

M.Pharm.
Semester-I Examination, Winter-2010,
Semester-II Examination, Summer-2011

Prospectus No. 20111431

संत गाडगे बाबा अमरावती विद्यापीठ
SANT GADGE BABA AMRAVATI UNIVERSITY

आयुर्विज्ञान विद्याशाखा
(FACULTY OF MEDICINE)

अभ्यासक्रमिका
औषधिनिर्माण पदव्युत्तर परीक्षा
सत्र-१, हिवाळी-२०१० व सत्र-२, उन्हाळी-२०११

PROSPECTUS
OF
MASTER OF PHARMACY (QUALITY ASSURANCE) EXAMINATIONS
SEMESTER-I, WINTER-2010
SEMESTER-II, SUMMER-2011



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Sant Gadge Baba Amravati University, Amravati

I N D E X

M.Pharm. (Quality Assurance) Semester-I & II

(Prospectus No.20111431)

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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 Candidates to Degrees
- Ordinance No.109 : Recording of a change of name of a University Student in the records of the University
- Ordinance No. 6/2008 : For 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.

Dineshkumar Joshi

Registrar

Sant Gadge Baba Amravati University

SANT GADGE BABA AMRAVATI UNIVERSITY

DIRECTION

No.: 22 / 2010

Date : 21/06/ 2010

Subject : Examination Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year - Four Semester Degree Course), Direction, 2010.

Whereas, the Sub-committee appointed by Board of Studies in Pharmaceutical Sciences have prepared and recommended the Schemes of Teaching and Examinations along with provisions to be incorporated in the Ordinance for M.Pharm. Semester-I to IV for the subjects (1) Pharmaceutics, (2) Pharmacology, (3) Pharmaceutical Chemistry, (4) Pharmacognosy, (5) Industrial Pharmacy, (6) Quality Assurance as per Semester Pattern and Credit Based Performance and Assessment System.

AND

Whereas, the Hon'ble Vice-Chancellor has accepted the aforesaid recommendations under sub-section (7) of Section 14 of the Maharashtra Universities, Act, 1994 on behalf of the Board of Studies in Pharmaceutical Sciences and faculty of Medicine on 27.5.2010.

AND

Whereas, the aforesaid recommendations were placed before the Academic Council in its meeting held on 28.5.2010 vide item No.45 and the Council resolved to accept the refer the Schemes/ provisions to be incorporated in the Ordinance to the Ordinance Committee for placing it directly before the Management Council.

AND

Whereas, the making of Ordinance/Regulation for M.Pharm. Semester-I to IV for the subjects (1) Pharmaceutics, (2) Pharmacology, (3) Pharmaceutical Chemistry, (4) Pharmacognosy, (5) Industrial Pharmacy, (6) Quality Assurance, is a time consuming process.

AND

Whereas, the Academic Session is starting from 14th June 2010 and it is necessary to provide the Schemes of examinations, eligibility criteria along with other details.

Now, therefore, I, Dr. Kamal Singh, Vice Chancellor of Sant Gadge Baba Amravati University, in exercise of powers conferred upon me under sub-section (8) of section 14 of the Maharashtra Universities Act., 1994, do hereby direct as under:

1. This Direction may be called "Examination Leading to the Degree of भेषजी पारंगत (Master of Pharmacy) (Two year - four Semester Degree Course), Direction, 2010".
2. This direction shall come into force from the date of its issuance.
3. In this Direction unless the context otherwise requires the expression "Department" shall mean the Department of Pharmaceutical Sciences and "College" shall mean affiliated college approved for conducting M.Pharm. course.
4. The several courses leading to the Degree of भेषजी पारंगत (Master of Pharmacy) shall be as follows, namely :
 - I) Pharmaceutics
 - II) Pharmaceutical Chemistry
 - III) Pharmacology
 - IV) Pharmacognosy & Phytochemistry
 - V) Biotechnology
 - VI) Quality Assurance
 - VII) Industrial Pharmacy
 - VIII) Bio pharmaceuticals

5. There shall be four examinations leading to the Degree of भेषजी पारंगत (Master of Pharmacy) namely the first semester examination at the end of first semester, second semester examination at the end of second semester, third semester examination at the end of third semester and Final semester examination at the end of final semester in each of the courses specified in paragraph 4 above. The duration of the course shall be of two Academic years (consisting of two semesters in each year).
6. The duration of each semester shall be of six months.
7. The Master of Pharmacy First, Third Semester Examination shall be held in November/December, and the Second and Fourth semester examination in April/May at such places and on such dates as may be fixed by the Board of Examination. Subject to the compliance with the provisions of this Direction and of other ordinance in force from time to time, an applicant for admission to -
 - A) The candidate appearing for Semester-I of First M.Pharm. shall have passed not less than one academic year previously the B.Pharm. examination of this University or of any other university recognised as equivalent thereto and shall have prosecuted a regular course of studies in the department/college as prescribed in this Direction.

Provided that, the first Semester examinee shall have passed the final B.Pharm. examination by securing not less than 50% marks for SC/ST category and 55% marks for others.”
 - B) The Final M.Pharm. (Semester-III & IV) Examinee shall have passed the First M.Pharm. Examination of this university, and shall have prosecuted a regular course of study in the Department/College as prescribed in this Direction. An applicant for the examination to the Final M.Pharm. (Semester-III & IV) shall not be allowed to take the examination if he/she fails to submit to his/her dissertation on or before the 20th December or 31st May of the calendar year in which he/she has to take the examination.
8.
 - A) Without prejudice to the other provision of Ordinance No.6 relating to the examination in general, the provisions of paragraphs 5,8,10,26 and 31 of the said ordinance shall apply to every collegiate candidate.
 - B) An unsuccessful examinee at the First M.Pharm. Examination (Semester-I & II), may be allowed to carry out his research work for dissertation for Final M.Pharm. (Semester-III & IV) Examination but shall not be permitted to appear for the Semester-IV of M.Pharm. Examination unless he/she passes in all the papers and practicals prescribed for first and second semester of M.Pharm. Examination.
9. The fee for each examination shall be as fixed by the University from time to time.
10. The sessionals, papers, practicals, dissertation, and viva-voce, and seminars if any, in which a candidate is to be examined, the maximum marks which each of the subject carries and the minimum marks which an examinee must obtain in order to pass the examination shall be as indicated in the **Annexures-I to VIII** appended with this Direction.
11. The scope of the subject shall be as indicated in the syllabus.
12. An examinee passing in a subject shall be exempted from appearing that subject at all subsequent examinations.
13.
 - i) An examinee for the Third and fourth semester of final year M.Pharm. examination shall carry out research for not less than six months under an approved guide who shall be the internal examiner. A person from industry or Research Institute possessing Post-Graduate qualification in Pharmaceutical Science in appropriate subject and not less than 5 yrs. experience in an industry or Research Institute in a responsible capacity may also be considered for appointment as guide/co-guide/Internal/External examiner
 - ii) The examinee shall submit three copies of his dissertation to the Head of the Department/Principal of the college not later than 30th December or 31st May of the calendar year in which he/she has to take the examination, duly certified by the guide that the work has been done satisfactorily under his guidance.
 - iii)
 - a) The examination based on the dissertation shall be carried out by
 - i) The Guide as Internal Examiner and
 - ii) One External Examiner out of University area
 - b) The examiners may after conducting the seminar, dissertation work and viva-voce examination shall award the marks, out of the marks prescribed for dissertation. In case of any dispute, the decision of the External examiner shall be final. The marks shall be sealed under the signature of the External examiner & shall be handed over to the Principal for sending it to the University
 - c) If the dissertation is not found up to the marks & if the candidate fails in the dissertation, the External examiner shall give his suggestions / recommendations for re-submission / modification in the dissertation to the Principal along with a copy to the Controller of Examination of University for information.
 - iv) An examinee who fails to submit his/her dissertation within the prescribed date or whose dissertation has not been accepted or fails to present himself for Viva-voce, may subject to other provisions of this Direction be readmitted to the examination at any subsequent examination provided,
 - a) he/she pays the prescribed fees as fixed by the University
 - b) his/her application is received by the Registrar not later than one month before the date of commencement of the examination.
 - c) he/she submits his dissertation on the same subject two weeks prior to the examination date. Examinee whose dissertation has not been accepted shall resubmit his/her work, with such additional work as may be directed at the next examination. However, an examinee wishing to submit dissertation on a fresh subject shall be required to join the department/college as a regular student.

14. Examinees who have passed in all the subjects prescribed for the first Year (semester I and semester II) and final M. Pharm. (Semester III and Semester IV) examinations shall be eligible for the degree of Master of Pharmacy. Those obtaining 75% or more marks in aggregate shall be placed in the first division with distinction; those obtaining 60% and above but less than 75% in the first division, and all other successful examinees in the second division, examinees passing all semester examinations leading to the Degree of भेषजी पारंगत (Master of Pharmacy) in the minimum prescribed period and obtaining the first place shall be placed in Merit list.
15. Provision of Ordinance no. 18 of 2001 relating to 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 deficiency of marks in a subject in all the faculties prescribed by the Statute No.18, Ordinance 2001 shall apply to the examinations under this Direction.
16. An examinee who does not pass or who fails to present himself/herself for the examination shall be eligible for admission to the same examination on payment of a fresh fee and such other fees as may be prescribed.
 - i) A candidate who has passed the M. Pharm. Examination in any course specified in paragraph 4 may offer himself/herself in any other course as a candidate for the M. Pharm. Examination. Such a candidate may be exempted from appearing in papers in which he/she has already passed under this Direction at the first semester examination, if there is equivalence in the syllabus. However he/she is required to appear for the Semester-II, III & IV of respective specialization.
 - ii) An examinee passing the examination under subparagraph (i) shall not be eligible for the award of Division or for inclusion of his name in Merit List.
17. Notwithstanding anything to the contrary in this Direction, no person shall be admitted to an examination under this Direction if he has already passed the same examination in the course or an equivalent examination of any other statutory University.
18. The Degree in the prescribed form shall be signed by the Vice-Chancellor.

Amravati
Dated : 19/06/2010
Chancellor

Sd/-
(Dr.Kamal Singh)
Vice-

SYLLABUS PRESCRIBED FOR MASTER OF PHARMACY IN INDUSTRIAL PHARMACY

(Implemented from the Session 2010-11)

The several courses leading to the Master Degree of Pharmacy covers following subjects namely

1. Pharmaceutics
2. Pharmacology
3. Pharmaceutical chemistry
4. Pharmacognosy
5. Quality assurance
6. Industrial Pharmacy

1. There are four semester leading to Degree of Master in Pharmacy. **The theory syllabus for first semester shall be compulsory to all above M. Pharm courses.** Second semester syllabus covers in the field of above mention specialization.
2. In third semester examination the research envisage for dissertation and one seminar on recent trends in Pharmaceutical science shall be assigned to him/her by the Guide within one month from the date of the commencement of the third semester.
3. In forth semester examination the dissertation work shall be perform by him/her and at the end student shall deliver the seminar on dissertation work and viva voce examination.

Seminar

Each candidate shall deliver 2 seminars per subject covering the current research interest as in journal in the field of pharmaceutical sciences. Evaluation of seminar shall be based on the communication, representation and skill in oral presentation

M.Pharm. Semester-I

COMMON TO ALL M. PHARM COURSES

Subject code: MC-101

Subject : RESEARCH METHODOLOGY & BIOSTATISTICS
THEORY

60 Hours (4 hrs. /week)

SECTION- A

I. Research

1. Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research) objects of research
2. Literature survey:
Using library, book and journals, MEDLINE- internet getting patents and reprints of articles as sources for literature survey.
3. Selecting a problem and preparing a research proposal for different types of research sources of procurements of grants.
4. Documentation:
Importance of documentation in case of research record and GMP/GLC
 - Techniques of documentation in case of research record and GMP and GLC
 - Uses of computer packages in clinical trials
 - Documentation in clinical trails
5. Research report/paper writing/thesis writing / poster presentation:
Different parts of research report or paper
 - Title-title of project with authors name
 - Abstract-statement of the problem, background list in brief, purpose and scope
 - Key words
 - Methodology-subject, apparatus/instrumentation and procedure
 - Results-tables, graphs, figures and statistical presentation
 - Discussion-support or non-support to hypothesis. Practical and theoretical implications
 - Acknowledgements
 - References
 - Errata
 - Importance of spell check
 - Use of foot notes

II. Methods and tools used in research:

- Research design (futures of good design, types of research designs, basic principles of experimental design).
- Qualitative studies, quantitative studies.
- Simple data organization, descriptive data organization.
- Limitations and sources of errors.
- Enquiries in forms of questionnaire, opinionnaire and interviews

III. Presentation:

- Importance, types, different skills
- Content of presentation format of model, introduction and endings.
- Posture, gesture, eye contact, facial expression, stage fright.
- Volume, pitch, speed, pauses and languages
- Visual aids and seating arrangements
- Question and answer session

SECTION- B

IV. Cost Analysis of Projects and Clinical Trials

V. Biostatistics

- Statistical analysis of data including variance, standard deviation, Parametric and Non-Parametric statistic test, correlation of data and its interpretation, computer data analysis, bio statistics for clinical trials.
- Scientific method in medicine
- Scientific equations of therapy

Reference Books

- (1) Research in education – John W. Best Jems V. Kahn
- (2) Research methodology – C. R. Kothari
- (3) Methodology and techniques of social research – Willkinson and Bhandarkar
- (4) Presentation skills – Michel Halton – Indian society for institute education
- (5) Practical introduction to copyrights – Gavin Mofariane
- (6) Thesis projects in sciences and engineering – Richard M. Devis
- (7) Scientist in legal system – Ann Labor Science
- (8) Thesis and assessment writing – Janolthon Anderson
- (9) Writing a technical paper – Donald Manzel
- (10) Effective business report writing – Lel and Brown
- (11) Protection of industrial property rights – Purshottam Das and Gokul Das
- (12) Spelling for millions – Edna Furness
- (13) Preparation for publications – King Edwards hospital foundation for London
- (14) Information technology – The hindu speaks
- (15) Documentation – genesis and development – 3792.
- (16) Ayurveda and modern medicine – R. D. Lele
- (17) How to write and publish a scientific paper – Robert A. Day Cambridge University Press 4th edition 1994
- (18) Lecture notes on patent TIFAC: DOC: 022, TIFAC July 2002.
- (19) Introduction to Statistical Methods- C. B. Gupta
- (20) A first course in Mathematical Statistics- C. E. Weatherborn
- (21) Introduction to Biostatistics-Mahajan

COMMON TO ALL M. PHARM COURSES

Subject code: MC-102

Subject : BIOTECHNOLOGY AND BIOINFORMATICS
THEORY

60 Hours (4 hrs. /week)

SECTION- A

1. **Genetics:** Structure and function of DNA replication & repair, expression of genetic information, structure and function of RNA, transcription, genetic code, translation, post translational modification.
2. **Recombinant DNA technology:** Constructing recombinant DNA molecules, restriction enzymes, vectors, gene cloning, genomic libraries, polymerase chain reaction based DNA cloning, restriction mapping, blotting technique, DNA sequencing, pharmaceutical applications of recombinant DNA.
3. **Gene therapy:** General introduction, potential target diseases for gene therapy, gene transfer methods, clinical studies, pharmaceutical production and regulation.
4. **Immunology:** Basics of immunology, Monoclonal antibodies & Hybridoma technology and its applications
5. **Vaccines-**conventional vaccines, modern vaccines technologies, genetically improved vaccines, genetically improved subunit vaccines, pharmaceutical considerations

SECTION- B

6. **Quality control testing methods of Biotech products:** Determining impurities/contamination (viral, bacterial endotoxins (in-vitro) rabbit Pyrogen, sterility, protein identification, finger prints by electrophoresis, isoelectric focusing immunogenicity, and partial sequential analysis.
7. **Immobilization of enzyme:** different techniques, effect on production of enzymes, applications.
8. **Plant Biotech products:** Substances produced by plant cell culture, Transgenic plants their application, Biotransformation with plant cell culture
9. **Molecular biology of cancer:** Causes of cancer and genetics of cancer, New strategy for combating cancer
10. **Introduction to Bioinformatics:** Biological databases, sequence analysis, protein structure, genetic and physical mapping, application of bioinformatics in pharmaceutical industries and in drug discovery.

Reference Books

1. Biotechnology-Applications and research-Paul N. Chermisinol (Technomic publishing co. Inc)
2. Molecular Biochemistry-Therapeutic applications and strategies (Salil D. Patel, John Wiley and sons).
3. Nelson, D.L, and Coy M.M. Lehninger's Principles of Biochemistry' Worth publishers, NewYork
4. Gene therapy: principle and Application by Thomas Blankenste in Bi""hausef Verlag Basel - Boston . Berlin
5. *Immunogenicity of Biopharmaceuticals* by Marco van de Weert, Eva Horn Møller (Springer)
6. Recombinant DNA technology by Watson and Trootze
7. Molecular biology of cell by Watson
8. Molecular biology of cell by Albert B, Johnson A, Lewin J.
9. Fundamental of Immunology by Paul W.E
10. Molecular biotechnology By Glick B.R and Pasternak J.J (ASM press)
11. Molecular biology and biotechnology by Walker J.M
12. Essential of genetics by Klug W.S. Cummings M.R
13. Bioinformatics by Baxevanis A.D, Frana, Duelette B.F.

COMMON TO ALL M. PHARM COURSES

Subject code: MC-103

Subject : QUALITY CONTROL OF PHARMACEUTICAL PRODUCTS

THEORY

60 Hours (4 hrs. /week)

SECTION- A

1. **Good manufacturing practices:** GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. GMP for ayurvedic products, Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP)
2. **Validation:** Pharmaceutical process validation, equipment validation and sterile products validation.
3. **Quality control of pharmaceutical dosage forms:** Solid and semi-solid dosage forms, disperse systems and parenteral dosage forms.

SECTION- B

4. **ICH Stability Guidelines, Schedule M and Schedule Y**
5. **Spectroscopic methods:** Theory and applications of UV, IR, FTIR, NMR, Mass Spectrometry, ESR and Emission spectroscopy, XRD
6. **Separation techniques:** Introduction and applications of Gas-liquid chromatography, HPLC, Gel chromatography, gel electrophoresis, GC-MS, HPTLC, Ion Pair Chromatography.
7. **Safety into the laboratory**
Designing safety into the laboratory: Laboratory accident and First aid for chemical burns and accident, egress, hazard zoning, emergency facilities, Hazards: slippery spill of Hazardous substances and their handling. Laboratory design-safety aspect: storage of laboratory chemicals, laboratory design; Principle of chemical storage; inventory control; segregation.

Reference Books

- 1) Automation and Validation of information in Pharmaceutical Processing – J. F. Despautz, Marcel and Dekker
- 2) Validation of aseptic pharmaceutical processing – F. J. Carleton and J. P. Agalloco, Marcel and Dekker
- 3) Pharmaceutical process validation – J. R. Berry and R. A. Nash, Marcel and Dekker
- 4) Good Manufacturing Practices for pharmaceuticals – S. H. Will and J. R. Stoker, Marcel and Dekker
- 5) Design of Experiments for process improvement and quality Assurance – R. F. Brewer
- 6) Encyclopedia of pharmaceutical technology, Marcel and Dekker
- 7) Achieving sterility in medical and pharmaceutical products – N.A.Halls, Marcel and Dekker
- 8) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- 9) Official and standardized methods of analysis by Colins Watson
- 10) Handbook of Quality Assurance for the analytical chemistry Laboratory by Jam Dux
- 11) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja , Neil Jespersen
- 12) Instrumental Methods of Analysis– Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
- 13) Pharmaceutical Analysis Modern Methods-Part A and Part B – J. W. Munson, Marcel and Dekker
- 14) Indian Pharmacopoeia-2007
- 15) Martindale: The complete Drug Reference – 2007

COMMON TO ALL M. PHARM COURSES

Subject code: MC -104

Subject : DRUG REGULATORY AFFAIRS

THEORY

60 Hours (4 hrs. /week)

SECTION- A

1. Aims, objects and salient features of following legislations affecting pharmaceutical industry.
 - Industrial Development and Regulation Act 1951.
 - Consumer Protection Act.
2. Australian TGA guidelines
3. US-FDA, CDER guidelines

4. New Drug Application
5. Pollution and Environmental Control Act

SECTION- B

6. Drug Master File
7. Intellectual Property Rights:
 - Protection of patents and trademarks and design and copy rights and patent system in India.
 - Present status of IPR future changes expected in Indian patents.
 - What may be patented
 - Who may apply for patent
 - Preparation of patent proposal
 - Registration of patent in India and foreign countries and vice versa
 - ICH guidelines for clinical trials, therapeutic drugs monitoring drugs and bioequivalence.
 - Exclusive marketing rights
 - Black box
 - IPR and IDMA views on patents
 - Human health and patent laws latent lethality
 - Indian patent act and copyright (Indian act)
8. Drug and Cosmetics Act 1940
9. Prevention of Food Adulteration Act 1954 (5 hrs)
10. Preparation of DMF, Site Master File, Master Formula Record. Procedure for filing of Patent.

Reference:

- (1) Guidelines of various countries like MCA, TGA, ICH.
- (2) Drug and cosmetic act 1940 and rules their under
- (3) IPR Lecture notes
- (4) GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
- (5) GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
- (6) I.P., B.P., U.S.P. International Pharmacopoeia
- (7) Pharmacokinetics, Regulatory, Industrial, academic prospective by P. G. Willing and F.T.S. Tse.

COMMON TO ALL M. PHARM COURSES

Subject code: MC -105

**Subject : PRODUCT DEVELOPMENT AND FORMULATION
THEORY**

60 Hours (4 hrs. /week)

SECTION- A

1. 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.

2. PREFORMULATION STUDIES

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

3. PHYSICAL PROPERTIES

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

4. 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.

SECTION- B

5. 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 :

6. LIQUID ORALS :

Cough and multivitamin syrup, anti flatulant and laxative emulsions, antacid and antidiarrhoeal suspensions.

7. TOPICALS :

Antibiotic ointment, analgesic gels.

8. TABLETS :

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

9. 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.

COMMON TO ALL M. PHARM COURSES

Subject code : MC-106

Subject : Laboratory course -1

Practical 8 hrs. /week

(Minimum 20 practicals should be conducted)

1. Combination Drug Analysis (any two)

Vitamins, Sulphas, Analysis of Antipyretics and Analgesics, Steroidal anti-inflammatory drugs, Antihistamins.

2. Illustrations of theoretical principles using assay of drugs form in various pharmacopoeias (any five).

This should cover titrimetric, gravimetric, spectro-photometric (including flame photometric) methods. HPLC etc. The titrimetric methods should include argentometric, conductometric, and potentiometric end point determination. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

Validation of equipments: Autoclave, hot air oven, membrane filter

(Minimum two practical).

Validation of an analytical method: Calibration of instruments as per official procedure (UV, FTIR, Conductivity meter, fluorimeter, Digital pH meter, Digital balance, Potentiometer, HPLC, Gas chromatography) (Minimum two practical).

3. Interpretation of UV, IR, NMR, C¹³ NMR spectra and Mass Spectroscopy of some chemicals and drugs. (Minimum three combined spectra).

Reference Books

- (1) Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis – F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy – C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound – J. R. Dyer, Prentice Hall Englewood

**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

10. **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.
11. **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. Invitro 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, Newyork 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 herble 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, C¹³ 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

12. **Thermal Analysis:** Theory, Instrumentation and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA).
13. **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 Livingstone, 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

PRACTICES

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.
