

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

Prospectus No. 101431

संत गाडगे बाबा अमरावती विद्यापीठ  
SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा  
(FACULTY OF MEDICINE)

अभ्यासक्रमिका  
औषधिनिर्माण पदव्युत्तर परीक्षा  
भाग-१, २०१० व भाग-२, २०११

**PROSPECTUS**

OF

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



2009

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PUBLISHED BY

**J.S.Deshpande**

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Sant Gadge Baba Amravati University,  
Amravati 444 - 602

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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 QUALITY ASSURANCE**

**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.

**TABLETS :**

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, Remington's 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.

**QA-1 : MODERN ANALYTICAL TECHNIQUES IN PHARMACEUTICAL RESEARCH****SPECTROSCOPIC TECHNIQUES**

- 1) Basic fundamentals, Theory & Instrumentation of UV, IR, Derivative spectroscopy including FT- IR & their applications to structural elucidation
- 2) Basic fundamentals, Theory & Instrumentation of NMR, C-13NMR, 2-D NMR their applications to structural elucidation
- 3) Basic fundamentals, Theory & Instrumentation & application of Mass Spectroscopy
- 4) X-ray diffractions & X-ray emission methods

- 5) Optical Rotatory Dispersion and Circular Dichroism – General Principle, Instrumentation of thermographs and applications.
- 6) Atomic Absorption Spectroscopy (AAS)

#### **SEPARATION TECHNIQUES**

- 1) Basic principle applications & recent trend in chromatography
  - a) Gas Chromatography, GCMS
  - b) High performances liquid chromatography, LCMS
  - c) HPTLC
  - d) Chiral Chromatography
  - e) Ion -pair Chromatography
  - f) Size exclusion Chromatography
  - g) Affinity Chromatography
  - h) Supercritical fluid Chromatography

#### **ELECTRO ANALYTICAL TECHNIQUES**

- 1) Pulse Polarography
- 2) Chrono amperometry
- 3) Electrophoresis
- 4) Electrogravimetry

#### **THERMAL METHODS**

Basic fundamentals & Theory of

- 1) Thermal gravimetry
- 2) Differential Thermal (DTA)
- 3) Differential Scanning calorimetric (DSC)

#### **SPECIAL TECHNIQUES IN DRUG ANALYSIS**

- 1) Principles and applications of RIA and Enzyme immunoassay.
- 2) Quality control and Application of radio pharmaceuticals.
- 3) Emission methods – Spark emission & plasma emission
- 4) Laser – Basic principles, Classification, instrumentation & application.

#### **BOOKS RECOMMENDED**

- 1) A. H. Beckett & J. B. Stenlke practical Pharmaceutical Chemistry, part -II the Athlone press university of London
- 2) K. A. Connors T. B. of Pharmaceutical Analysis of drug wiley inter science
- 3) L. G. Chatten, T. B. of Pharmaceutical Chemistry, Vol -II Marcel Dekkar New York
- 4) Willard Instrumental Methods of Analysis Van No Stand comp
- 5) Florey Analytical profiles of drugs substances series. Academic prast
- 6) B. K. Sharma, “Instrumental methods of Chemical analysis” 16 th,
- 7) G.W. Ewing, “Instrumental methods of Chemical analysis”.
- 8) D.A. Skoog & P.M. West, “Principle Of Instrumental Analysis”
- 9) Robert M. Silverstain, A Text Book Of Pharmaceutical Analysis.
- 10) Munson Janues W. “Pharmaceutical Analysis” Marcel Dekker.
- 11) W. Kemp, “Organic Spectroscopy”

#### **QA-2: QUALITY ASSURANCE AND MANAGEMENT**

- 1) Concept of Total quality management, Philosophy of c-GMP & GLPs.
- 2) Organization and Personnel, Responsibilities, training, hygiene, personal records.
- 3) Premises : Location, Design, Plant layout, construction, maintenance, sanitation, environmental control, utilities & services like gas, water, electricity, Maintains of sterile areas, control of contamination.
- 4) Equipment; selection, purchase specifications
- 5) Raw material; purchase specifications, stores, selection of vendors, controls on raw materials
- 6) Manufacture of and controls on dosage forms, documents, Master formula batch formula records, standard operating procedure, quality audits of manufacturing processes and facilities
- 7) In process quality controls on various dosage forms sterile & non sterile standard operating procedures for various operations like cleaning, filling, drying compression, coating polishing, disinfection fumigation, sterilization

- 8) Quality control laboratories responsibilities good laboratory practices, Routine control instrument, reagents, sampling plans standard test procedures, protocols, non-clinical testing. Controls on animal house. Data generation and storage. Quality control documentation, retention of sample records, audits of quality control facilities.
- 9) Finished products release, Quality reviews Quality audits, batch release documents
- 10) Ware housing, good ware housing practices, Materials & Management
- 11) Distribution & selection of records, Handling of returned good, recovered materials & reprocessing.
- 12) Complaints & recalls, evaluation of complaints, recall procedures & selected record, documents, waste disposal, scrap disposal procedures & records.
- 13) Pharmaceutical process validations
- 14) Quality Management of cosmetics
  - i) Preparations for facial skin: - Vanishing cream, cold & moisturizing cream, face powder
  - ii) Preparations for Oral hygiene: - Dentifrices, mouthwashes
  - iii) Preparations for hair: - Shampoos, Hair dyes, & Conditioners
  - iv) Body cosmetics: - Antiperspirants & deodorants, talcum Powder

#### **BOOKS RECOMMENDED**

- 1) Drug & Cosmetics Act 1945 Rules (Govt. of India)
- 2) Bernard T. Laflus & Rabert A. Nash Pharmaceutical process validation in drugs & Pharmaceutical sciences Vol 23, Marcel & Dekker
- 3) Sidney H. Willing, Murray M. Tukerman Good Manufacturing Practices for Pharmaceutical - A plan for total quality control, Volume - 16 2 Marcel Dekker
- 4) Allen F. Hirsch Good laboratory practices regulations in Drugs and the Pharmaceutical Sciences, Volume -38, Morce :- Dekker
- 5) Preparations & evaluation of cosmetics by P. P. Sharma
- 6) Web Resources In Pharmacy, Inpharma Publication, Bangalore.
- 7) Mueen Ahmed K.K. "Web Resources in Pharmacy"

#### **QA-3 : ADVANCES IN PHARMACEUTICAL SCIENCES**

- 1) Non-traditional Topical Drug Delivery System - Microsponges, Liposome, Surfactant Association Colloids Gels Silicones
- 2) Controlled Drug Delivery System - Rational design & fabrication of following controlled drug release System - Oral ocular Intervaginal & Intrauterine, transdermal parental & Implantable controlled drug delivery system, other specialized controlled drug delivery system like liposome, Micro particulates macromolecule drug carriers & Antibodies for drug delivery.
- 3) Lipoproteins - Lipoproteins in biological fluids cellular Interactions with vascular endothelium lipoproteins & Micro emulsions as carriers of therapeutic chemical agents
- 4) Biodegradable Polymers for controlled Drug Delivery :- Introduction General consideration, Design & formulation options drug release kinetics
- 5) Packaging materials - Cosmetics & their relation to drug:- comparison on the basis of composition of preparations safety & performance - Formulation aspects preparations for skin, hair, nail and face, teeth, mouth. And safety of colours and perfumes used.
- 6) General Principles of Toxicology - Toxicology testing methods, special toxicity test like teratogenicity, toxicity testing in cosmetics.
- 7) Regulatory Affairs
  - i) GLP Guidelines.
  - ii) ISO & ICH requirements of quality.
  - iii) Registration of new drugs for importing and manufacturing in India.
  - iv) Introduction to IND, NDA, ANDA for registration in USA.

#### **BOOKS RECOMMENDED**

- 1) Roninson & Lee controlled Drug Delivery - Fundamentals & applications, Marcal Dekker Ins.
- 2) Y. W. Chein, Novel Drug Delivery System Marcel Dekker Ins.
- 3) S. D. Bruck controlled Drug Delivery Vol-I & II CRS press
- 4) III u, David, Polymers in controlled Drug Delivery weight publishing co.

- 5) Devid W. Osberne, Anton H. Aman, Topical Drug Delivery formulation Mircel Dekker Ins
- 6) Michael Shaw, Lipoproteins as carries for Pharmacological Agents Marcel Dekker Ins
- 7) Mark Chasin, Robert Longer, Biodegradable Polymers as Drug delivery system Marcel Dekkar Ins
- 8) James Searbrik, James Daylen, Encyclopedis pf Pharmaceutical Technology Vol- I to 8 Maracel Dekker Ins
- 9) Cosmctics & the skin F. V. Wells, Reinhold book corporation
- 10) Cosmetic Sciences & technology Vol 1,2,3, by M. S. Balsam Wiley Inter sciences
- 11) Preparation & evaluation of cosmetics by P. P. Sharma.
- 12) Web Resources In Pharmacy, Inpharma Publication, Bangalore.
- 13) Mueen Ahmed K.K. "Web Resources in Pharmacy"

#### QA-4 : SELECTED TOPICS IN QUALITY ASSURANCE

1. WHO guide lines of the standardization of Herbal raw materials and finished products.
2. Morphological, microscopical and chemical examinations of crude drugs and finished products.
3. Microbial counts, bioburden and Pharmacopoeial microbial assays.
4. Standardization of food products. Concepts of nutritional requirements at different age, sex, and in different conditions like normal, pregnancy and diseases like diabetes, hypertension and atherosclerosis, jaundice etc. Different types of additives used and analysis of these ingredients in ethical and non ethical foods.
5. Standardization of Herbal products. Physicochemical characterization in whole form, separation and identification of active principles, excipients and their estimation by different techniques.
6. Factors affecting stability of a formulation, ICH guidelines, Methods of stabilizations and Methods of stability testing. Concept of development of stability indicating analytical methods.
7. Screening and evaluation Techniques of the following : Analgesics, Anti-inflammatory agents, Drugs used in Diabetes, CNS Stimulants, Cardiotonics, Anti-Hypertensive drugs, Diuretics, Sedatives and Hypnotics.
- 8 Determination of  $LD_{50}$ .

#### BOOKS RECOMMENDED :

1. Food additive- R. J. Taylor
2. Antimicrobial in food- Alfred larry branen. P Michael division publishing corporation
3. Method of protein analysis by Istran kerese.
4. Cosmetic analysis- selective methods and techniques by P. Borc
5. Harry's cosmeticology- Martin M. Rieger.
6. Herbal cosmetics. Beauty through Herbs- Dr. Urjita jain.
7. Morris B. Jacobs. The chemical analysis of foods and food products.
8. S. Suzanne Neilson. "Introduction to chemical analysis of foods."
9. Jemns T Cartenson. Drug stability- Principles and Practices. 2nd edition, Marsel deckker.
10. Applied Microbiology. Vinita Kale Kishor Bhusari.
11. Michael J. Pelezar/ Chan/ Kricg. "Microbiology. 5th edition,
12. Tortora, Funke, Case. "Microbiology" - An introduction. 8th edition.
13. P.P.Sharma.- Cosmetics Formulation, Manufacturing and Quality control.
14. WHO Guide line for the quality control of herbal plant material.
15. The Practical Evaluation of Phytopharmaceutical by Brain & Turner
16. Indian Herbal Pharmacopoea- Vol-I & II
17. Bernard T. Laflus & Rabert A. Nash Pharmaceutical process validation in durgs & Pharmaceutical sciences Vol 23, Marcel & Decker.
18. Drug Discovery & Evaluation by H.Gerhard Vogel.
19. Pharmacology & Pharmacotherapeutics by Satoskar & Bhandarkar.
20. Goodmann & Gilman's The Pharmacological Basis of Therapeutics – J.GHardman & L.E.Limbird.
21. Fundamentals of Experimental Pharmacology by M.N.Ghosh.
22. Handbook of Experimental Pharmacology – by S.K.Kulkarni.
23. Screening Methods In Pharmacology by Robert A. Turner

**QA-5 : PRACTICALS IN QUALITY ASSURANCE**

- 1) Working knowledge, calibration and validation of the Modern analytical Instruments like UV spectrometer, IR-spectrophotometer, HPLC, etc.
- 2) Analysis of pharmaceutical and cosmetic raw materials with the help of instruments.
- 3) Screening and evaluation of Analgesics & Anti-inflammatory agents, CNS Stimulants, Cardiotonics, Anti-Hypertensive drugs, Sedatives and Hypnotics, etc.
- 4) Determination of Bioavailability of drug by blood concentration and urinary excretion method.
- 5) Determination of concentration of drugs by Interpolation, Matching & Three Point Bioassay method.
- 6) Microbial assay of antibiotics
- 7) Dissolution studies of solid dosage forms.
- 8) Stability testing of pharmaceutical dosage forms.
- 9) Patch test for cosmetics & dermatological products.
- 10) Development and evaluation of cosmetic preparations like shampoo, creams, dentifrices, lipsticks etc.
- 11) Development, evaluation and Standardization of Dosage Forms, including Solids, semi solid, liquid and sterile dosage forms.
- 12) Determination of LD<sub>50</sub>.
- 13) Experiments on Chromatography.
  - (a) Thin Layer Chromatography.
  - (b) Paper Chromatography.
    - 1) Ascending Technique.
    - 2) Descending Technique.
    - 3) Circular Technique.
- 14) Two dimensional Paper Chromatography and TLC.
- 15) Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
- 16) Assay of some official formulations by official methods. (Minimum one for each analytical method)
- 17) Testing containers, closures, liners, glass, plastics used for packing.

- 18) Test of packaging materials, cartons, aluminium foils, strip packing, blister packing, ampoules, vials, etc.

**QA6 : 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.

**QA7 : 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.

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