UCPSc-Kakatiya University

Course outcomes (CO's and PO's) for M.Pharmacy

M. Pharmacy (Pharmaceutics)
M. Pharmacy (Pharmaceutical Chemistry)
M. Pharmacy (Pharmacognosy)
M. Pharmacy (Pharmacology)
M. Pharmacy (Industrial Pharmacy)
M. Pharmacy (Pharmaceutical Analysis)

Master of pharmacy (Pharmaceutics and Industrial pharmacy)

Program Outcomes (PO's)

Master of pharmacy (Pharmaceutics and Industrial pharmacy) is a dynamic and interdisciplinary field that aims to integrate fundamental principles of physicochemical properties of drug and excipients and engineering, biochemistry, and biology to understand how to optimize delivery of drugs to the body and translate this integrated understanding into new and improved therapies against human disease. The program is designed to strengthen the basic knowledge in the field of development of researchers and educators in pharmaceutical dosage form science. Who can work in areas of modern pharmaceutical industry, including biotechnology and clinical research organization. The course input is for the development of Professional Identity, technical knowledge in the area of design, evaluation and manufacture of various dosage form, planning abilities, professional Communication, Problem analysis/ cognitive ability, entrepreneurship / Leadership skill, Pharmaceutical Ethics, pharmaceutical regulation.

Program Specific Outcomes (PSO's)

1. Imparting knowledge on various aspects viz. preformulation studies, Active Pharmaceutical Ingredients, design and evaluation of various types of dosageforms and manufacturing of bulk, formulations in pharmaceutical industries.
2. The knowledge of Biopharmaceutics & Pharmacokinetics is for understanding ADME of drugs following various routes of administration and development of skills necessary for understanding Pharmacokinetics, dose calculations, dose adjustments under disease conditions and to and apply biopharmaceutics theories in practical problem solving.
3. To understand physicochemical properties and principles involved in dosage forms/formulations.

Theory and practical components of the subject which help to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

4. To understand various aspects of quality assurance in pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, equipment validation and mainatance quality certifications Industrial Management, Optimization Techniques, Pilot Plant Scale Up Techniques, Stability Testing
5. In depth knowledge in the area of advances in novel drug delivery systems, drug targeting protein and peptide drugs and macro molecular drug delivery. This shall enable students to know the approaches for development of novel drug delivery systems, criteria for selection of drugs, polymers and delivering system and about the formulation and evaluation of Novel drug delivery systems.

6. The information on regulatory affairs serves to gain advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA.

Course Outcomes

Bio Pharmaceutics & Pharmacokinetics

On completion of this course it is expected that students will be able to understand,

1. Understanding of ADME process for the drugs
2. The use of raw data and derive the pharmacokinetic models and parameters the bestdescribe the process of drug absorption, distribution, metabolism and elimination.
3. To critically evaluate Biopharmaceutics studies involving drug product equivalency.
4. To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters

Pharmaceutical formulation technology

On completion of this course it is expected that students will be able to understand,

1. To understand elements of preformulation and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product
2. To impart fundamental knowledge on pharmaceutical product development (solids, liquids,

semisolids, aerosols, parenteral dosageforms and translation from laboratory to market.

Quality Assurance

On completion of this course it is expected that students will be able to understand,

1. Understanding of Plant layout designs to manufacture various types of dosageforms
2. To understand the responsibilities of QA & QC departments
3. Stability testing of drug and drug substances
4. Statistical approaches for quality
5. Applications of Optimization to achieve best quality

Physical Pharmaceutics

On completion of this course it is expected that students will be able to understand,

1. Solubility and its importance, techniques to enhance solubility
2. Interfacial phenomenon and formulation and stability of disperse systems
3. Principles of chemical stability and testing, evaluation of shelf life
4. Dissolution and its importance and equipment
5. Polymers the their properties and application
6. Compression and consolidation of powers.

Pharmaceutical Production Management

On completion of this course it is expected that students will be able to understand,

1. Pilot plant scale up studies, and technology transfer
2. Handle the scheduled activities in a Pharmaceutical firm and documentation
3. Types of business organizations and their maintenances
4. Marketing and Sales pharmaceuticals

Novel drug delivery systems - I

On completion of this course it is expected that students will be able to understand,

1. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms related to oral, parenteral, transdermal, implants, bio adhesives and site specific drug delivery systems.
2. Understand the concept of basis of drug targeting, and various approaches for drug targeting
3. To formulate and evaluate various carrier based drug delivery systems and their application in drug targeting.

Novel drug delivery systems – II

On completion of this course it is expected that students will be able to understand,

1. Role of biological barriers in the absorption of lipids, macro molecules.
2. Concepts of Gene therapy and their applications,
3. Various types of vaccines and vaccine delivery systems.
4. Proteins and peptides as drugs and their delivery methods
5. Monoclonal antibody based drugs and their delivery and targeting

Pharmaceutical equipment

At completion of this course, it is expected that students will be able to understand

1. The concepts of calibration, qualification and validation
2. Construction, working and regular maintance of important equipment
3. The qualification of various equipments and instruments
4. Process validation of different dosage forms
5. Validation of analytical method for estimation of drugs

Drug regulatory affairs

At completion of this course, it is expected that students will be able to understand

1. Drug Regulatory Aspects (India) . Indian drug regulatory authorities, Central and State regulatory bodies (FDA) . Drugs and Cosmmetics Act and Rules with latest Amendments (Selective) Special emphasis – Schedule M and Y
2. concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA
3. Students be aware of technical aspects pertaining to the marketing authoritization application (MAA)
4. It covers the important aspects like cGMP, GLP quality certifications like ISO9000, TQM, Intellectual property rights

Program Specific Outcomes - M. Pharmacy (Pharmaceutical Chemistry)

PSO.1 Detail knowledge about addition, elimination and substitution reaction mechanisms in organic chemistry; named reaction and various heterocyclic ring systems.

PSO.2 Systemic study, SAR, mechanism of action, synthesis and structural elucidation of various classes of agents.

PSO.3 In-depth knowledge about advances in organic chemistry, different techniques and develop synthetic routes of organic synthesis and their applications to process chemistry as well as drug discovery.

PSO.4 Knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

PSO.5 Detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds.

PSO.6 Ability of isolation, purification and characterization of medicinal compounds from natural origin.

PSO.7 Knowledge on the current state of the art techniques involved in computer assisted drug design.

PSO.8 Knowledge with various hyphenated analytical instrumental techniques for identification, characterization, and quantification of drugs.

PSO.9 Deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs.

Course Outcomes

On completion of this course it is expected that students will be able to understand

SEMESTER – I

Advanced Organic Chemistry-I

CO1. To gain in-depth knowledge about SN1, SN2, E1, E2 and rearrangement reactions.

CO2. Structures, ring synthesis, reactions of heterocyclic compounds.

CO3. Structures, synthesis, reactions and applications of five membered heterocyclic rings.

Advanced Medicinal Chemistry-I

CO1. General aspects of drug design and development with respect to Pharmacological activity; approaches to lead discovery and analog design; concepts of screening; prodrugs; soft drugs; isosterism; recombinant DNA technology.

CO2. Correlation of physicochemical parameters affecting drug action and pharmacokinetics; able to differentiate SAR and QSAR; apply cheminformatics, bioinformatics on the designed molecules.

CO3. Study on origin, development, classification, structures, mechanism of action, SAR, uses and toxicity of histamine antagonists, Gastric-proton pump inhibitors, NSAIDs, Analgesics, Immuno agents Anticancer and Anti-viral agents.

Spectroscopic identification of organic compounds

CO1. To learn basic principle & instrumentation and a detailed study on applications of spectroscopic techniques in the determination of structure of various classes organic compounds.

CO2. Study on two dimensional NMR techniques like DEPT, COSY, HMQC, HETCOR, HMBC and TOCSY.

CO3. Problems solving and work out on structure determination.

Screening methods in Pharmacology

CO1. To learn the Principles and techniques involved in pharmacological screening against various activities.

CO2. To know the importance and applications of toxicokinetic Studies and Alternative methodsto animal toxicity testing.

CO3. To infer the data using biostatistics technique like “t” test, ANOVA and chi square tests and other important tests.

SEMESTER - II

Advanced Organic Chemistry-II

CO1. Target selection, disconnection approach, functional group interconnection, reagents, synthons, retrosyntheis.

CO2. Strategies of organic synthesis like one group disconnection, two group disconnection, retromass fragmentation of studies of Disparlure, retronecine, lignofoline.

CO3. Students gain knowledge about Importance of stereochemistry, concept of eutomer, distomer, stereoselctive andstereospecific reactions.

CO4. Imporatnace of green synthesis and its applications.

CO5. Synthesis, structure and its modification of six membered ring.

Advanced Medicinal Chemistry-II

CO1. Biochemical basis of mental disorders, abnormal protein factors, endogenous amines and related substances.

CO2. Knowledge on Screening methods, structure, SAR, mechanism of action, ring modifications ofantipsychotics, anxiolytics, sedatives and hypnotics.

CO3. Mechanism of action, uses, toxicity of anxidepressants and antiepileptics.

CO4. Anatomy and pharmacology of nephron, classification, mechanism of action, uses of diuretics, phosphodiesterases, antihyperlipidemics and quinoline antibiotics

Chemistry of Natural Products

CO1. Biological source, structure, peripheral groups, structural modifications, mechanism of cation and toxicity of alkaloids

CO2. Structure, SAR, synthetic derivatives of natural anticancer agents,

CO3. History, industrial Development of steroid, nomenclature, numbering, SAR of steroids and steroidal hormones.

CO4. To study the History, classification, structure, SAR of cephalosporins.

CO5. Structure elucidation of compounds by UV, IR, NMR(1H,13C) and 2DNMR

Chromatographic Separation Technology

CO1. Theory and instrumentation, column materials, detectors of Gas Chromatography, High Pressure Liquid Chromatography, HPTLC.

CO2. Principle, methodology, advantages, disadvantages and applications of Paper chromatography, thin layer chromatography, super critical fluid chromatography.

CO3. To study about the Column chromatographic modifications like flash, vaccum liquid and medium pressurechromatographies, gel permeation technique

CO4. Theory, principle and applications of electrophoresis.

MASTER OF PHARMACY PROGRAMME – PHARMACEUTICAL ANALYSIS

PROGRAM OUTCOMES (PO'S)

Master of pharmacy (Pharmaceutical analysis) program designed to acquire knowledge on various chromatographic and spectroscopic techniques and differentiate with volumetric analysis. The student will be able to categorize assumptions and disclose the data according to guidelines. To utilize the principles of analytical techniques with clear and critical thinking, while solving problems and making decisions. To learn, choose and apply appropriate hyphenated methods and procedures and related computing tools with thoughtfulness of their applications. To believe and follow ethics and guidelines specified by the regulatory authorities of various countries and Government of India for good laboratory practice. To provide knowledge about the importance of analysis of drugs in biological matrices. The course is designed to gain an overall knowledge in developing newer methods, impurity profiling and validation protocols those are useful in routine and laboratory purpose. Understand and engage in problem solving and ability to develop, conduct, analyze and interpret data of pharmaceutical experiments in various departments as per the needs of pharmaceutical industries.

PROGRAM SPECIFIC OUTCOMES (PSO'S)

1. To deal with various hyphenated instrumental techniques for identification, characterizationand quantification of drugs.
2. To provide studies on drug bioavailability, pharmacodynamics and ensure the efficacy and safety use of various medicine according to WHO guidelines.
3. To understand calibration, validation methodologies and their applications in industry.
4. To determine the assay of drugs by spectroscopical and chromatographical methods and preservatives in food and food products.
5. To understand quality assurance aspects of pharmaceutical industries such as cGMP, documentation, certification, GLP and other regulatory guidelines.
6. To impart knowledge about extraction and separation of drugs from biological samples by different analytical techniques.
7. To deal with detection of impurities in pharmaceutical formulations and development of protocol for stability testing of products.

COURSE OUTCOMES (CO'S)

After completion of course student is able to know about

SEMESTER - I

Advanced Pharmaceutical Analytical Techniques

CO1. To gain knowledge on principle, theory, instrumentation and various techniques of spectroscopy, chromatography, electrophoresis and their applications for analysis of drugs mentioned in IP, BP and USP.

CO2. Able to choose the spectroscopic techniques for analysis of pharmacopoeial compounds.

CO3. Deal with various advanced hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.

CO4. Able to interpret spectra include UV-Vis, IR, Mass and NMR for identification and structure determination of various pharmaceuticals.

Pharmaceutical Analysis – I

CO1. To learn the principle and procedure involved in analysis of various drugs using different titrimetric and electrometric methods.

CO2. To understand different functional groups in molecular structure of organic compounds and their quantitative determination.

CO3. Understand the principle and procedure involved in analysis of drugs using various reagents.

CO4. To gain knowledge in determination of various pharmaceutical preparations and dosage forms using conventional and hyphenated instrumental techniques.

Quality Control of Pharmaceutical Dosage Forms

CO1. To analyze the various pharmaceutical dosage forms include solids, semisolids, liquid oral preparations, parentrals, inhalations, topicals, transdermal, sprays, suppositories, pessaries, surgical dressings and novel drug delivery systems.

CO2. To understand and carryout the quality control for tests for tablets, capsules, parentrals, liquid orals and other dosage forms.

Biological Standardization

CO1. To understand about extraction, separation of drugs from biological samples using different techniques and guidelines for analytical methods.

CO2. Detail study about bioassay of vaccines, hormones, blood and blood related products, antitoxins, histamines, biotechnology products and radiopharmaceuticals.

CO3. Understand the microbiological assay of vitamins, antibiotics, vaccines and toxins.

CO4. To gain knowledge about principle, procedure, instrumentation of RIA and ELISA and their applications for analysis of pharmaceuticals.

SEMESTER - II

Quality Assurance

CO1. To gain knowledge on principle, theory, instrumentation and various techniques of spectroscopy, chromatography, electrophoresis and their applications for analysis of drugs mentioned in IP, BP and USP.

CO2. Able to choose the spectroscopic techniques for analysis of pharmacopoeial compounds.

CO3. Deal with various advanced hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs.

CO4. Able to interpret spectra include UV-Vis, IR, Mass and NMR for identification and structure determination of various pharmaceuticals.

Pharmaceutical Analysis – II

CO1. To learn the principle and procedure involved in analysis of various drugs using different titrimetric and electrometric methods.

CO2. To understand different functional groups in molecular structure of organic compounds and their quantitative determination.

CO3. Understand the principle and procedure involved in analysis of drugs using various reagents.

CO4. To gain knowledge in determination of various pharmaceutical preparations and dosage forms using conventional and hyphenated instrumental techniques.

Analytical method development and validation

CO1. To know and understand the concept of validation, calibration, qualification parameters.

CO2. To learn the principle and procedure in development of analytical method, optimization and validation using various analytical instruments for pharmaceutical dosage forms, bulk drugs, active pharmaceutical ingredients (API) and pharmaceutical aids.

CO3. Development, optimization and validation of various drug extraction techniques from biological samples and bioanalytical methods.

CO4. Preparation of protocols for process, cleaning of equipments and facilities. To know the auditing and trade analysis. Also gain knowledge on control parameters, deviations and revalidation.

Regulatory affairs

CO1. Steps involved in the development of a new drug; guidelines on clinical trials for manufacture of drug products as per Drugs and Cosmetics act; submission of new drug application to NDA. To know about intellectual property rights and patents.

CO2. To learn the concepts of importance, statutory requirement and description of documentation for manufacture of pharmaceutical dosage form.

CO3. To gain knowledge about cGMP, GLP as per WHO; quality certifications like ISO9000, GATT and TQM.

Master of Pharmacy (Pharmacognosy &Phyto chemistry)

Programme Out Come:

Master of Pharmacy (Pharmacognosy &Phyto chemistry) is a dynamic and interdisciplinary field that aims to acquire the knowledge about various systems of medicine (Ayurveda, Siddha, Unani, Homeopathy) and also to known the traditional uses of different medicinal plants used for the treatment if different diseases. The programme is designed to strength the knowledge in the field of Herbal drug industry both in National and International Scenario and to understand the concept of Neutraceuticals and Cultivation, Collection of Medicinal Plants. Students will acquire both theoretical and Practical Concepts in Herbal Products.

Advanced Pharmacognosy -I

On completion of this course it is expected that students will be able to understand:

1. Advances in the field of cultivation and isolation of drugs of natural origin
2. Knowledge of various phytochemicals, neutraceuticals and their health benefits.
3. Pharmacovigilance of drugs of natural origin

Phytochemistry:

1. On completion of this course it is expected that students will be able to understand Knowledge of natural products and their drug discovery
2. Able to isolate, identify and extract the phytoconstituents
3. Phytochemicalfingerprinting of Phytochemicals and structural elucidation of phytoconstituents
4. Knowledge of biosynthetic pathways of phytoconstituents and their properties

Advanced pharmacognosy -II

On completion of this course it is expected that students will be able.

1. To Understand Adulteration, deterioration that occurs in natural drugs and alsodetection methods of the same
2. Able to study herbal remedies and their validation including screening methods of herbal drugs for various diseases and their evaluation techniques

Herbal Drug Technology:

On completion of this course it is expected that students will be able to understand

1. preparation and standardization of herbal medicines
2. To aware about the Current Good manufacturing practices of herbals
3. Regulatory authorities of herbals of national and international standards.

Industrial and Research aspects of Pharmacognosy

Programmes Specific Out Come

PSo-I: To understand the Principles of various systems of medicine Ayurveda, Unani, Siddha, Homeopathy. Various forms of drugs in above systems of medicine and also acquire the knowledge of various tradition plants used for the treatment of variousailments.

Pso-2: Imparting knowledge on different Organizations involved in research and development of natural products and key component. To understand the knowledge of different technologies developed for herbal products including standardized extracts, photochemical by different research institutes and companies (National and Internationals). Like CIMAP, RRL, CDRI, NBRI, CSIR. National centre for development of natural products (NCDNP), NCI, Natural Product Research Institute (NPRI – Seoul), Arizona, Bristol – Mayer's Squibb, CIPLA, NCL (Pune) Chemiloids, Mehta Pharmaceuticals, Amsar etc.

PSo -3: Acquire the knowledge of biologically active newer - Semi synthetic/ Synthetic like Quinine (Ex.Aminoquinolines) , Morphine , Salicin and Salicylic acid , Ephedrine , Atropine , Cocaine , Podophyllotoxin , Vinca alkaloids , Ergot alkaloids, Carotene, Diosgenin, 10-Deacetylbaccatin

PSo-4: To Know the International Scenario Herbal Drug Industry

PSo-5: To Know the National Scenario Herbal Drug Industry.

PSo-6: In-depth Knowledge of WHO guidelines for quality control of herbal drugs, Ayurvedic Pharmacopoeia of India, Patent laws, proposed amendments as applicable to herbal/natural products

M. PHARM REVISED SYLLABUS
(2008-2009)

EFFECTIVE FROM 2008-2009
ACADEMIC YEAR ONWARDS

UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
KAKATIYA UNIVERSITY, WARANGAL-506 009.

KAKATIYA UNIVERSITY
WARANGAL

RULES AND REGULATIONS TO M.PHARM. COURSES OFFERED UNDER SEMESTER SYSTEM

General Schedule

There shall be 16 weeks for each semester and it takes two years to complete the course. III and IV semester contains the project work

Academic Schedule

Each semester will have **4 theory and two practical papers** with **six periods** per week. There also seminars and assignments in I and II semester and comprehensive viva in third semester

Question Paper Pattern

There will be **four questions** in each paper. Each question will have 3 bits

Distribution of marks:
I and II semester (4 theory and 2 practical and seminar and assignment)
Theory

Four question	4x25=100 marks

Practicals:

	100 marks
Seminar	50 marks
Assignments	50 marks
III semester seminar	50 marks

Comprehensive viva voice 50 marks

IV semester seminar 50marks
Disseratation evaluation 200 marks
Disseration viva voice 50 marks

Promotion:

A student has to not only put in 75% of attendance and register for examination for each semester but also appear all paper in each semester for promotion to next semester. A students with 4 papers has block lag can be promoted to M.Pharm second year. There shall be no supplementary examinations.

The minimum pass marks shall be 50% in each paper (Theory & Practicals) separately.

Award of division

Aggregate marks of all the semesters:

I Division with Distinction ----- 75% and above
I Division ……. 60% and above and below 70%
II Division ……. 55% and above and below 60%
III Division (PASS) ……. 50%

A candidate in order to become eligible for I/II division shall be required to pass all the papers of final semester in one attempt, besides passing I/II/III semester papers, either earlier to or along with the final semester.

Whenever the syllabi and scheme of examination are changed, in such cases two examinations will be conducted as per old syllabus and scheme. Thereafter, the candidates who have availed/ not availed and not qualified shall have to take the backlog papers as per the changed syllabi and scheme of examination.

The candidates who could not put up required percentage of attendance and detained, however be eligible to seek readmission in the same semester (with at least 40% of attendance in aggregate). Such students have to pay 50% of the tuition fee prescribed.

Distributions of papers:

I semester …….. All papers compulsory
II semester …….. All papers compulsory
III semester (Seminar
Comprehensive viva voice)
IV Semester project work

Improvement:

a) Improvement during the course of study

"A candidate who has passed in the papers of I/II/ semesters completely can improve his /her performances in one or more papers of I/II/ semesters in the immediately following examination with the provision to retain the better of the two".

Important Guidelines:

1. There shall be four major subjects and two practical during the first two semesters.

2. One seminar and one assignment will be conducted during each semester (I&II). Each will be evaluated for 50 marks by three average of it is taken for awarding marks.

3. One seminar pertaining to the topic of dissertation including concept, literature plan of work will be conducted at the end of IIIrd semester and will be evaluated by minimum of three PG teachers which would include the concerned supervisor. The average marks will be taken into account.

4. Thesis marks will be awarded only by the external examiners.

5. The viva-voce marks are to be awarded by the supervisor and external examiner jointly.

6. Comprehensive viva shall be conducted at the end of third semester and evaluated by the external examiner and all faculty members within each specialization.

7. One assignment related to specialization (related to specific topics and supported by original articles) is given in each of I & II semesters, which shall be evaluated by two examiners. Average marks is taken into account.

8. One seminars each semester during I & II shall be conducted before all the faculty and PG students and will be evaluated by minimum of three PG teachers. Average marks are taken into account.

9. There shall be two practical examinations each of six hours duration on two consecutive days at the end of first and second semesters. There shall be one internal examiner for each practical examination. However, the external examiner shall be common for both the practical examinations.

SPECIALIZATIONS:

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacognosy
4. Pharmacology
5. Industrial Pharmacy
6. Pharmacy Practice
7. Pharmaceutical analysis

M.Pharm. I Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

M.Pharm. II Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

M.Pharm. III Semester

	Marks
Seminar (Pertaining to the topic of research and work plan)	50
Comprehensive viva-voce	50
Total	**100**

M.Pharm. IV Semester

	Marks
Seminar (Experimental Work, Results, Discussion and Conclusion)	50
Dissertation evaluation	200
Dissertation Viva-Voce	50
Total	**300**

M.PHARM. (PHARMACEUTICAL ANALYSIS)

I SEMESTER

Theory		**hours/week**
1.1.T	Advanced Pharmaceutical analytical techniques	3
1.2.T	Pharmaceutical Analysis-I	3
1.3.T	Quality control of Pharmaceutical dosage forms	3
1.4.T	Biological standardization	3

Practicals

1.1.P	Advanced Pharmaceutical analytical techniques	9
1.2.P	Pharmaceutical Analysis-I	9

II SEMESTER

Theory

2.1.T	Quality assurance	3
2.2.T	Pharmaceutical Analysis-II	3
2.3.T	Analytical method development and validation	3
2.4.T	Regulatory Affairs	3

Practicals

2.1. P	Analytical method development and validation	9
2.2.P.	Pharmaceutical Analysis-II	9

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

1.1. T. ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit I

a. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds and applications for pharmaceutical analysis
b. HPTLC: Theory, instrumentation and various applications for pharmaceutical and herbal products.
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative analysis
d. Electrophoresis: Theory, instrumentation and various techniques (e.g. paper, capillary electrophoresis etc.) applications for analysis pharmaceuticals.

Unit II

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: Preparation and operation, detectors, derivitazation and pharmaceutical applications: GC-MS and application mentioned for the substances in IP.
b. HPLC: Principles and instrumentation, columns and detectors used, pharmaceutical applications.
c. LC-MS, MS-MS and its applications for analysis or drug substances as mentioned in IP, BP and USP.

Unit III

a. UV-Visible spectroscopy : Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy.
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications.

Unit IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, interpretation of spectra and applications for identification and structure determination.

Unit V

NMR: Theory, instrumentation, and it applications in analysis of pharmaceuticals

REFERENCES:

1) Instrumental Methods of Chemical Analysis - B.K Sharma
2) Organic spectroscopy - Y.R Sharma
3) A Text book of Pharmaceutical Analysis - Kerrenth A. Connors
4) Vogel's Textbook of Qualitative Chemical Analysis - A.I. Vogel
5) Practical Pharmaceutical Chemistry - A.H. Beckett and J.B. Stenlake
6) Organic Chemistry - I. L. Finar
7) Organic spectroscopy - William Kemp
8) Quantitative Analysis of Drugs - D.C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations - P. D. Sethi
10) Spectrophotometric identification of Organic Compounds - Silverstein
11) HPTLC - P.D. Seth
12) Indian Pharmacopoeia - 2007

Practicals

1.1 P Advanced Pharmaceutical analytical techniques: The experiments should be conducted based on theory

1.2.T. PHARMACEUTICAL ANALYSIS – I

Unit I

An advanced study of the principles and procedures involved in Non – aqueous, Complexometric, Oxidation – reduction and Diazotization methods

Unit II

An advanced study of the principles and procedures involved in the electrometric methods: Conductometry, Potentiometry, Polarography and Amperometry

Unit III

Detailed study of the principles and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy

Unit IV

Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples

i. MBTH(3-methyl – 2- benzothiazolone hydrazone)
ii. F.C. Reagent (Folin – Ciocalteau)
iii. PDAB (Para Dimethyl Amnio Benzaldehyde)
iv. 2,6 – Dichloroquinone Chlorimide
v. 2,3,5 triphenyl tetrazolium salt
vi. 1,2 napthoquinone-4-sulfonate reagent

Unit V

Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of the Alkaloids (Pilocarpine and quinine sulphate) Antibiotics (Cephalosporins, Griseofulvin), Vitamins (Vitamin A and Vitamin E), Glycosides (Sennoside and Diosgenin), Steroids (dexamethasone and estrogens) and Diuretics (Spiranolactone, Frusemide).

REFERENCES

1) Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2) Pharmaceutical Chemistry – Becket and Stanlake
3) Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4) Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5) Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6) Indian Pharmacopoeia – 1996
7) Instrumental Methods of Chemical Analysis – B.K. Sharma
8) A Text Book of Pharmaceutical – Kenneth A. Conners
9) Journals (Indian Drugs, IJPS etc.)

Practicals

1.2 P Pharmaceutical analysis-I: The experiments should be conducted based on theory

1.3.T. QUALITY CONTROL OF PHARMACEUTICAL DOSAGE FORMS

Analysis of Pharmaceutical Dosage form monographs as mentioned in various Pharmacopoeias (I.P., B.P., E.P and U.S.P)

Unit I

Solid dosage forms (Tablets, Capsules, Powders), Semisolid dosage forms (Ointments, Creams)

Unit II

Liquid oral preparations,(suspensions, gels, Emulsions, solutions and elixirs) Eye/Ear and Nasal Drops

Unit III

Parenterals (large volume and small volumes), Inhalations (Aerosols, Nebulizers)

Unit IV

Topical preparations, Transdermal drug delivery systems, Sprays, Suppositories, Pessaries, Surgical Dressings, Novel Drug Delivery Systems

Unit V

Various in process quality control tests carried on the following dosage forms
Tablets, capsules, parentrals, Liquid orals and other dosage forms

RECOMMENDED BOOKS:

1) Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2) Microbiological Assays – Barton J. Wright
3) Pharmaceutical Chemistry – Becket and Stanlake
4) Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
5) Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
6) Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
7) Indian Pharmacopoeia – 1996

1.4 T. BIOLOGICAL STANDARDIZATION

Unit-I. Detailed study of principles & procedures involved in bio assay of.

(a) Heparin, Insulin, Posterior Pituitary
(b) Diphtheria, Typhoid0

Unit-II. Principles and Procedures involved in Biological tests of the following.

(a) Living contaminants in vaccines.
(b) Endotoxins
(c) Histamine like substances
(d) Toxic elements

Unit-III Microbiological assay of
(a) Vitamins e.g.cyanocobalamin
(b) Antibiotics such as Neomycin sulphate,
(c) Vaccine e.g. Diptheria

Unit-IV

a) Biological assay evaluation of oxytocin, rabbies vaccine and tetanus antitoxin

b) Radioimmuno assay: General principles, scope of limitations R.I.A of Insulin and digitalis, ELISA (instrumentation, Principle and application for analysis of pharmaceuticals)

C) Radiopharmaceuticals (indium (^{111}In) pentetate injection, strontium (^{89}Sr) chloride injection, Technitium (^{99m}Tc)macrosalib injection

Unit-V

Detailed study of principles & procedures involved in bio assay of estrogens, Hepatitis vaccine, Biological assay of Gas-gangrene antitoxin, Blood and blood related products(Anti-blood grouping serum, Human albumin, Human plasma protein fraction, Human coagulation factors), Biotechnology products(erythropoietin, Interferons, streptokinase).

Books Material Recommended

1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
2. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
3. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
4. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
5. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
6. British Pharmacopeia, Department of Health U.K.
7. Classification of cosmetic raw materials

2.1. QUALITY ASSURANCE

Unit I

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NBL and OSHA 18000

Unit II

a. Organization and personal, responsibilities, training hygiene
b. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination
c. Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials

Unit III

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities
b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.
c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit V

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.
b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.

2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash

REFERENCE BOOKS:

1. Basic tests for Pharmaceutical substances – WHO (1988)
2. Basic tests for Pharmaceutical substances – WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940 – Vijay Malik
5. Q.A. Manual - D.H. Shah
6. SOP Guide lines - D.H. Shah
7. Quality Assurance Guide - OPP

2.2. PHARMACEUTICAL ANALYSIS - II

Unit I

An advanced study of the principles and procedures and applications of instrumental methods in the development of medicines (GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS)

Unit II

a) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
b) X-ray spectroscopy: x-ray diffraction, principle, instrumentation , method and application for the analysis of pharmaceuticals

C) Optical rotator dispersion technique for the analysis of chiral compounds

Unit III

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit IV

Thermal method of analysis, theory, instrumentation and applications of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA) and DSC.

Unit V

Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation

Methodology involved

a. Moisture content determination in dosage forms
b. Alcohol determination
c. Essential oil determination
d. Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conners

2.2. P. Pharmaceutical Analysis – II. The experiments should be conducted based on theory

2.3. ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Unit-I

Analytical method development: Introduction, quantification of calibration of various analytical instruments for drug analysis and maintenance of Instruments

Unit-II

Analytical methods development, optimization and validation using the instruments such as UV/Vis spectrometer, FT-IR spectrometer for pharmaceutical dosage forms, active pharmaceutical ingredients (API) and pharmaceutical aids.

Unit-III

Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.

Unit-IV

Drug analysis from biological samples, extraction using various extraction techniques and Development, optimization and validation of bioanalytical method.

Unit V

Validations

Concept, Type of Validations, Master plan, Protocol for process, cleaning, equipment and facilities including sterile and non-sterile areas, analytical method validations, vendor validation and audit, sample testing and trade analysis.

Prevalidation activities: Protocol preparations, protocol executions, Deviations and Change Controls, Summary and Certification, Revalidations.

Recommended books:

1. Analytical Method Development and Validation, Michael Swartz, Swartz Swartz, Michael Swartz, CRC press.1997
2. Modern HPLC for practicing scientists, Michael W.Dong (google.com)
3. Practical HPLC method development 2nd edition , Llyod R.synder (google.com)
4. Pharmaceutical process validation, NashRA and Watcher AH, CBS publishers and Distributors, Newdelhi
5. Modern Pharmaceutical analysis, Volume1-4, Satish Ahuja, CBS publishers and Distributors, Newdelhi

2.1. P. Analytical method development and validation: The experiments should be conducted based on theory

2. 4 . REGULATORY AFFAIRS

1. New Drug Application: Steps involved in the development of a new drug. Procedure for submission of new drug application (NDA) and abbreviated NDA. Requirements and guidelines on clinical trials for import and manufacture of drug products as per Drugs and Cosmetics act. Clinical trials, study design, documentation and interpretation.

2. Documentation: Importance of documentation, statutory requirement and procedure for documentation, description of documents generated in manufacture of pharmaceutical dosage form.

3. Current good manufacturing practices (CGMP) as per WHO.

4. Good laboratory practices (GLP)

5. ISO 9000 series, GATT, TQM

6. Intellectual property rights and Patent laws in India