

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

Prospectus No. 20111417

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 (INDUSTRIAL PHARMACY) EXAMINATIONS
SEMESTER-I, WINTER-2010
SEMESTER-II, SUMMER-2011



2010

Price Rs.-/-

Visit us at www.sgbau.ac.in

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."

Sant Gadge Baba Amravati University, Amravati

I N D E X

M.Pharm. (Industrial Pharmacy) Semester-I & II

(Prospectus No.20111417)

Sr. No.	Subject	Page Nos.
1.	Special Note	1
2.	Direction No. 22 of 2010	2-13
Semester-I		
3.	Research Methodology & Biostatistics	14
4.	Biotechnology and Bioinformatics	15
5.	Quality Control of Pharmaceutical Products	16
6.	Drug Regulatory Affairs	16
7.	Product Development and Formulation	17
8.	Laboratory Course -1	18
Semester-II		
8.	Advanced Industrial Pharmacy –I	19
9.	Advanced Industrial Pharmacy –II	19
10.	Pharmaceutical Process Validation and Production Management	20
11.	Selected Topics in Industrial Pharmacy –I	20
12.	Selected Topics in Industrial Pharmacy –II	21
13.	Laboratory Course –II	22

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 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 Troomze
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. (Industrial Pharmacy)
Semester – II**

Subject code : MIP-201

50 Hours (4 hrs. /week)

Subject : ADVANCED INDUSTRIAL PHARMACY - I

SECTION- A

PRINCIPLES OF IMPROVED TABLET PRODUCTION SYSTEM DESIGN

Introduction, benefits of improved tablet production system, material handling, processing step combination or elimination, unit operation improvements, Role of computer process control.

COMPRESSION

Process of compression, The properties of Tablets influenced by compression, Measurement of compressional force, energy expenditure, transmission of force, nature of material. Manufacture and formulation techniques of Chewable Tablets, Medicated Lozenges and Specialised Tablets.

Compression coating-Formulation, Layered Tablets and its formulation, Inlay Tablets.

PELLETIZATION TECHNOLOGY

Introduction, Pelletization process and formulation, equipments for pelletization.

STERILE DOSAGE FORMS

Formulation and processing of large volume parenterals, small volume parenterals and related parenteral products, parenteral devices.

SECTION- B

DRYING AND DRYERS

Introduction, mode of heat transfer, internal mechanism of moisture flow, psychrometry, drying mechanisms, drying methods for pharmaceutical granulation and equipments.

EVAPORATION AND EVAPORATORS

Introduction, types of evaporators, design of evaporators, operation of evaporators.

PILOT PLANT SCALE UP TECHNIQUES

General consideration, purpose and functions, concepts of pilot plant for development and control, planning for pilot plant, size of pilot plant. Organization and personnel, basic consideration in developing the process for production of dosage forms, GMP consideration.

Transfer of Analytical methods to Quality assurance, Product consideration, Pilot plant study design for solid dosage forms, liquid orals and semi-solids.

Reference Books

1. G.S.Bankar, Modern Pharmaceutics, Marcel Dekker.
2. Gennaro, Remingtons Pharmaceutical Sciences, Mack Publishing Company.
3. Lacman, Theory and Practise of Industrial Pharmacy, Lea and Febiger.
4. Liberman, Lachman and Schwartz, Pharmaceutical Dosage form Tablets, Vols. I,II and III, Marcel Dekker.
5. Liberman, Lachman and Avis, Pharmaceutical Dosage Forms Parenteral Medications., Vols I and II, Marcel Dekker.
6. King and Turco, Sterile Dosage Forms, Lea and Febiger.
7. Ghebre Sellasie, Pharmaceutical pelletization Technology, Marcel Dekker.
8. Swarbrick and Boylan, Encyclopedia of Pharmaceutical Technology, Vols. 4 and 5 Marcel Dekker.

Subject code : MIP-202

50 Hours (4 hrs. /week)

**Subject : ADVANCED INDUSTRIAL PHARMACY – II
THEORY**

SECTION- A

Inventory management, Material Management and Maintenance

Management: Costs in inventory, inventory categories - special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock - stock out, lead time - reorder time methods, modern inventory management systems, inventory evaluation. Materials - quality and quantity, value analysis, purchasing - centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposal of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unit-load, palletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.

Human Resource Development: Human resource planning, Interviews & principles required for impressive personality, Recruitment, Selection Orientation and placement, Personal training, Job analysis, Job design & job specification & Motivation. Job enlargement and enrichment, Performance appraisal and Labor welfare.

SECTION- B

Current Good manufacturing practices

Manufacturing facilities for tablets, capsule, liquid orals, semisolids and parenterals as per schedule M. Certification for pharmaceutical industries, Schedule U and U1. Master formula record as per WHO GMP and US FDA. Drug Master files US FDA, environment management system clauses. Technology transfer guidance.

ENGINEERING

Adequate knowledge of mechanical, electrical and electronic parts of pharmaceutical machinery and equipment, preventive maintenance assessing plant and machinery efficiency and life. Material handling, transfer, transport and conveyance of bulk material.

SAFETY MANAGEMENT

Industrial hazards due to fire, accident, mechanical and electrical equipment, chemicals and pharmaceutical safety measures.

References:

- a. Evans, Anderson, Sweeney and Williams Applied production and operations management 3rd edition, West publishing company Ltd. St. Paul.
- b. Peter F. Drucker. Management (task, responsibility and practices) Allied publication. Bangalore
- c. HWTomski A Text of Pharmacy management Kogan Page Ltd. London
- d. Harold Koonz, Cyril a Donnell, Heinz, Wehrich Essentials of Management McGraw Hill Book Company. New Delhi.
- e. Lachman L Liberman Theory and practice of industrial pharmacy by 3rd edition
- f. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
- g. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt Ltd.
- h. Pharmaceutical Production and management by C.V.S. Subrahmanyam, Vallabh Prakashan.

Subject code : MIP-203

50 Hours (4 hrs. /week)

Subject : PHARMACEUTICAL PROCESS VALIDATION AND PRODUCTION MANAGEMENT THEORY

SECTION- A

INTRODUCTION

Definition, regulatory history of process validation, regulatory basis of process validation.

ORGANISATION

Structure, responding departments, scope of validation work, protocol and documentation.

VALIDATION OF STERILE DOSAGE FORMS

Theoretical approaches, validation of steam, dry heat and ethylene oxide, sterilization cycle. Validation of radiation and sterilizing filters.

VALIDATION OF SOLID DOSAGE FORMS

Definition and control of process variables, guidelines for process validation of solid dosage form, validation of raw material and analytical methods.

SECTION-B

PROSPECTIVE PROCESS VALIDATION

Introduction, organisation and documentation, Formulation development and development of manufacturing capability, Scale up studies, qualification trials master product documents, Experimental design and analysis.

PROCESS OF RAW MATERIAL

Cost versus risk analysis, Establishment of specifications, test, procedure for sampling. Establishment of optimum storage conditions.

ANALYTICAL METHODS VALIDATION

Assay validation during development phase, Retrospective and prospective analytical methods validation.

PRODUCTION PLANNING CONTROL AND MANAGEMENT

Space allocation, environmental factors, manufacturing, materials management, forecasting cost control, Industrial relation, Entrepreneurship development, Production planning and control.

Reference Books

1. Loftus and Nash, Pharmaceutical process validation. Marcel Dekker.
2. Balchandra and Nambudri, Production Management, Text and cases, Prentice Hall of India.
3. Lachman, Liberman and Knaig, The Theory and Practise of Industrial pharmacy, Varghese Publisher.

Subject code : MIP-204

50 Hours (4 hrs. /week)

Subject : SELECTED TOPICS IN INDUSTRIAL PHARMACY – I THEORY

SECTION- A

FUNDAMENTALS OF CONTROLLED RELEASE DRUG DELIVERY SYSTEM

Fundamentals, rationale of sustained/controlled release drug delivery, factors influencing the design and performance of sustained / controlled release products, drug targeting, pharmacokinetic/Pharmacodynamic basis of controlled drug delivery system, regulatory assessment.

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.

SECTION- B

DESIGN AND FABRICATION OF CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

Novel chemical approaches for sustained drug delivery system, Prodrug approach, parenteral products, implantable therapeutic system transdermal system, ocular, intravaginal and intrauterine system.

BIOCHEMICAL AND MOLECULAR BIOLOGY APPROACHES TO CONTROLLED DRUG DELIVERY

Microparticulate drug carriers : Liposome, microspheres and cells, selective endocytosis of macromolecular drug carriers, antibodies for drug delivery, released erythrocytes, neosomes.

Reference Books :

1. Lachman, Liberman and Knaig, The Theory and Practice of Industrial Pharmacy, Vargese publishers.
2. Robinson and Lee, controlled drug delivery : Fundamentals and applications. Marcel Dekker.
3. Chein, Novel drug delivery system, Marcel Dekker.

Subject code : MIP-205

50 Hours (4 hrs. /week)

Subject : SELECTED TOPICS IN INDUSTRIAL PHARMACY – II

THEORY

SECTION- A

OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL FORMULATION AND PROCESSING

Concept of optimization, Optimization parameters, Classical optimization, Statistical design, and Optimization methods.

STABILITY TESTING

Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages.

BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES

Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC. Estimating absorption rate of drugs; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Drug dissolution rate & bioavailability. *In vitro* drug dissolution testing models. In-vitro in-vivo correlation. Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

SECTION- B

METHODS OF ENHANCING BIOAVAILABILITY

Solubilization, Prodrugs, and enhancement of dissolution characteristics, cyclodextrin, permeation enhancer, solid dispersion, surfactant, bioavailability enhancers.

PACKAGING MATERIAL SCIENCE:

Packing design and specification, packaging validation trials, materials of construction, component product validation, regulatory requirements, quality control testing and standards, GMP requirements and its deficiencies. In process control during component manufacture, documentation, Sterilisation of packing component, packaging and filling equipment, pharmaceutical packaging including sterile area.

MANUFACTURING TECHNIQUES AND EVALUATION OF COSMETICS

Manufacturing of Cosmetics like creams, powders, compacts, shampoo, lipstick liquids, foam, aerosol cosmetics and their Performance, physicochemical and microbiological evaluation. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives.

References:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
2. Modern Pharmaceutics; By Gillbert and S. Banker.
3. Physical Pharmacy; By Alfred martin
4. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
5. Bentley's Textbook of Pharmaceutics – Rawbins.
6. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
7. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
8. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
9. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics; By Swarbrick.
11. Modern Cosmetics by Thomson.

Subject code : MIP-206

Subject : Laboratory Course – II

Practical 8 hrs. /week

(Minimum 20 practical should be conducted)

Practicals:

- 1) To study the effect of particle size, moisture content and lubricants on flowability and compressibility of powders.
- 2) To study various micromeritic properties of granules.
- 3) Development and formulation of the following dosage forms: Cough syrup, multivitamin syrup, antibiotic dry syrup and suspension, antibiotic dispersible tablet, chewable tablet, antibiotic ointment, external application, lozenges and sterile dosage of antibiotics and antiinflammatory drugs.
- 4) To perform sugar coating and non-enteric and film coating on tablets.
- 5) To prepare and evaluate sustained release drug polymer matrix,
- 6) To prepare and evaluate microcapsules of different drugs by various technique.
- 7) To prepare pellets by suspension and emulsion by particle size and zeta potential measurement
- 8) To study the influence of air-entrapment on Rheology of cream.
- 9) To study in-vitro release of medicaments from ointments.
- 10) To evaluate antibiotic ointment by microbiological assay.
- 11) To evaluate acid neutralising capacity of marketed antacid preparation.
- 12) Preparation and standardization of vaccine and sera.
- 13) Evaluation of potency of antibiotics by different methods.
- 14) Workshop technology to acquaint with working of lathe, grinders, vices, welding and jobs related to them.
- 15) Formulation and stability of multiple emulsion.
- 16) Studies on drug excipients interactions.
- 17) Evaluation of polymers used in formulations.
- 18) Evaluation of dermatological and transdermal formulation.
- 19) Preparation and evaluation of microspheres.
- 20) Formulation and evaluation of gastro retentive systems.

Reference Books

Refer all the books mention for theory subjects.
