

SHAURASHTRA UNIVERSITY



FOUR STARS
(Accredited by NAAC)

Syllabus For

Master of Pharmacy

(M. Pharm)

2006 - 07

(Two year full time course)

PHARMACOGNOSY (HERBAL DRUG TECHNOLOGY)

Department of Pharmaceutical Sciences

Saurashtra University

Rajkot - 360 005

SAURASTRA UNIVERSITY

RAJKOT

M. PHARM – I Examination

M. Pharm. R.1:

A candidate for the degree of master of pharmacy must have taken the degree of B. Pharm. Of this university or any other university recognized by the university & have passed the M. Pharm I & M.Pharm II after keeping terms as laid down, that is two terms for each , & have completed the courses as laid down in the relevant regulation.

Registration as post graduate student is essential, within one month of his admission to the course. In the registration, candidate must specify the subjects & the paper of study for M. Pharm.

M. Pharm. R.2:

A candidate who has failed in more than one head of passing at M. Pharm I, examination (theory & practical are considered as a separate heads) will not be allowed to pursue courses for M. Pharm.-II. However, a candidate who has failed in one head of passing & secures 50% of the total marks assigned to the whole M. Pharm - I examination will be allowed to keep terms for the M.Pharm II, but his results of M.Pharm II will be declared only after he passes in all heads of M.Pharm - I examination.

M. Pharm. R.3:

M. Pharm I & M.Pharm II examination will be held twice a year (in April & in October)

M. Pharm. R.4:

Candidates for M. Pharm I examination shall be examined after they have satisfactorily completed the prescribed courses of study & have kept two terms in an institution recognized for the purpose under the recognized post graduate teachers in prescribed subjects.

M. Pharm R.5:

75 hours of teaching (including seminars) for each theory paper & 150 hours of laboratory works for each practical is essential. Regular records of both theory & practical class work, conducted at the recognized institution, imparting training for this course, shall be maintained for each student & 20% of the total marks for each subject in theory and 20% of total marks for each subject in practical shall be allotted for these records.

Normally there shall not be less than three periodic examination during the year and the aggregate of two entire performance shall form the basis for the calculating the average for computation of sessional marks. The average sessional marks thus calculated will be made available confidentially to all examiners in theory and practical in each subject at the commencement of the relevant examination. The record shall be maintained

for each student & must be submitted to the university before the commencement of M. Pharm –I examination.

M. Pharm R.6:

The syllabus laid down for various paper & practical of M. Pharm I & M.Pharm II examination, is as Appendix -I.

M. Pharm R.7:

To pass an examination, candidate must obtain at least 40% of the marks in theory & practical separately & in addition must obtain at least 50% of the total marks assigned to the M. Pharm I examination.

No class shall be awarded to the successful candidate at the M Pharm- I examination.

M. Pharm. R.8:

A candidate who has secured 50% of the total marks in any paper of the subject (which include theory & practical) at the M Pharm- I examination, may at his option, be exempted from appearing in that paper & he has passed in all the head of the passing in that paper & practical of the subjects.

For the of determining whether a candidate has obtained 50% of the total marks in the aggregate, the marks obtained by him in a papers on the previous occasions entitling him to claim exemption in the paper at a subsequent appearance would be carried forward if the claims exemption in a paper or papers.

M. PHARM – II Examination

M. Pharm R. 9:

Every candidate for the M. Pharm -II examination shall be required to have passed the M.Pharm – I examination of this University & have passed & have completed the courses as laid down in the relevant regulations.

M. Pharm R.10:

A candidate who has failed in more than one head of passing at M. Pharm I examination (Theory & practical are considered as a separate heads) will not be allowed to pursue courses for M. Pharm - II. However, a candidate who has failed in one head of passing will be allowed to keep term for the M. Pharm - II. Results of M. Pharm –II will be declared only after the passes in all heads of M. Pharm – I examination.

M. Pharm R.11:

Candidates for M Pharm II examination shall be examined after they have satisfactorily completed the prescribed courses of study & have kept two terms in an institution recognized for the purpose under the recognized post graduate teachers, in the prescribed subjects.

M. Pharm R.12:

75 hours of teaching (including seminars) for each theory paper & 150 hours of laboratory works for each practical is essential. Regular records of both theory & practical class work, conducted at the recognized institution, imparting training for this course, shall be maintained for each student & 20% of the total marks for each subject in theory and 20% of total marks for each subject in practical shall be allotted for these records. 20% marks shall be allotted for presentation of dissertation with the help of modern audio visual aids.

Normally there shall not be less than three periodic examination during the year and the aggregate of two entire performance shall form the basis for the calculating the average for computation of sessional marks. The average sessional marks thus calculated will be made available confidentially to all examiners in theory and practical in each subject at the commencement of the relevant examination. The record shall be maintained for each student & must be submitted to the university before the commencement of M. Pharm –I examination.

M. Pharm R.13:

The syllabus laid down for various paper & practical of M. Pharm –II examination, is as Annexure - I.

M. Pharm R.14:

Every candidate presenting himself M. Pharm- II for the first time, is required to submit three computerized copies of a dissertation, forwarded by the Head/Principal of recognized institution to the university office, containing the results of his own study of

the investigation, carried out at the recognized institution, under the supervision & guidance of a recognized university post graduate teacher in the subject.

The dissertation is to be submitted after completion of the M. Pharm - II & after presentation on dissertation.

The dissertation examination is to be conducted by the examiners appointed for the purpose by the university, during April or October University examination.

M. Pharm R.15:

One a new application being forwarded & fresh fee paid, a candidate who already passed the M. Pharm Degree Examination, may present himself again for the examination in the subject of specialization, not offered by him. Fresh registration & keeping of fresh term are required.

M. Pharm R.16

To pass an examination, candidate must obtain at least 40% of the marks in theory, practical & dissertation work separately & in addition must obtain at least 50% of the total marks assigned to the M. Pharm II examination.

Success full candidates awarded classes as under after adding marks of M. Pharm – I & M. Pharm – II examination:

Distinction:

70% or more average marks of M. Pharm – I & M. Pharm – II examination.

First Class:

60% or more marks average of M. Pharm – I & M. Pharm – II examination.

Second Class:

50% or more average marks of M. Pharm – I & M. Pharm – II examination

ANNEXURE – I

SAURASTRA UNIVERSITY RAJKOT

M.Pharm Syllabus for Pharmacognosy (Herbal Drug Technology)

M. Pharm - I

	THEORY	PRACTICAL
Pharmacognosy – I (Advance Pharmacognosy) (3+6 hours)	Internal – 20 External – 80	Internal – 20 External – 80
Modern Analytical Techniques in Pharmaceutical Research (3+6 hours)	Internal – 20 External – 80	Internal – 20 External – 80
Advances in Pharmaceutical Sciences & Process Validation (3 hours)	Internal – 20 External – 80	-
Methods in Drug Evaluation (3 hours)	Internal – 20 External – 80	-

Hours per week = 24 + Seminar work

M. Pharm-II

	THEORY	PRACTICAL
Pharmacognosy – II (Advances in Herbal Drug Technology) (3+6 hours)	Internal – 20 External – 80	Internal – 20 External – 80
Patents and Product Registration (3 hours)	Internal – 20 External – 80	-
Standardization and Stabilization Methods (3 hours)	Internal – 20 External – 80	-
Project Work Seminar on Introduction of Thesis (Internal) Thesis (University Exam)	Seminar – 40 Thesis – 160	

15 hours per week + thesis work

M.PHARM.– I

PHARMACOGNOSY –I (ADVANCE PHARMACOGNOSY)

THEORY: 3 hours / week (100 Marks)

PRACTICAL: 6 hours/week (100 Marks)

- 1.1 General Introduction to Pharmacognosy and its importance in herbal drug industry.
- 1.2 The classification and vegetable drug with special reference to chemotaxonomy.
- 1.3 Herbal nutraceuticals as new source of medicine.
- 2.1 WHO Guidelines for cultivation and collection of Herbal Drugs.
- 2.2 Factors affecting cultivation of crop including Plant Growth Regulators.
- 2.3 Influence of Mutation, Polyploidy, Hybridization in chemo demes.
- 2.4 Insecticides & pesticides of herbal origin and their suitable utilization.
- 2.5 Systematic methods of cultivation of Dioscorea, Isapgol, Umbelliferous fruits, Ginger, Turmeric, Aloes, Digitalis, Vinca, Ephedra, Senna, Guar, Peppermint, Colchicum, Lemongrass, Piper spp.
- 3.1 Application of microscopy in evaluation – T.S./L.S./Surface views of Plant drugs.
- 3.2 Use of microtome and preparation of histological slides.
- 3.3 Determination of various diagnostic features of identification of different organs as per different herbal pharmacopoeias. Determination of Numerical values.
- 4.1 Basic metabolic pathways. Use of radiotracers, enzymes, cofactors etc.
- 4.2 Biosynthetic schemes of some important Phyto-constituents.
- 4.3 Detailed studies on phytochemical screening methods including HPTLC fingerprinting.
- 5 Commercial sources, method of isolation and separation, chemical properties, characterization (excluding synthesis) and therapeutic uses of some medicinally important class of Plant Phenolics, Alkaloids, Glycosides, Terpenoides, Steroids and Resinous substances.
- 6 Review of recent literature along with methods used for bio screening of Antiallergic, Anticancer, Antidiabetic, Antihepatotoxic, Anti-inflammatory agents, Immunomodulator, Cardiovascular, Respiratory, Psychotropic and Neurotropic, Analgesic, Antipyretic, Anti-obesity, Anti-atherosclerotic of herbal origin.

Practicals:

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

M.PHARM. – I

MODERN ANALYTICAL TECHNIQUES IN PHARMACEUTICAL RESEARCH

THEORY: 3 hours/week (100 Marks)

PRACTICAL: 6 hours/week (100 Marks)

1. Spectroscopy

- 1.1 Basic theoretical background of NMR spectroscopy, interpretation of PMR spectra of common organic compounds, Basic of FT-NMR, C13 NMR, Application of 2D NMR.
- 1.2 Basic fundamentals of Mass spectroscopy, various ions sources, analysis. Interpretation of mass spectra of simple compounds.
- 1.3 Basics of FT-IR, Advantages of FT-IR. Interpretation of IR spectra of compounds.

2. Chromatography

- 2.1 Basic concept and instrumentation, recent trends in the techniques and pharmaceutical application of HPLC, and its various modes.
- 2.2 Adsorption, partition, reverse-phase, chemically bonded phase, ion-exchange, ionic, ion-pair, affinity, size-exclusion and chiral separation.
- 2.3 HPTLC- Detailed theory, instrumentation and application.
- 2.4 GC – Detailed theory, instrumentation and application.

3. Thermal Methods

- 3.1 Introduction of various thermal methods. TGA, DTA and DSC – theory, instrumentation of thermographs and applications.

4. Miscellaneous Methods

- 4.1 Optical Rotatory Dispersion and Circular Dichroism – General Principle, Instrumentation of thermographs and applications.
- 4.2 Electron Microscopy, Scanning probe microscopy.
- 4.3 Electron Diffraction, X-ray diffraction methods.
- 4.4 Particle size analysis.
- 4.5 Principles and applications of RIA and Enzyme immunoassay.
- 4.6 Quality control and Application of radio pharmaceuticals.

5. Bio-statistics and its application in Pharmaceutical Research.

Practicals:

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

M.PHARM. – I

ADVANCES IN PHARMACEUTICAL SCIENCES & PROCESS VALIDATION

THEORY: 3 hours/week (100 Marks)

1. Pharmacokinetic approach to New Drug Discovery:
Basic concepts and Definition, Importance of ADME parameters in disposition, therapeutic and development – their implications on drug discovery.
2. Overview on Computer Aided Drug Design (CADD) including QSAR, QSPR, Combinatorial Chemistry, High Throughput Screening (HTS).
3. Molecular Basis of Drug Action.
4. Drug Latentiation:
Basic concept, Prodrug of functional groups, Bioprecursor prodrug, Chemical delivery system
5. Basic concept of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Process Analytical Technology, Quality audits etc.
6. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical interference in estimation of hypothesis testing, statistical procedures in assay development.
7. Development of new analytical method and its validation.
8. In-process quality control test for various dosage forms including packaging and labeling operations.
9. Factors affecting the stability of a formulation including solid state stability. Methods involved in stabilization and stability testing.
10. Concept of validation, validation of manufacturing and analytical equipments. Process validation in production of pharmaceuticals.

M.PHARM. – I

METHODS IN DRUG EVALUATION

THEORY: 3 hours/week (100 Marks)

1. Pharmacological approach of modern medicine.
2. New approach in drug discovery.
3. Evaluation of drug for cardiovascular, respiratory, psychotropic and neurotropic, analgesic, anti-inflammatory, antipyretic, immuno-modulator, anti-diabetic and anti obesity, anti-atherosclerotic activities.
4. Guidelines for the use and care of laboratory animals.
5. Techniques in the estimation of enzyme and the endogenous substances in the body fluids in the physiological and pathological condition.
6. Bioassay of various drugs and hormones.
7. Clinical trials and toxicological evaluation of various drugs. Guidelines for Investigational New Drug Application (IND).

M.PHARM – II

PHARMACOGNOSY – II (ADVANCES IN HERBAL DRUG TECHNOLOGY)

THEORY: 3 hours/ week (100 Marks)

PRACTICAL: 6 hours/week (100 Marks)

1. GMP and other regulatory and safety requirements as per amendments made from time to time in the schedules of Drug and Cosmetic Act and Rules for Herbal, Ayurvedic and other Drug of traditional origin.
- 2.1 Preparation and standardization whole powder / extract.
- 2.2 Plant and equipment, processing and project profile of herbal extracts.
- 2.3 Recent Methods (UV, HPLC, HPTLC, etc.) of assay of Andrographolide, Amarogenin, Asiaticosides, Atropine, Solasodine, Bacoposide, Caffeine, Cubebol, Citral, Curcumin, Digitoxin, Diosgenin, Embelin, Emetine, Ergometrine, Eugenol, Gingerol, Gycerrhetinic acid, Hesperidine, Kutkosides, Piperine, Plumbagin, Quinine, Quinidine, Recinolic acid, Sennosides, Taxol, Vinca alkaloids, Withaferin, etc. in extract / formulations.
- 3.1 General principles of formulation including physico-chemical properties like pH, solubility, distribution coefficient etc.
- 3.2 Methods of preparation of different conventional solid and liquid dosage forms incorporating herbal extracts.
- 3.3 Methods of preparations of these products used as cosmetics.
- 4.1 Basic principles of treatment in Ayurvedic System of medicine.
- 4.2 Salient features of the techniques of preparation and standardization of some of the important class of formulation as per Ayurvedic Pharmacopoeia and texts.
- 5.1 Plant tissue culture: Introduction and description of techniques like cell-culture, micro-propagation, hairy root culture, biotransformation, bioconversion and other recent advances of the technique with special reference to medicinal plants.
- 5.2 Plant Genetics: Cytogenetic, Genetic codes, Reproduction, Variation, Heritability
- 5.3 Gene transfer in plants.
- 5.4 Application of transgenic plants.

Practicals:

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

M.PHARM – II

PATENTS AND PRODUCT REGISTRATION

THEORY: 3 hours/ week (100 Marks)

Patents:

1. Intellectual property, importance and types of intellectual property.
2. Paris conventional, World Trade Organization and GATT.
3. The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005.
4. The US Patent and Trade organization, The European Patents Office.
5. Patents, Importance and parts of patent, type of patent in United States, Europe and India, provisional application.
6. PCT route to filling of patents.
7. Concepts of patentability – issue of novelty, inventive steps and industrial application with special reference of differences in Indian, United States and European patents.
8. Priority dates, filling dates, unity of invention and importance.
9. Examination of patent application, differences in Indian, United states and European patents, office actions.
10. Continuation, continuation – in – part and divisional applications.
11. Interference proceedings
12. Oppositions
13. Allowance and tissue of patent, patent terms and extensions and renewal fee requirement in the United States, Europe and India.
14. Patent infringement – literal infringement and doctrine of equivalents
15. Patent search engines, keywords and databases.

NDA/ANDA (Product Registration)

1. US FDA, food and drug administration act, history, Hatch Waxman amendments.
2. New Drug Application (NDA) and Abbreviated New Drug Application (ANDA).
3. Chemistry, Pharmacy, Manufacturing: Pharmaceutical Development, Packaging materials, Active ingredients, Excipients, Controlled test on the finished products, stability data, Analytical method validation, Bio-pharmaceutics.
4. Preclinical Pharmacology and toxicology: single dose, repeat dose, reproductive, toxicities, mutagenicity, oncogenicity / carcinogenicity, animal pharmacokinetics and toxicokinetics
5. Clinical: Clinical pharmacology and Pharmacodynamics, Pharmacokinetics in man, Ethnic, Genetic and environmental factors. Good clinical p[ractice, clinical trials general aspects of design and interpretation, statistical analysis of clinical data.
6. Biological products and biotechnology: clinical aspect of recombinant DNA products, Preclinical pharmacological and toxicological requirement for biological and biotechnological products.
7. Preclinical studies: Clinical trials, phases and interpretation.
8. New Drug Application, content and format, guideline for filling NDA.
9. New Drug Approval, exclusivities, Orangebook.
10. ANDA, Contents and format, guidelines for filling ANDAs.
11. Bio-waver requirements in ANDA, Para I, II, III and IV approvals.
12. 505(b) 2 application.
13. DMFs and their importance.

M.PHARM – II

STANDARDIZATION AND STABILIZATION METHODS

THEORY: 3 hours/ week (100 Marks)

- 1.1 Concept of evaluation of herbal medicine as per WHO guidelines.
- 1.2 Review of general methods of evaluation of drugs and foods.
- 1.3 Morphological, Microscopical, Cytomorphological examinations of raw materials and finished products.
- 1.4 Determination of physical and chemical constants. Extractive values. Techniques of separation, identification, estimation and characterization of active principles.
- 1.5 Microbial counts, bioburden and other determination.
- 2 Nutraceuticals – concept of nutritional requirements at different age, sex and in different conditions like normal, diseases, pregnancy etc.. Different types of additives used. Analysis of these nutritional and other ingredients in ethical and non-ethical foods.
- 3 Cosmetics – Information on ingredients used in various products such as creams, powders, lotions, hair products, nail polishes, lipsticks, depilatories, toiletries etc. and their analysis. The sources and description of raw materials of herbal origin used like fixed oils, waxes, gums, hydrophilic colloids, colours, perfumes, protective agents, bleaching agents, preservatives, antioxidants and other ancillary agents.
- 4 Herbal Products – Evaluation of herbal products using physico-chemical studies in whole form. Identification of active principles, excipients, additives and their estimation using different techniques. Analysis of a few selected indigenous herbal formulations.

M.PHARM – II

PROJECT WORK

Marks - 200

Project Work

Seminar on Introduction of Thesis (Internal)

Thesis (University Exam)

Seminar – 40

Thesis – 160