

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

Prospectus No. 20111430

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 (PHARMACEUTICAL CHEMISTRY) 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. (Pharmaceutical Chemistry) Semester-I & II

(Prospectus No.20111430)

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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 मेषजी 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 fourth semester examination the dissertation work shall be performed 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 (features 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. (Pharmaceutical Chemistry)
Semester – II**

Subject code : MPC – 201
Subject : ADVANCED ORGANIC CHEMISTRY
THEORY 60 Hours (4 hrs. /week)

SECTION- A

1. STEREOCHEMISTRY

Molecular dissymmetry, compounds with one, two or more unequal asymmetric carbon atoms and racemic modifications and its resolution, configuration absolute and relative, synthesis of optically active compounds, conformations in cyclic compounds, optical isomerism, shapes of cyclohexanes, five and six-membered heterocyclic rings including methods of preparation and their reaction mechanisms, shapes of rings other than six membered. Stereoselective synthesis, role of inductive, resonance and steric effects in structure and relativity.

2. MECHANISM, STEREOCHEMISTRY AND APPLICATIONS OF

Birch reduction, Clemensen reduction, Meerwein-Ponndorf reduction, Oppenauer oxidation, Wolf Kishner reduction, Wittig Reaction, Pinacol and related rearrangements, Beckmann rearrangement, Hoffman rearrangement, Claisen rearrangement, Schmidt, Lossen and Curtius rearrangement, Grignard Reagents and hydrides, Aldol condensation Cannizzarro's reaction, Reformatsky reaction, Perkin reaction, Knoevenagel reaction, Haloform reaction and Mannich reaction, Whitmore-1,2-shift, Baeyer-Villiger oxidation, Benzilic acid rearrangement, Fries rearrangement, Cope rearrangement, Sandmeyer reaction, Gomberg reaction, Phase Transfer Catalysis, Allylic bromination, ozonolysis, free radical reactions, use of diazomethane and peracids in synthesis, Study of some reduction of synthetic importance: Reduction with metallic hydroxides, hydrogenation.

SECTION- B

3. PERICYCLIC REACTIONS

Basic theory, orbital symmetry rules and their applications, mechanism, types of pericyclic reactions-cycloaddition, electrocyclic reaction, and sigmatropic rearrangement

4. PHOTOCHEMICAL REACTIONS

Introductions and basic principles, photochemistry of carbonyl compounds, photo rearrangements, photochemistry of alkenes and dienes.

5. SYNTHON APPROACH

- Definition of terms- disconnection, synthon, functional group interconversions.
- Basic rules in disconnection.
- Use of synthon approach in synthesis of following components:
Trimethoprim, Ibuprofen, Propranolol, Piroxicam.

6. Green Chemistry Approach: Purposes and Application.

Reference Books

- Advanced Organic chemistry, Reaction mechanisms and structure, J. March, John Wiley and Sons, N.Y.
- Mechanism and structures in Organic chemistry, E.S Gold, Hold Richard and Winstone, New York.
- The Organic chemistry of Drug Design and Action, R.B. Silverman, Academic press In., San Diego, 1992.
- Asymmetrical Synthesis, R.A Aitkin and S.M. Kilengi, Ed., Blackie Academic and professional London, 1995.
- Organic chemistry, Clayden, Greeves, Warren and Wothers., Oxford University press 2001.
- Organic chemistry, Vol I and II. I. L. Finar. ELBUS, Sixth ed., 1995.
- A guide to mechanisms in Organic chemistry- Peterskyes Orient Longman, New Delhi.
- Reactive intermediates in Organic chemistry- Tandom and Gowel.
- Molecular reaction and photochemistry- C.H. Deupuy and O.L. Chapman
- Drug stereochemistry Wainer Stering 1st Edn. 1996 Marcel Decker.
- Photochemistry and Pericyclic reactions, Jagdamba Singh, Jaya Singh, 2nd edition, New edge International Publishers.
- Reaction Mechanism In Organic Chemistry, S. M. Mukherji, S.P.Singh, 3rd edition, Macmillan India Ltd.
- Comprehensive book of stereochemistry- by Eliel
- Text Book of Organic chemistry – by Morrison and Boyd
- Text Book of Organic chemistry – by S. K. Ghosh

Subject code : MPC – 202
Subject : ADVANCED MEDICINAL CHEMISTRY
THEORY 60 Hours (4 hrs. /week)

SECTION- A

1. MEDICINAL CHEMISTRY OF

- Antiviral Agents and agents under development of HIV infection.
- Immunosuppressant and Immunostimulants.
- Agents used in Neurodegenerative disease Like Alzheimer's and Parkinsonism.
- GABAnergic Agonists.

- e. Antidiabetic agents like Peroxisome Proliferator Activated Receptors inhibitors, Dipeptidyl Peptidase 4 (DPP 4) Inhibitors like Sitagliptin, Vildagliptin, Protein Tyrosine Phosphatase 1 B (PTP 1 B).
 - f. Antihypertensives like Direct Renin Inhibitors e.g. Aliskiren
2. **GASTRIC PROTON PUMP INHIBITORS**
Introduction, Gastric acid secretion and its inhibitors, test assay for studying gastric acid inhibitors, irreversible gastric proton pump inhibitors
3. **PROTEINS AND PEPTIDE DRUGS**
Chemistry, structure and stability, Reactivity of proteins and peptides. Different ways to synthesize these Drugs- Study of insulin, Relaxin, Somatostatin, DNase interferon.
4. **COMBINATORIAL CHEMISTRY**
- a. Introduction
 - b. Combinatorial approaches
 - c. Chemical peptide and small molecule libraries
 - d. Applications, methodology
 - e. Combinatorial Organic Synthesis
 - f. Assays and screening of combinatorial libraries synthetic methodologies including solid-phase synthesis (SPS) and solution phase chemistry, Library Purification Methodology.

SECTION- B

5. **STRATEGIES IN THE SEARCH FOR NEW LEAD COMPOUNDS**
Introduction, improvement of existing drugs, systematic screening including extensive screening, random screening and High-throughput screening, screening of synthetic intermediates, selective optimization of side activities (SOSA) approach, new use for old drugs – An illustrative study with suitable examples.
6. **CHIRAL TECHNOLOGY**
Introduction to chirality and Techniques used in asymmetric synthesis of Vitamin C, Ampicillin, dextra-propoxyphen, Citrenalol, propanolol
7. **PRODRUG DESIGN**
Introduction, chemical bond, gastrointestinal absorption, parenteral administration, distribution, transdermal absorption, pharmacokinetics and biopharmaceutical aspects, rational of prodrug design and practical considerations

REFERENCES

1. Burger: Medicinal Chemistry series, John Wiley & Sons N.Y.
2. Foye: Principals of Medicinal Chemistry (Varghese & Co.)
3. Lednicer: Organic drug synthesis Vol.1,2,3,4; John Wiley & Sons N.Y.
4. Ariens: Medicinal Chemistry series.
5. Elies & West: Progress in Medicinal Chemistry series.
6. Wilson & Gisvold: Text book of Medicinal Chemistry, J. B. Lippin
7. Comprehensive Medicinal Chemistry series I-IV, Academic Press.
8. Combinational Chemistry-synthesis and applications- Stephen R. Wilson
9. Recent advances in chiral separations, Ed. Stevenson & Wi, Latest 1990, Plenum Press.
10. Chiral Technology, R. A. Steldon, Marcell Dekker Inc. New York.
11. Combinatorial Chemistry Ed. Fennirl Hicham 2000 Oxford University

Subject code: MPC -203

Subject : MODERN ANALYTICAL TECHNIQUES

THEORY 60 Hours (4 hrs. /week)

SECTION- A

1. **Spectroscopic methods:** Theory, Instrumentation, chemical applications and structural elucidation by UV, IR, FTIR, Near IR (NIR), Raman, ¹H NMR, ¹³C NMR (2-D NMR, COSY), Mass Spectrometry (MALDI, TOF, Quadrapole Analysers), Electron Spin Resonance and Atomic and Molecular Emission spectroscopy, X – Ray Crystallography, Refractometry, Circular Dichroism.
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), Differential Scanning Calorimetry (DSC).
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.
- (8) Introduction to High Performance Liquid Chromatography – R. J. Hamilton, Chapman and Hall, London
- (9) Pharmaceutical Analysis Modern Methods-Part A and Part B – J. W. Munson, Marcel and Dekker
- (10) Indian Pharmacopoeia-2007
- (11) Martindale: The complete Drug Reference – 2007
- (12) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- (13) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja , Neil Jespersen
 1. An introduction to thermogravimetry by Keatch/Dollimore
 2. Jenkins Quantitative Pharmaceutical chemistry, Adelbert M. Khevel, Frans Diangani
 3. Thermal analysis: theory and application by R.T.Sane, Jagdish K. Gadge
- (14) Practical HPLC Method Development, 2nd Edition- Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch

Subject code : MPC – 204

Subject : RATIONAL DRUG DESIGN

THEORY 60 Hours (4 hrs. /week)

SECTION- A

1. DRUG DISCOVERY

- a. Historical Perspective
- b. Drug Discovery studies in Direct Drug Design(Structure based) ND Indirect Drug Design
- c. Target Selection and Lead Identification
 - i) Natural Product Sources
 - ii) Fermentation/ microbial sources
 - iii) Synthetic
- d. Introduction to Pharmacogenomics.

2. APPROACHES TO THE RATIONAL DESIGN OF ENZYME INHIBITORS

a. Introduction

- i) Enzyme inhibitors in Medicine
- ii) Enzyme inhibitors in basic Research
- iii) Drug Design based on Antagonism and Enzyme Inhibition

b. Rational design of non covalently & covalently binding enzyme inhibitors

Rapid reversible inhibitors, slow & tight binding inhibitors, Transition state analogs, multisubstrate inhibitors.

3. QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP

- a. History and development of QSAR
- b. Drug-Receptor Interactions
- c. Quantitative model parameters: lipophilicity, electronic and steric factors
- d. Hansch Analysis, Free Wilson analysis, relationship between them and their application.
- e. Statistical methods-regression analysis, partial-least square analysis (PLS) and other multivariate statistical methods
- f. 2D, 3D, 4D QSAR & CoMFA and CoMSIA approaches.

SECTION- B

4. MOLECULAR MODELING

- a. Introduction to Molecular Modeling- concepts and methods
- b. Molecular mechanics-Force field (potential energy function)
- c. Quantum Mechanics- Calculation of affinity, unknown receptors, Pharmacophore models
- d. Known receptor sites
- e. Searching for similarity, molecular comparison and finding common pattern
- f. Energy Minimization methods- Steepest, descent, conjugate gradients, Newton methods (Non mathematical)
- g. Conformational Analysis
 - i) Systematic search
 - ii) Monte Carlo Simulations
 - iii) Molecular Dynamics Simulations
- h. Ligand design based on 3D structure

5. Introduction to recent advances in drug design

Quantitative structure pharmacokinetic relationship (QSPR), Bioinformatics, Genomic & Proteomics

6. Study of software for QSAR, Docking, Molecular modeling and protein sequencing.

Reference Books

1. QSAR & Strategies in the design of Bioactive Compound J. K. Seydel Latest after 1984 Deuts che Bibliofech.
2. Nucleic acid targeted Drug Design Propst & Thomas 1997 Marcel Decker.
3. Structure based Drug Design Pandi veera Pandian 1997 Merck Decker

4. A Guide to chemical Basis of Drug Design Burger Alfred 1997 Wiley interscience.
5. Computer aided Drug Design Perun 1st 1989 / Latest Marcel Decker
6. Computational Medicinal Chemistry for Drug Design Patrick Bultinck 1st 2004 Marcel Decker.
7. Nucleic acid targeted Drug Design Propst & Thomas 1997 Marcel Decker
8. Principles of Drug Design by Smith
9. Strategy of Drug Design by Brucell
10. The organic chemistry of the Drug Design and Drug action by Richard B. Silverman
11. Introduction to Quantitative Drug Design by Y.C.Martin
12. Drug Design volumes by Ariens
13. QSAR: Hansch Analysis and Related Approaches by Hugo Kubinyi
14. Textbook of Drug Design and Discovery, Third Edition, Larsen, Liljeors and Madsen

Subject code : MPC – 205

Subject : CHEMISTRY OF NATURAL PRODUCTS

THEORY 60 Hours (4 hrs. /week)

SECTION- A

1. NATURAL PRODUCTS AS LEAD FOR NEW PHARMACEUTICALS

- a. Introduction
- b. Primary and secondary metabolites in plants
- c. Study of natural products as leads like cannabinoids, etoposide, teniposide, khellin, artemisin etc.

2. ALKALOIDS

- a. Detailed chemistry and properties of alkaloids
- b. Isolation, purification and structural elucidation of morphine, vincristine, reserpine, ephedrine, atropine, β -Carotene, Digitoxin, Digoxin.

3. STEROIDS

- a. General introduction
- b. Stereochemistry, nomenclature and structural elucidation of sterols (cholesterol), sapogenin (diosgenin), and solasodine.

4. FLAVONOIDS

Detailed chemistry and properties of Flavonoids and chemical account of rutin & quercetin

SECTION- B

5. ANTIBIOTICS

- a. β - Lactum Antibiotics
Mechanism of action, penicillins, cephalosporins, nocardicilins and monobactams, carbopenams and penams, β - Lactamaseinhibitors and other β -Lactum agents
- b. Non β –Lactum Antibiotics
Aminogycosides, macrolides, linomycins & polypeptide antibiotics

6. ROLE OF RECOMBINANT DNA TECHNOLOGY AND DRUG DISCOVERY

Cloning DNA, expression of clonal DNA, manipulation of DNA sequence information new biological targets for drug developments, novel biotechnology derived pharmaceutical products. Antibody, antisense oligonucleotide therapy and gene therapy.

7. Advances of the active constituents of some drugs used in the following indigenous system of medicines

1. Diabetic Therapy- Gymnes sylvestre, salacia reticulate, pterocarpus marsupiam, swertia, chirata, trigonella, foenum-gracum
2. Liver Disfunction- phyllanthus niruri
3. Antitumor- curcuma longa linn, taxol, teniposide, etoposide.

Reference Books

1. Natural product chemistry by Nakanishi Goggolo
2. Modern methods of plant analysis – Peech and M. V. Tracey
3. Phytochemistry Vol I & II by Miller, Jan, Nostrant, Rein Hid
4. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles
5. Natural Product Chemistry “A laboratory guide” by Rapheal Ikan.
6. The alkaloid chemistry and physiology by THF Manske
7. Introduction to molecular Phytochemistry – CH Wells, Chapmannstall
8. Organic chemistry of natural products Vol I & II by Gurudeep Chatwal
9. Organic chemistry of natural products Vol I & II by O. P. Agarawal
10. Organic chemistry Vol I & II by I. L. Finar
11. Elements of Biotechnology by P. K. Gupta
12. Pharmaceutical Biotechnology by S. P. Vyas and V. K. Dixit
13. Biotechnology by Purohit and Mathoor
14. Phytochemical methods by Harborne

Subject code : MPC-206

Subject : LABORATORY COURSE-2

Practical 8 hrs. /week (Minimum 20 practical should be conducted)

1. Mixture analysis of 2/3 organic compounds (At least 6)
2. Synthesis of drugs using 3/4 steps, and/ OR Synthon approach and their structure confirmation molecular distillation, fractional crystallization and purification by column chromatography, preparative TLC and structural confirmation by spectroscopic methods. (At least 4)
3. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis co chromatographic techniques for identification of isolated compounds and interpretation of UV&IR data of following (Any 3)
Eugenol from Clove, Curcumin from Turmeric, Sennosides from Senna, Hesperidine from Orange peel, Embelin from embela Ribes, Glycyrrhizin from glycyrrhiza glabra, Plumbigin from Plumbago Rosea, Solarin from potato, Naringen from grape fruit peel, Trimystin and Myristin from Nutmeg, Azylic acid from Castor oil, Pectin from Orange peel, Lycopene from Tomato peel, Epicatechin from Cashew kernel, outer kernel, Piperin from Black pepper
3. To perform the following reaction of synthetic importance (Any 8)
Birch reaction, Clemmenson's reduction, Meerwin-Pondroff's reduction, Grignard reaction, Oppeneaur oxidation, Benzylic acid rearrangement, Beckmann rearrangement, Friedal Craft Acylation and Alkylation, Claisen condensation etc.

REFERENCES

1. Organic synthesis: Fisher and William Son (CBA Publisher)
2. Mann and Saunders, 'Practical Organic chemistry' (Orient Longman)
3. A.I.Vogel, 'Practical Qualitative and Quantitative Organic Chemistry, (Orient Longman)
4. Systematic Identification of Org. Compounds Shriner & Herman 1998, John Wiley & sons
5. Reaction Synthesis in Organic Chemistry Laboratory Tiezel/ Ether 1989, University Science.
