

M.Pharm.Semester-I to IV

Prospectus No. 20121431

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 (QUALITY ASSURANCE)
EXAMINATIONS

SEMESTER-I & III, WINTER-2011

SEMESTER-II & IV, SUMMER-2012



2011

Visit us at www.sgbau.ac.in

Price Rs.

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

-
- © “या अभ्यासक्रमिकेतील (Prospectus) कोणताही भाग संत गाडगे बाबा अमरावती विद्यापीठाच्या पूर्वानुमती शिवाय कोणासही पुनर्मुद्रित किंवा प्रकाशित करता येणार नाही.”
- © “No part of this prospectus can be reprinted or published without specific permission of Sant Gadge Baba Amravati University.”

M. Pharm. (Quality Assurance)**Semester – II****Subject code: MQA -201****Subject : QUALITY ASSURANCE TECHNIQUES****THEORY : 60 Hours (4 hrs. /week)****SECTION-A**

1. Concept of total quality management [TQM], Different quality management systems, ISO 9001: 2000, ISO 14000: their philosophy, awards and accreditation. Quality Audit of process, systems, facility and vendor.
2. Documentation requirements in pharmaceutical industry for GMP compliance. Product developments in stage documentation, Site master file, manufacturing documents such as master formula record, Batch records, retention samples and records, Quality control documentation, batch release documents, distribution and recall records, complaints files and log books.
3. Steps involved in Pharmaceutical Manufacturing Documentation, preparation, issue and use of documents, storage, retrieval and disposal of documents.

SECTION-B

4. Regulatory basis for process validation, validation of medical devices, solid dosage form, biotechnology processes, transdermal system, lyophilization, inhalation aerosol, pharmaceutical ingredients, water and air handling system, integrated packaging and sterilization. Validation of aseptic process, raw material and cleaning processes. Validation in contract manufacturing.
5. Statistical methods for uniformity and dissolution testing change control, SUPAC and PAT.
6. Method development protocols with special reference to U.V., HPLC, and FTIR.

Books and References Recommended

1. Wiling S.H., Tuckerman M.M and Hitchings W.S.; “Good manufacturing practices for pharmaceuticals” Drugs and Pharm.Sci. Series, Marcel Dekker Inc., N.Y.
2. Lofts, B.T. and Nash, R.A.; “Pharmaceutical process validation”, Drug and pharm.Sci. Series, Marcel Dekker.
3. Swarbrick and Boylan; Encyclopedia of pharmaceutical technology, Marcel Dekker Inc., N.Y.
4. Carlton, F.J. and Agalloco J.P.; validation of aseptic pharmaceutical processes, Marcel Dekker Inc., N.Y.
5. Despautz, J.F; “automation and validation of information in pharmaceutical processing, Marcel Dekker Inc., N.Y.

6. Rothary B.; ISO 14000 and ISO 9000; gower.
7. Barry D.A.; Statistical design and analysis in pharmaceutical sciences,; Marcel Dekker Inc. N. Y.
8. Bergman, S.W. and Gittins J.C.; Statistical methos for pharmaceutical research and planning, Marcel Dekker Inc, N. Y.
9. Willard, “Instrumental method of analysis”.
10. <http://www.who.int/en>
11. www.fda.gov.

Subject code: MQA -202**Subject : Drug Evaluation and Standardization****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. **Preclinical evaluation** of following categories of drugs.
 1. Neuropharmacological screening: Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, anticonvulsants, local anesthetics, CNS stimulations
 2. Analgesic, anti-inflammatory, antipyretic agents, antihypertensives, Antiulcer agents, Diuretics, Immunomodulators, Hypoglycemics, Cholesterol lowering agents, antifertility agents, Dermatological agents, Antitumor agents.
 3. **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.

SECTION-B

4. General method for microbial counts and bioburden determination.
5. Microbiological assays of antibiotics and vitamins.
6. Clinical trials for drugs and dosage forms.
7. Standardization of cosmetic products and Herbal formulations.
8. Thermal analysis of drug and excipients.

Book and References Recommended

1. Turner R.A., Screening methods in pharmacology.

2. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
3. Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
4. Mutagenicity testing and related analytical techniques by R. W. Frei & U.A.Th.Brinkman
5. Quantitative methods in Pharmacology by H. De Jonge
6. In vitro toxicity testing by John M. Fraizer
7. OECD and EPA Guidelines
8. Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, New York Chicago
9. General and Applied toxicology by Bryan Ballantyne, T. Mars & P Turner
10. Safety evaluation of drugs and chemicals by W. Eugene Llyod
11. Ayurvedic formulary of India, Govt of India, 1962.
12. Indian herbal pharmacopoeias, Vol-1998.
13. British herbal pharmacopoeias, 1996.
14. WHO publications.
15. Pharmacopoeias of various countries.

Subject code: MQA -203

Subject : ADVANCED ANALYTICAL TECHNIQUES

THEORY : 60 Hours (4 hrs. /week)

SECTION-A

1. **Spectroscopic methods:** Theory, Instrumentation, chemical applications and structural elucidation by UV, IR, FTIR, NMR, C^{13} NMR, Mass Spectrometry, ESR and Emission spectroscopy.
2. **Separation Techniques:** Fundamental principles, theory, instrumentation and applications of Gas-liquid chromatography, HPLC, Gel chromatography, GC-MS, HPTLC, normal and reverse phase chromatography, and Ion Pair Chromatography. **Counter-current chromatography, droplet counter-current chromatography, solvent system, ion exchange affinity, size exclusion, cation/anion exchange, gel electrophoresis for protein and DNA**

SECTION-B

3. **Thermal Analysis:** Theory, Instrumentation and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).
4. **Immunochemical Techniques:** Immunoelectrophoresis, Immunoprecipitation, ELISA, Radioimmunoassay.

References:

- 1) Theory and applications of ultraviolet spectroscopy – M. Orchin and H. H. Jaffe, John Wiley and Sons, N. Y.

- 2) Spectrometric identification of organic compounds – Silverstein, Basseler, Morrill, John Wiley and Sons, N. Y.
- 3) Instrumental Methods of Analysis– Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
- 4) Applications of Absorption Spectroscopy of Organic Compounds – J. R. Dyer, Prentice Hall, London
- 5) Chemical Applications of Infra-red spectroscopy – C. N. R. Rao., Academic Press, N. Y.
- 6) Quality assurance of drugs in Pharmaceutical chromatography by P.D.Sethi.
- 7) Introduction to High Performance Liquid Chromatography – R. J. Hamilton, Chapman and Hall, London
- 8) Pharmaceutical Analysis Modern Methods-Part A and Part B – J. W. Munson, Marcel and Dekker
- 9) Indian Pharmacopoeia-2007
- 10) Martindale: The complete Drug Reference – 2007
- 11) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- 12) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja, Neil Jespersen
- 13) An introduction to thermogravimetry by Keatch/Dollimore
- 14) Jenkins Quantitative Pharmaceutical chemistry, Adelbert M. Khevel, Frans Diangani
- 15) Thermal analysis: theory and application by R.T.Sane, Jagdish K. Gadge
- 16) Practical HPLC Method Development, 2nd Edition- Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch

Subject code: MQA -204

Subject : Packaging Technology

THEORY : 60 Hours (4 hrs. /week)

SECTION-A

1. Concept in Pharmaceutical packaging
2. The packaging function
3. Regulatory aspects of pharmaceutical packaging system
4. Package design research
5. Packaging materials with special reference of glass, plastics, metals and polymers.
6. Control of packaging materials.
7. Ancillary materials used in packaging
8. Types and testing of containers and closures, Pharmacopoeial tests and specifications closure system.

SECTION-B

9. Types of packaging with special reference to blister, strip, sachet, child resistant and tamper evident packaging.
10. Packaging of parenteral, ophthalmic and aerosols.
11. Stability of packages and packaging materials
12. Sterilization of packaging materials
13. Printing and decoration of labels and packages
14. Package testing
15. Defects in packaging.

Books Recommended

1. Swarbric, J and Bolyln, J. C., Encyclopedia of Pharmaceutical Technology Vol. 1-3, Marcel Dekker, Inc., New York.
2. Dean, D. A. Evans, E. R. and Hall, j. H. "Pharmaceutical Packaging Technology", Taylor and Francis, London.
3. Banker, G. S. and Rodes, C. "Modern Pharmaceutics", Marcel Dekker, Inc. N. Y.
4. Aulton, M.E., Pharmaceutics – The Science of dosage form design, Churchill Livgstone, U.K.
5. Lachman, L. Lieberman, H.A. and Kanig, J. L. Varghese Publishing House, Bombay
6. Gennaro, A. R. "Remington – The science and practice of Pharmacy" Lippincott Williams and Wilkins, Philadelphia

Subject code: MQA -205

Subject : Selected topics in Quality Assurance

THEORY : 60 Hours (4 hrs. /week)

SECTION-A

1. Fundamental of cosmetic product development
Regulatory requirements for cosmetic products, consumer safety consideration with microbiological preservation of cosmetic, intellectual property issue: patents of trade secrets.
2. Quality management of cosmetics
 1. Preparation of facial cream-vanishing cream, cold and moisturizing cream, face powder
 2. Preparation for oral hygiene-Dentrifices, mouthwashes
 3. Preparation for hair-shampoos, Hair des and conditioners
 4. Body cosmetics- Antiperspirant and deodrant, talcum powder
3. Immunoassay
Application of Immunoassays in Research Quality control, Pollution enzyme electrode, immunosensor
4. Design and Application of Prodrugs

Prodrug Concept, Prodrugs of various functional groups like carbonyl, hydroxyl, amide, amines. Application of prodrug approach to: i) Improvement of bioavailability ii) Prevent first pass metabolism iii) Reduction of side effects iv) Prolong duration of action v) Site specific delivery.

SECTION-B

5. General principle of Toxicology
Toxicological testing methods, special toxicity test like teratogenicity. Toxicity testing in cosmetics
6. **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.
7. Polymer science
Introduction, Polymer-classification, Applications of Polymers in formulation of controlled drug delivery systems, Biodegradable and Nonbiodegradable polymers, Properties of following commonly used polymers- Starch, Gelatin, Chitosan, Albumin, Cellulose derivatives and Poloxamers.
8. Novel drug delivery system
Introduction and design: Sustained and control release drug delivery system, transdermally, mucoadhesive, ocular, intrauterine, peptide and targeted drug delivery system.

Reference Books

1. Drug and cosmetic Act 1945 Rules (Govt. of India)
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. Butterworth: Progress in Medicinal Chemistry Series
7. Novel drug delivery system; By Y.M.Chien, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Liebermann et.al, Marcel Dekker, Inc.
9. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
10. Preparation and evaluation by P.P. Sharma
11. Toxicology, The basis science of poison by Cassarate and Doulls mc Graw hill medical, Newyork Chicago

12. General and Applied toxicology by Bryan Ballantyne , T. mars & P Turner
13. Safety evaluation of drugs and chemicals by W. Eugene Llyod

Subject code: MQA -206

Subject : Laboratory course II

PRACTICLES : 60 Hours (4 hrs. /week)

1. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
2. LD50 determination as per OECD guideline
3. Evaluation for Pyrogen testing in Pharmaceutical product
4. Development, evaluation and Standardization of dosage forms, including solids, semisolid, liquid and sterile dosage form.
5. Experiments on chromatography: TLC and paper Chromatography
6. Determination of water in sorbitol, sodium citrate and Ampicillin
7. Assay of some official formulations by official methods (minimum one for each analytical methods)
8. Testing container, closure, liners, glass, plastics, used for packaging
9. Test for packaging material, cartons, aluminum foils, strip packing, blister packing, ampoules, vials etc.

Reference Books

1. Turner RA, Screening Methods in Pharmacology, Academic Press, London
2. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
3. Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
4. IP, BP, USP
5. Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
6. Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
7. All books mentioned as reference books for theory should be used.
