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. (Pharmacology)

I – SEMESTER

Theory

1. Advanced Pharmacology – I	3 Hours
2. Advanced Pharmacology – II	3 "
3. Advances in Preclinical Evaluation – I	3 "
4. Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)	3 "

Practicals

1. Advanced Pharmacology	9 Hours
2. Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)	9 "

II – SEMESTER

Theory

1. Clinical Pharmacology & Toxicology	3 Hours
2. Advances in Preclinical Evaluation – II	3 "
3. Clinical Research	3 "
4. Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development	3 "

Practicals

1. Clinical Pharmacology & Toxicology	9 Hours
2. Advances in Preclinical Evaluation	9 "

III – SEMESTER

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

IV – SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

I - SEMESTER

M.PHARM. (PHARMACOLOGY)
M.I.COL.T.1. ADVANCED PHARMACOLOGY – I
(Theory) 3 Hrs per week

I. Drugs acting at synoptic and neuro effecto junctional sites.
- A. Autonomic & somatic nervous systems.
- B. Muscarinic receptor agonists & antagonists.
- C. Anticholinesterases
- D .Agents acting at NMJ and autonomic ganglia
- E. Sympathomimetic drugs. Catecholamine and adrenergic antagonists.

II. Drugs acting on the Central Nervours System.
- A. Neurotransmission and CNS.
- B.Drugs used in the treatment of
  1. Anxiety & Psychosis
  2. Depression & Mania
  3. Epilepsy
  4. Migraine
  5. CNS degenerative disorders
  6. Parkinson's Disease
  7. Pain

III. Drugs affecting renal and cardiovascular function
- A.Diuretics
- B.Renin & Angiotensin
- C.Drugs used in the treatment of
  1. Myocardial Ischemia
  2. Hypertension
  3. CHF
  4. Hyperlipidemia

IV .Drugs acting on the blood & blood forming organs
- A. Growth factors
- B. Anticoagulants, thrombolytics & antiplatelet drugs.

M.I.COL.T.2. ADVANCED PHARMACOLOGY – II
(Theory) 3 Hrs per week

I Autacoids; Drug therapy of Inflammation
- A. Histamine, Bradykinin & their antagonists
- B .Eicasonoids & PAF
- C. Anti-inflammatory, analgesic & antipyretic agents

D. Antiasthmatic agents.

II .Drugs affecting gastro intestinal function.

A. Agents for control of acidity and antiulcer drugs

B. Emetics & anti emetics

III. Chemotherapy of

A. Malaria

B. Microbial infections.

(i) Fluroquinolones

(ii) Cephalosporins and other newer agents

(iii) Antifungal and antiviral drugs including Anti HIV drugs.

C. Neoplastic diseases

IV. Oral hypoglycemic agents , Thyroid and anti-thyroid agents.

V. Estrogens, Progestins and Androgens.

M.I.COL.T.3.Advances in Preclinical Evaluation -I

(Theory) 3 Hrs per week

1. Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA proforma for performing experiments on animals.

2. Organization of preclinical screening programme (Blind screening)

3. Drug discovery process: Principles, techniques and strategies used in drug discovery .High throughput screening, human genomics.

4. Preclinical and clinical models employed in the screening of new drugs belonging to following categories.

I. Drugs acting on Autonomic nervous system: Sympathomimetics, Parasympathomimetics, Anticholinesterages, anticholinergics, adrenolytics. Muscle relaxants (peripheral)

II. Cardiovascular Pharmacology: Cardiac glycosides, antiarrhythmics, antihypertensives,antiatherosclerotics .

iii. Screening of free radical scavenging activity

IV .Immunopharmacology: Specific (Cell and humoral mediated) and non-specific methods.

v. Drugs for metabolic disorders: Anti-diabetic agents, Hepatoprotective agents, Anti-hyperlipidemic agents

5. Principles of Toxicological evaluations, ED 50, LD50 and TD values,acute,sub-acute and chronic toxicity studies.

6. Introduction to biostatistics, parametric and non parametric tests.

M.I.COL.T.4. (Theory) –Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)

(Theory) 3 Hrs per week

1. DRUG ABSORPTION

Factors affecting drug absorption.
Gastro intestinal, percutaneous and rectal absorpton
Absorption kinetics, Wagner Nelson & Loo Riegelman methods
BCS classification – significance

2. DRUG DISTRIBUTION

a. Plasma Protein binding – factors affecting plasma protein binding.
b. Kinetics of protein binding, use of different plots (Scatchard plots etc.,) in characterizing binding kinetics
c. Tissue binding.
d. Transfer of drugs through biological barriers, their therapeutic implication in drug action with emphasis on drug transporters.

3. EXECRETION OF DRUGS

a. Routes of excretion of drugs. Extensive study of contribution of each route with specific examples
b. The role of kidney and factors influencing excretion

4. BIOAVAILABILITY AND BIOEQUIVALENCE OF DRUG PRODUCTS

Factors affecting bioavailability & importance of bioequivalence studies.
Conduct of BE studies – Different approaches
US FDA, EMEA & DCGI guidance on BE studies in fasted, fed conditions
BE study waivers

5. METABOLISM OF DRUGS

a. Phase-I and Phase-II metabolic reactions, microsomal and non-microsomal biotransformation reactions.
b. Drug metabolism in liver, kidney, intestine and other extra-hepatic sites.
c. Drug metabolism in placenta, fetus, new born and aged.

6. FACTORS INFLUENCING DRUG METABOLISM

a. Stereochemical, physicochemical and biological factors.
b. Physiological and environmental factors, species, strain, sex, and age differences.
c. Pathological states.
d. Genetic factors – Introduction to the role of genetics in drug metabolism, Polymorphism in drug oxidation and other metabolic reactions.

7. CLINICAL PHARMACOKINETICS

i. Revision of basic concepts
ii.Dose – response in man
iii.Influence of renal and hepatic disease on pharmacokinetics
iv.Therapeutic drug monitoring
v.Population pharmacokinetics

8. PHARMACODYNAMICS & PK/PD modeling

a. Drug receptor interaction dynamics – Application of stoichmetry principles
b. Understanding of pharmacokinetics - pharmacodynamic relationships
c. Different pharmacodynamic models: Linear, Emax, Biophase distribution & Indirect response models.

PRACTICALS

M.I.COL.P.1 Advanced Pharmacology Practicals based on M.1.COL.T.1 & T.2

M.I.COL.P.2 Pharmacokinetics, Pharmacodynamics & Drug Metabolism practicals based on (PPDM) theory M.I.COL.T.4

II - SEMISTER

Paper –1: Clinical Pharmacology & Toxicology

(Theory) 3 Hrs per week

PART 1. Clinical Pharmacology (70% weightage)

1. Adverse Drug Reactions, Drug Interactions and ADR monitoring. Mechanisms of ADR.

2. Pathophysiology and drug therapy of the following disorders.

Schizophrenia, anxiety, depression, epilepsy, Parkinson's, Alzheimer's diseases, migraine hypertension,
angina pectoris, arrhythmias, atherosclerosis, myocardial infaraction, TB, leprosy, leukemia, solid tumors,
lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditis, fungal and HIV infection,
rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

3. Drug therapy in special populations
   A. Geriatrics
   B. Pediatrics - neonate, infants & adolescents
   C. Pregnancy & Lactation

V. Pharmacogenomics: Interracial and individual variability in drug metabolism and drug action.

PART 2. Principles of Toxicology (30% weightage)

a. Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinectics, mutagenesis and carcinogenesis.
b. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC , WHO etc.,
c. Behavioural, Inhalation, cellular and sub-cellular toxicity
hypersensitivity and immune response, range finding tests.
d. Acute, sub-acute and chronic toxicity studies according to guidelines.
e. Application of toxicology in clinical medicine.

Paper –2: Advances in Preclinical Evaluation - II

(Theory) 3 Hrs per week

1. Bioassays: Basic principles of bioassays,official bioassays,experimental models and statistical designs employed in biological standardization : Acetylcholine, Adrenaline, Digitalis, Heparin, Insulin, d-tubocurarine, Histamine,HCG, Corticotrophine, Vasopressin, oxytocin Biological standardization of vaccines and sera: Pertussis vaccine ,rabies vaccine and Plague vaccine

2. Preclinical evaluation of following categories of drugs.
   i.CNS Pharmacology: Sedatives, hypnotics, anxiolytics, antidepressants, Muscle relaxants (Central). CNS stimulations anticonvulsants, antipsychotics, Noortropics, antiparkinsonian agents,
   ii.Analgesics, antipyretics, anti-inflammatory agents and local anesthetics.
   ii. Gastrointestinal drugs: Antiulcer agents, laxatives
   iii.Respiratory pharmacology: bronchodilators, antitussives,
   iv. Diuretics.
   v. Histamine antagonists
   vi.Reproductive pharmacology: antifertility agents
   vii.Anticancer agents

3. Cell culture technology :
   Animal cell culture – General requirements for establishing the animal cell culture, media, conditions and methods for cell cultures. Applications in Pharmacy.

4. Alternatives to animal screening procedures , Cell-line, patch clamp technique, In-vitro models, molecular biology techniques.

5. Concept of transgenic animals, knockout animals, nude animals, receptor binding assays, principles of immunoassay, patch clamp techniques.

Paper – 3 : Clinical Research
M.Pharm (Pharmacology / Pharmacy Practice)

(Theory) 3 Hrs per week

1. Introduction to Clinical Research

Definitions and terminology used in clinical trials

- Historical development in clinical research practice
- Drug development process

2. Research Design Methods

Planning and execution of clinical trials, Various Phases of clinical trials

Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)

Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study)

Health outcome measures (Clinical& Physiological, Humanistic and Economic)

2. Bioavailability and Bioequivalence studies

4. Ethics and Guidelines in Biomedical Research

- Ethical Issues in Biomedical Research – Principles of ethics in biomedical research,
- Ethical committee [institutional review board], its constitution and functions,
- Good clinical practice [ICH GCP guidelines, CDSCO regulations, MPA, European, Japan, Health Canada and MHRA guidelines, schedule Y and USFDA in the conduct of clinical trials]

5 Clinical research

- Establishing and functioning of Contract Research Organisation (CRO)
- Roles and responsibilities of clinical trial personnel
- Trial initiation, volunteer recruitment, trial supplies and site management,
- Designing of clinical trial documents
- Monitoring and auditing of clinical trials
- Trial report generation
- Site closure

6. Data Management

Medical Writing and Ethics of publication

Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Reference books (Latest editions)

1. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

2. Designing Clinical Research. Edtd by Stephen B Hulley, Steven R Cummings

ASSIGNMENTS FOR CLINICAL RESEARCH

1. Design of Protocol for different types of studies
2. Correspondence procedures for constitution of IRB
3. Designing of informed consent process
4. Designing of CRF
5. Clinical data monitoring

Paper –4 : Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development

(Theory) 3 Hrs per week

This course primarily focuses on study of the following from molecular and biochemical perspective.
The purpose is to enable the student to understand the trends in modern drug discovery.

General Principles:

1. A general treatment of the approaches to drug design: including the methods of variation, study of the use of biochemical and physiological information involving new drugs.
2. Drug Receptor theory:
   Concept of receptors, theories of drug receptor interaction, forces involved in drug receptor interaction. Receptor polymorphism and dimerization and its importance in drug design.
   A detailed study of Ion channel modulators, Tyrosine kinase and G-Protein coupled receptor, Cyclic neucleotides

Drug Design:

1. Physiochemical properties in relation to biological action and drug design.

   a. Complex of events between drug administration and drug action.
   b. Solubility & partition coefficient.
   c. Rational drug design.
   d. Selected physiochemical properties like isosterism, steric behaviour, ionization, hydrogen bonding, chelation, oxidation- reduction potential, surface actions.

2. Guidelines for drug and analog drug design:

   a. Basic considerations of drug design, de- novo drug design, lead seeking methods, rational drug design.
   b. Structural factors in drug design.
   c. Prodrug concepts.

3. Principles of Computer aided drug design.

4. The quantitative analysis of structure activity relationships
   a. Fundamentals of QSAR- objectives, expressions of biological activity.
   b. QSAR parameters related to chemical structure, correlative methods and analysis of results.

5. Molecular & Biochemical pharmacology Basis:

a. Application of molecular & biochemical pharmacology to drug design.
b. Introduction to cell structure and function.
c. Cell signaling, organization of signal transduction pathway and biosensors.A detailed study on:
TNF, Apoptosis
Neurosteroids and Cannabinoids
Nitric oxide
ANF, Anti oxidants : Melatonin
Neuropeptide, Substance P
Angiotensin II modulators
Novel peptide based drugs
d. Protein structure prediction and molecular modeling.

PRACTICALS

M.II.COL.P.1 Clinical Pharmacology & Toxicology Practicals based on theory M.1I.COL.T.1.

M.II.COL.P.2 Advances in Preclinical Evaluation Practicals based on theory M.I.COL.T.3.& M.II.COL.T.2.

REFERENCES

ADVANCED PHARMACOLOGY – I & II

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2 Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication,California
3. H.P.Rang , M.M. Dale, J.M Ritter, P K Moore, Pharmacology, Churchill Livingstone, New York.
4. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
5. Richard D Howlard, Mary J. Mycek, Lippincott Williams & wilkins, Lippincott's illustrated reviewed, Pharmacology. New York
6. Herfindal & Gourtey,Text book of therapeutics-drug,disease and management,Williums and Wilkins publications.
7. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
8. Review articles from published journals.

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1. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
2. Turner RA, Screening Methods in Pharmacology, Academic Press, London
3. Lawrence DR and Bacharach AL, Evaluation of Drug Activities:Pharmacometrics, Academy Press, London.
4. N S Parmar and Shiv Prakash,Screening methods in Pharmacology,Narosa publishing house,New Delhi.
5. S K Gupta, Drug Screening Methods,Jaypee brothers,New Delhi.
6. J H Burn, D.J.Finney and I G Goodwin, Biological Standardisation,Blackwell Scientific Publications, Oxford.
7. Ghosh M N, Fundamentals of experimental Pharmacology,Hilton & Company,Kolkata.
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Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)

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2. Applied Biopharmaceutics & Pharmacokinetics, Eds Leon Shargel et al, Prentice Hall International.
3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Hand Book of Basic Pharmacokinetics. Wolfgang A. Ritschel, Gregory L. Kearns.Fifth Edition
6. Biopharmaceutics and Pharmacokinetics -A treatise. DM Brahmankar, Sunil B. Jaiswal: Vallabh Prakashan Pitampura, Delhi
7. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
8. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
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12. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 Publication, Hyderabad
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Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development

1. A guide to chemical basis of drug design by Alfred Rurger (John Willey &Sons)
2. Introduction to the principles of drug design by John Smith and Hawel Williams (Wright PSG).
3. Burgers Medicinal Chemistry – The basis of Medicinal Chemistry by Manfred E.Wolff-1 (John Willey & Sons).
4. Computer assisted drug design by Edward O Olson (American Chemical Society-ACS symposium series 112).
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6. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
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