sexual transmitted diseases.
8. Community pharmacist as a source of drug and poison information.
9. Important techniques adopted in community health care services (BP/Pulser/Temperature, Respiration, Parental drug administration).
10. Code of ethics for practicing pharmacists : (Community and ward pharmacy practice, hospital and clinical).
11. Prescribed medication order - interpretation and legal requirements.
12. Over-the-counter (OTC) drugs (non-prescription) and prescription drugs sales.
13. The concept of Essential drugs and Rational drug use.
14. Patient counselling - General considerations, importance and steps and procedure involved.
15. Communication skills - Principle and elements of communication skills, non verbal communication in pharmacy, barriers in Communication, listening skills, questioning skills, explaining skills and ethics in communication.

Community Pharmacy**Practical (50 Hours)****IV.P.1**

1. Interpretation of prescription.
2. Identification of incompatibilities and irrationality in prescription.
3. Demonstration of use of self-monitoring medical instruments like glucometer, BP apparatus, inhalers, sprays and diagnostic indicators.
4. Demonstration of important techniques like recording of BP, pulse, temperature, respiration rate, artificial respiration and parenteral drug administration.
5. First aid treatment.
6. Posology of commonly used (essential) drugs.
7. Project report on availability and use of essential drugs in PHC or CHC or General hospital.
8. Visit to two-community pharmacy for schedule N compliance.
9. Report on OTC drugs sales over a period of one week in a local community pharmacy.
10. Audit of controlled drugs over a period of one month in a nearby community pharmacy.
11. Project report on visit to nearby community on the rational use of drugs.
12. Exercises on patient counselling in respect of some of selected diseases like tuberculosis, malaria, diabetes, cerebro vascular disease, asthma, diarrhoea, hepatitis.
13. Patient counselling in respect to drugs - oral contraceptive pills, cortisones, aspirin, antimalarials, antitubercular drugs, antibiotics and antineoplastics.
14. Preparation of patient medication information for glyceryl trinitrate, captopril, digitalis and warfarin.

IV.T.2**Clinical Pharmacy & Pathology****(Theory 75 Hours)**

1. Definition, scope, history and development of clinical pharmacy.
2. Professional activities of the clinical pharmacist : Drug therapy monitoring (medication chart review, clinical review, TDM, pharmacist interventions), ward round participation, adverse drug reaction management, drug information and poison information, medication history review, patient counselling.

3. **Patient data analysis** : Clinical laboratory tests used in the evaluation of common disease states and interpretation of test results of Liver function tests, pulmonary function tests, haemogram, renal function tests. The patient's case history, its structure and use in evaluation of drug therapy.
4. **Basic and general principles of drug therapy** :
 - a) **Monitoring of drug therapy** : Therapeutic, pharmacokinetic and pharmacodynamic monitoring of drug therapy.
 - b) **Adverse reactions to drugs** : Incidence, classification and surveillance methods of adverse reactions to drugs.
 - c) **Pharmacogenetics** : Pharmacokinetic and pharmacodynamic aspects of pharmacogenetics.
 - d) **Drug interactions** : Incidence, pharmacokinetic and pharmacodynamic drug interactions.
5. General prescribing guidelines in paediatric, geriatric patients, pregnancy and lactation.
6. **Clinical pharmacokinetics and dosage monitoring** : Introduction to clinical pharmacokinetics, physiologic pharmacokinetic model and its clinical applications. Estimation and determination of bioavailability, calculation of loading and maintenance dose, dose adjustment in renal failure, hepatic dysfunction, geriatric and paediatric patients.
7. Definition, scope & various branches of pathology.
8. Pharmacotherapy of diseases : Pathophysiology, drug therapy & critical analysis of rationale use of drugs in CVS disorders, respiratory disorders, Renal disorders, Haematological disorders, endocrine disorders, Hepatic disorders, Nervous disorders, Psychiatric disorders, GI disorders, Infectious disorders, Immunity disorders & Neoplasm.
9. **Drug and poison information services** : Interpretation of drug information resources available, design of literature searches, critical evaluation of drug information and literature, preparation of written and verbal reports, development of a drug information data base, emergency treatment of poisoning.
10.
 - a) **Pharmacotherapy of diseases** : Pathophysiology, drug therapy and critical analysis of rationale use of drugs in the following disorder.
 - b) **Cardiovascular disorders** : Hypertension, congestive cardiac failure, ischaemic heart disease, arrhythmias, hyperlipidaemias.
 - c) **Respiratory disorders** : Asthma, chronic obstructive airways disease.

- Renal disorders** : Acute renal failure, chronic renal failure, drug dosing in renal impairment.
- d) **Haematological disorders** : Anaemia, drug induced haematological disorders.
Endocrine disorders : Diabetes, thyroid disease, hormone replacement therapy.
 - e) **Nervous disease** : Epilepsy, Parkinson's disease, headache.
 - f) **Psychiatric disorders** : Schizophrenia, depression, anxiety disorders, sleep disorders.
 - g) **Gastrointestinal diseases** : Ulcer disease, inflammatory bowel diseases, hepatitis, alcoholic liver disease, drug induced liver disease.
 - h) **Infectious disease** : Respiratory tract infections, gastroenteritis, pneumonia, typhoid, urinary tract infections, tuberculosis, leprosy, protozoal infections, haematiniasis, sexually transmitted diseases, AIDS.

IV.T.3 **Bio-pharmaceutics & Pharmacokinetics**

Theory (75 Hours)

1. Introduction to bio-pharmaceutics and Pharmacokinetics, various terms used and their role in related discipline.
2.
 - a) **Bio-pharmaceutics** : Definition, physico-chemical, factors altering biological performance of drugs with special emphasis on pH, partition, hypothesis, dissolution rate, Physiological considerations including membrane, gastro-intestinal physiology and environment like presence of food, motility etc. Influence of formulation factors on absorption of drugs.
 - b) **Bio-availability and Bio-equivalence**; Concept and significance, methods of determination of bio-availability using blood level and urinary excretion data, Parameters used to evaluate bio-equivalence.
3.
 - a) **Pharmacokinetics** : Absorption, distribution, metabolism and excretion of drugs. Protein binding, pharmacokinetic parameters, determinations and their significance.
 - b) **Compartment kinetics** : One and two compartment models, pharmacokinetics of single dose administration as applied to intravenous bolus and oral administration. Curve fitting, method of residuals as applied to plasma concentration profile for two compartment model.
 - c) **Brief introduction to non-linear pharmacokinetics** : Concepts and applications, Kinetics of multiple dosing and dosage regimen.

4. **Sustained release products** : Definitions and importance, types of S.R.products, design and development of oral and indictable S.R.products, evaluation of S.R.Products.
5. **Novel drug delivery systems** : Introduction and concepts, classification, basic back ground information on different types of novel delivery systems like Occuserets, osmotic pumps, transdermal systems, implants and inserts. Introduction to the concept of targeted drug delivery.

IV.T.4 INDUSTRIAL PHARMACY-II

THEORY (50 hours)

1. **Capsules** : Advantages and disadvantages of capsule dosage forms, material and methods for production of hard gelatin capsules, size of capsules, formulations, methods of capsule filling and equipment involved, soft gelatin capsule shell and capsule content, importance of base absorption and minim./gm factors in soft capsules, quality control, stability testing and storage of capsule.
2. **Micro encapsulation** : Types of microcapsules, importance of microencapsulation in pharmacy, microencapsulation by phase separation, co-acervation, multi-orifice, spray drying, spray congealing, polymerization, complex emulsion, air suspension technique, coating pan and other techniques, evaluation of microcapsules.
3. **Tables** : Formulation and manufacturing of different types of tablets, physics of tablet compaction, different types of tablet compression machinery and equipment employed. Process evaluation of tablets.
Coating of Tablets : Types of coating, film forming, materials, formulation of coating solution, equipments for coating, processing problems, evaluation of coated tablets.
4. **Parenteral products** : Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment, formulation techniques, types of containers and closures and their selection, facility design for parenteral manufacture as per GMP : Aseptic techniques, source of contamination and methods of prevention, design of aseptic area. Laminar flow bench services and maintenance, prefilling treatment, washing of containers and closures, preparation of solution and suspensions, filling and sealing of ampoules, vials, infusion fluids, lyophilization and preparation of sterile powders, equipment for manufacture of SVP and LVP and evaluation.

5. **Packaging materials from pharmaceutical products** : Packaging components, types, specifications and methods of evaluation, stability aspect of packaging, packaging equipments, factors influencing choice of containers, legal and other official requirements for containers, package testing.
6. Polymer science and application in formulation design.
7. GMP and validation, general aspect of plant design.

IV.P.2 Industrial Pharmacy-II

Practical (75 Hours)

1. Preparation, evaluation and packaging of liquid orals like solutions, suspensions and emulsions, ointments, suppositories, eye drops, eye ointments etc.
2. Collection, processing storage and fractionation of blood.
3. Formulation of various types of cosmetics for skin, hair, dentifrice and manicure preparations.
4. Experiments to illustrate preparation stabilization, physical and biological evaluation of pharmaceutical products like powders, capsules, tablets, parenterals, microcapsules, surgical dressing etc.
5. Evaluation of materials used in pharmaceutical packaging.
6. Experiments for determination of pharmacokinetics parameters & bioavailability based on salivary & urinary excretion of drug formulations using human volunteers.
7. Formulation of oral S.R.Products & their evaluation by invitro dissolution profile.
8. To study influence of pH, salt form & Pharmaceutical adjuvants on dissolution of drugs.
9. To study the influence of simulated gastric & intestinal pH on stability & hydrolysis of drugs.

IV.T.5 MEDICINAL CHEMISTRY-II

THEORY (75 (hours)

1. **Principles of drugs design** : Traditional analog (QSAR) and mechanism based approaches, introduction to graph theory, application of quantum mechanics, computer aided drug designing (CADD) and molecular modelling.
2. Synthetic procedures of selected drugs, mode of action (biochemical and molecular basis wherever applicable), structure activity relationship including physicochemical properties of the following classes of drugs :

Steroids and related drugs : Steroid nomenclature and stereochemistry, androgens and anabolic agents, estrogens and progestational agents, adrenocorticoids.

Antihistamines Eicosanoids, analgesics - antipyretics, antiinflammatory agents (NSAID), oxytocics, hypoglycaemic agents, thyroid hormones and antithyroid drugs.

Antimetabolite concepts, sulfonamides, chemotherapeutic agents and urinary antiseptics, antiseptics and disinfectants, drugs used in tuberculosis and leprosy, antibiotics, antiamebic agents, antimalarials, drugs used for trypanosomiasis and other protozoan diseases, anthelmintics, antifungal agents, antineoplastic and antiviral agents. Diagnostic agents, surface active agents and other pharmaceutical aids. Immunomodulators.

3. Concepts and brief introduction to gene therapy, nucleotidomimetics (antisense oligonucleotides), peptidomimetics.
4. Concepts and brief introduction of genetic engineering in medicinal chemistry.
5. Brief introduction to combinatorial chemistry.

IV.P.3 Medicinal Chemistry-II

Practical (75 Hours)

1. Workshop on stereomodel use of some selected drugs.
2. Synthesis of selected drugs from the course content involving two or more steps of synthesis and their spectral analysis.
3. Establishing the Pharmacopoeial standards of drugs synthesized.
4. Determination of partition coefficient, dissociation constant and molar refractivity of compounds for QSAR analysis.

IV.T.6 PHARMACEUTICAL ANALYSIS-II

THEORY (75 hours)

1. **Quality assurance :** GLP, ISO 9000, TQM, Quality review and quality documentation, ICH.
2. Regulatory control, regulatory drug analysis, interpretation of analytical data.
3. Validation, quality of equipment, validation of equipment, validation of analytical instruments.
4. **Chromatography :** Principles and techniques involving separation of drugs from excipients, the following techniques be discussed with relevant examples of pharmacopoeial products :

TLC, HPLC, GLC, HPTLC, paper chromatography and column chromatography.

5. The theoretical aspects, basic instrumentation, elements of interpretation of data/spectra, and application of analytical techniques be discussed on potentiometric titrations (including Karl Fisher titration), conductometric titrations, polarography, amperometric titrations, coulometric titration, polarometry, UV and visible spectrophotometry, infrared spectrophotometry, brief introduction to a nuclear magnetic resonance spectroscopy, brief introduction to mass spectrometry, flame photometry, emission spectroscopy, atomic absorption spectroscopy, fluorimetry, thermal analysis including DSC, DTA.

IV.P.4 Pharmaceutical Analysis-II

Practical (75 Hours)

1. Quantitative estimation of at least 5 formulations containing single drug or more than one drug, using instrumental techniques.
2. Estimation of Na⁺, K⁺, Ca⁺⁺ ions using flame photometry.
3. IR of samples with different functional groups (-COOH, -COOR, -CONHR, -NH₂, -NHR, -OH, etc.)
4. Workshop to interpret the structure of simple organic compounds using UV, IR, NMR and MS.
5. Exercises involving potentiometry, conductometry, polarography, fluorimetry and polarometry.

IV.T.7 PHARMACOGNOSY-III

THEORY (50 hours)

1. Role of medicinal and aromatic plants in national economy, importance and status of herbal medicines and cosmetics.
2. **Enzyme biotechnology :** Introduction, general methods of isolation and purification of enzymes, enzyme reactors, applications of immobilised enzymes in drug and drug analysis, Source, method of preparation, chemical nature and uses of papain, bromelain, streptokinase, urokinase, hyaluronidase, asparaginase, diastase, pepsin, trypsin, pancreatin.
3. Plant bitters and sweeteners.
4. Worldwide trade in medicinal and aromatic plants and their derived product. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants and their products in India.
5. Novel medicinal agents from marine sources.

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