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