ACADEMIC REGULATIONS
COURSE STRUCTURE AND SYLLABI

FOR

M. PHARMACY PHARMACOLOGY

(with effect from 2009 – 10)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
Kukatpally, Hyderabad – 500 085 AP.

ACADEMIC REGULATIONS 2009 FOR M.PHARM (Regular) DEGREE COURSE

(Effective for the students admitted into first year from the academic year 2009-2010)

The M.Pharm Degree of Jawaharlal Nehru Technological University Hyderabad shall be conferred on candidates who are admitted to the programme and fulfill all the requirements for the award of the Degree.

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above programme shall be made subject to the eligibility, qualifications and specialization prescribed by the University from time to time.

Admissions shall be made on the basis of merit rank obtained by the qualifying candidate at an Entrance Test conducted by the University or on the basis of any other order of merit approved by the University, subject to reservations prescribed by the university from time to time.

2.0 AWARD OF M. PHARM. DEGREE

2.1 A student shall be declared eligible for the award of the M.Pharm degree, if he pursues a course of study and completes it successfully for not less than two academic years and not more then four academic years.

2.2 A student, who fails to fulfill all the academic requirements for the award of the degree within four academic years from the year of his admission, shall forfeit his seat in M.Pharm course.

2.3 The minimum instruction for each semester 90 clear instruction days.

3.0 COURSE OF STUDY

The following specializations are offered at present for the M.Pharm course of study.

1. Hospital and Clinical Pharmacy
2. Pharmaceutics.
3. Pharmaceutical Chemistry.
4. Pharmacology.
5. Pharmaceutical Analysis and Quality Assurance.
6. Quality Assurance

and any other course as approved by the authorities of the University from time to time.

4.0 ATTENDANCE

The programmes are offered on a unit basis with each subject being considered a unit.

4.1 A candidate shall be deemed to have eligibility to write end semester examinations in a subject if he has put in at least 75% of attendance in that subject.

4.2 Shortage of attendance upto 10% in any subject (i.e. 65% and above and below 75%) may be condoned by the College Academic Committee on genuine and valid reasons on representation by the candidate with supporting evidence.

4.3 A candidate shall get minimum required attendance atleast in three (3) theory subjects to get promoted to the next semester. In order to qualify for the award of the M. Pharm Degree in concerned specialization, the candidate shall complete all the academic requirements of the subjects, as per the course structure.

4.4 Shortage of attendance below 65% shall **in no case be condoned**.

4.5 A stipulated fee shall be payable towards condoned.

5.0 EVALUATION

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practicals, on the basis of Internal Evaluation and End Semester Examination.

5.1 For the theory subjects 60 marks shall be awarded based on the performance in the End Semester Examination, 40 marks shall be awarded based on the Internal Evaluation. The internal evaluation shall be made based on the better of the marks secured in the two Mid Term-Examinations conducted one in the middle of the Semester and the other immediately after the completion of instruction. Each mid term examination shall be conducted for a duration of 120 minutes with 4 questions to be answered out of 6 questions.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations, 40 marks shall be awarded based on the day-to-day performance as Internal Marks.

5.3 There shall be two seminar presentations during I year I semester and II semesters. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the Department in a report form and shall make an oral presentation before the Departmental Committee. The Departmental Committee consists of Head of the Department, supervisor and two other senior faculty members of the department. For each Seminar there will be only internal evaluation for 100 marks. A candidate has to secure a minimum of 50% to be declared successful.

5.4 There shall be a Comprehensive Viva-Voce in II year I Semester. The Comprehensive Viva-Voce will be conducted by a Committee consisting of Head of the Department and two Senior Faculty members of the Department. The Comprehensive Viva-Voce is aimed to assess the students' understanding in various subjects he/she studies during the M.Pharm course of study. The Comprehensive Viva-Voce is valued for 100 marks by the Committee. There are no internal marks for the Comprehensive viva-Voce

5.5 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.6 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 5.4) he has to reappear for the End Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and he has failed in the end examination. In such case candidate must re-register for the subject(s) and secure required minimum attendance. Attendance in the re-registered subject(s) has to be calculated separately to become eligible to write the end examination in the re-registered subject(s). The attendance of re-registered subject(s) shall be calculated separately to decide upon the eligibility for writing the end examination in those subject(s). In the event of taking another chance, the internal marks and end examination marks obtained in the previous attempt are nullified.

5.7 In case the candidate secures less than the required attendance in any subject(s), he shall not be permitted to appear for the End Examination in that subject(s). He shall re-register the subject when next offered.

5.8 Laboratory examination for M.Pharm courses must be conducted with two Examiners, one of them being Laboratory Class Teacher and second examiner shall be other than Laboratory Teacher.

6.0 EVALUATION OF PROJECT / DISSERTATION WORK

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the Project Review Committee.

6.1 A Project Review Committee (PRC) shall be constituted with Principal as chair person Heads of all the Departments which are offering the M.Pharm programs and two other senior faculty members.

6.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects (theory and practical subjects).

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work to the Departmental Committee for its approval. Only after obtaining the approval of Departmental Committee the student can initiate the Project work.

6.4 If a candidate wishes to change his supervisor or topic of the project he can do so with approval of Departmental Committee. However, the Departmental Committee shall examine whether the change of topic/supervisor leads to a major change of his initial plans of project proposal. If so, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit status report (in a bound-form) in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated in the beginning of the second year and the duration of the project is for two semesters. A candidate is permitted to submit Project Thesis only after successful completion of theory and practical courses with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. For the approval of PRC the candidate shall submit the daft copy of thesis to the Principal (through Head of the Department) and shall make an oral presentation before the PRC.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College / School / Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the University. For this, Principal of the College shall submit a panel of 5 examiners, who are eminent in that field with the help of the concerned guide and head of the department.

6.9 If the report of the examiner is not favorable, the candidate shall revise and resubmit the Thesis, in the time frame as described by PRC. If the report of the examiner is unfavorable again, the thesis shall be summarily rejected.

6.10 If the report of the examiner is favorable, viva-voce examination shall be conducted by a board consisting of the supervisor, Head of the Department and the examiner who adjudicated the Thesis. The Board shall jointly report candidates work as:

A. Excellent
B. Good
C. Satisfactory
D. Unsatisfactory

Head of the Department shall coordinate and make arrangements for the conduct of viva-voce examination.

If the report of the viva-voce is unsatisfactory, the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination, he will not be eligible for the award of the degree.

7.0 AWARD OF DEGREE AND CLASS

A candidate shall be eligible for the respective degree if he satisfies the minimum academic requirements in every subject and secures 'satisfactory' report on his thesis/dissertation and viva-voce.

First class with Distinction:	70% or more
First class	below 70% but not less than 60%
Second class	below 60% but not less than 50%

8.0 WITH-HOLDING OF RESULTS:

If the candidate has not paid any dues to the university or if any case of in-discipline is pending against him, the result of the candidate will be withheld and he will not be allowed into the next higher semester. The issue of the degree is liable to be withheld in such cases.

9.0 TRANSITORY REGULATIONS:

Candidate who have discontinued or have been detained for want of attendance or who have failed after having undergone the course are eligible for admission to the same or equivalent subjects as and when subjects are offered, subject to 5.5 and 2.0

10.0 GENERAL:

10.1 The academic regulations should be read as a whole for purpose of any interpretation.

10.2 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

10.3 The University may change or amend the academic regulations and syllabus at any time and the changes and amendments made shall be applicable to all the students with effect from the date notified by the University.

10.4 Wherever the word he, him or his occur, it will also include she, her and hers.

10.5 There shall be no transfers within the constituent colleges of Jawaharlal Nehru Technological University.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from classwork and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief	In case of students of the college, they shall be

	Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	expelled from examination halls and cancellation of their performance in that subject and all other subjects the candideate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from classwork and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and projectwork and shall not be permitted for the remaining examinations of the subjects of that

		semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
   (i) A show cause notice shall be issued to the college.
   (ii) Impose a suitable fine on the college.
   (iii) Shifting the examination center from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. PHARMACY (PHARMACOLOGY)
COURSE STRUCTURE AND SYLLABUS

I YEAR I SEMESTER

Code	Group	Subject	L	P	Credit
		Modern Pharmaceutical Analytical Techniques	3	0	3
		Advanced biostatistics and research methodology	3	0	3
		Advanced Pharmacology – I	3	0	3
		Pharmacokinetics and Drug Metabolism	3	0	3
		Clinical Pharmacology and Pharmacotherapeutics	3	0	3
	Lab	Modern Pharmaceutical Analytical Techniques Lab	0	3	2
	Lab	Advanced Pharmacology - I Lab	0	3	2
		Seminar	-	-	2
		Total Credits			21

I YEAR II SEMESTER

Code	Group	Subject	L	P	Credit
		Intellectual Property Rights & Regulatory Affairs	3	0	3
		Screening methods and clinical research	3	0	3
		Advanced Pharmacology – II	3	0	3
		Advanced Screening Methods and Toxicology	3	0	3
		Advances in Pharmaceutical Sciences	3	0	3
	Lab	Advanced Pharmacology – II	0	3	2
	Lab	Screening Methods in Pharmacology	0	3	2
		Seminar	-	-	2
		Total Credits			21

II YEAR - I Semester

Code	Group	Subject	L	P	Credi
		Comprehensive Viva	-	-	2
		Project Seminar	0	3	2
		Project work	-	-	18
		Total Credits			22

II YEAR - II Semester

Code	Group	Subject	L	P	Credi
		Project work and Seminar	-	-	22
		Total Credits			22

I Year – I Sem M.Pharm (Pharmacology)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit-I

A detailed study of separations and determination involved in the following chromatographic techniques.

a. Column chromatography : Theory, preparation, procedures, methods of detection.
b. This layer chromatography : Theory, preparation, procedures, detection of compounds
c. Paper Chromatography : Theory, different techniques employed, filter papers used, quantitative and quantitative detections.
d. Counter current extraction, soild phase extraction techniques.

Unit-II

a. Gas chromatography: fundamentals, Instrumentation, columns preparation and operations, detection, derivitasation, LC-MS, GC-MS.
b. HPLC : Principles and Instrumentations.

Unit-III

a. UV-Visible Spectroscopy : Principle, Beer Lambert's law, study and working principle of instrumentation, applications in pharmaceutical analysis and derivatives spectroscopy.
b. IR Spectroscopy: Theory, different types of molecular vibrations, sampling techniques, instrumentation and applications in pharmaceutical analysis, FTIR
c. Flurorimetry: Theory, fluorescence and chemical structure, factors affecting the fluorescence, study of working principles of the instrument and applications in pharmaceutical analysis.

Unit-IV

a. NMR: theory, Chemical-shift, spin-spin coupling, shielding, working principle of instrumentations and applications in pharmaceutical analysis, HNMR, and cosy ^{13}CNMR.
b. Mass: principle, different methods of production of ions metastable ions, working principle of mass spectrometer and applications in pharmaceutical analysis.

Unit-V

a. Differential thermal analysis, partial thermal analysis.
b. Radiometric techniques, Radio immunoassay, Elisha test.
c. X-ray diffraction, polarimetry.

Recommended Books:

1. Munson J.W. "Pharmaceutical Analysis"; Mercel Dekker.
2. Willard Dean Merrit "Instrumental Methods of Analysis"
3. David underwood, Text Book of Quantitative analysis.
4. Skogadwest, Instrumental methods of analysis.

I Year – I Sem M.Pharm (Pharmacology)

ADVANCED BIOSTATISTICS AND RESEARCH METHODS

Unit-I :
Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal

Variables—Definition of Variable, Types of variables—Dependent and Independent variables, Confounded variables, Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

Unit-II :
Validity, Types of validity—Internal validity, Construct validity, External validity, Threats to validity.

Control: Subject as own control (Within Subject control), Statistical control.

Unit-III:
Non-experimental Research:
Part 1—Observational, Archival and Case-Study Research: The Hermeneutic Approach.
Observational Research: Naturalistic Observation, Participant-Observer Research.
Archival Research: Archival Data Collection and Compilation.
Case Studies: Characteristic of Case Studies.

Non-experimental Research: Survey Research—Designing of Questionnaire, Methods of Administration, Response Rates. Types of Samples—Haphazard Samples, Purposive Samples, Convenience Samples and Probability Samples.

Unit-IV :
True Experiments: Single-Factor Designs, Factors, Levels, Conditions, and Treatments. Within-Subject Designs.

True Experiments Part-2—Factorial Designs—Main Effects, Interactions, A Mixed Factorial Design.

Unit V :
Single-Subject Experiments: Advantages and Disadvantages.
Quasi Experiments: The differences between Quasi and True Experiments.
Design without Control Groups—Interrupted Time Series Designs and Repeated Treatment Designs.

Text Books
1. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)
2. Statistics for business and economics 3rd edition by-Hooda-R.P- MC. Millan Business books
3. Biostatistics & Computer applications by GN Rao and NK Tiwari

Reference Books
1. Remingtons pharmaceutical Sciences
2.. Theory & Practice of Industrial Pharmacy by Lachman

I Year – I Sem M.Pharm (Pharmacology)

ADVANCED PHARMACOLOGY – I

Unit-I

Drugs acting at Synaptic and neuro effector junctional sites.

A. Autonomic & Somatic nervous systems.
B. Muscarinic receptor agonists & antagonists.
C. Anticholinesterases.
D. Agents acting at Neuro Muscular Junction and autonomic ganglia.
E. Sympathomimetic drugs, Catecholamines and Adrenergic antagonists.

Unit-II

Drugs acting on the Central Nervous 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
c. Drug addiction,dependence and abuse.

Unit-III

Drugs affecting renal and cardiovascular function.

d. Diuretics
e. Renin & Angiotensin
f. Drugs used in the treatment of
   1. Myocardial Ischemia
   2. Hypertension
   3. CHF
   4. Hyperlipidemia

Unit-IV

Drugs acting on the blood & blood forming organs.

g. Growth factors
h. Anticoagulants, Thrombolytics & antiplatelet drugs.

Unit-V

Dermatological pharmacology,Vitamins & Chelating agents

I Year – I Sem M.Pharm (Pharmacology)

Pharmacokinetics and Drug metabolism

Unit - I

Drug Absorption: Gastrointestinal, percutanceous and rectal kinetics and factors affecting drug absorption.

Unit - II

Drug Distribution: Plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action.

Unit - III

Elimination of drugs: Concept of renal clearance and excretion of drugs – biological half – life.

Unit - IV

Bioavalability of drug products: Bioavilability ests. Reaction of the body to foreign substances: Biotransoformation of drugs, phase I and phase II metabolic reactions.

Unit - V

Drug interaction: Pharmacokinetic, Pharmacodynamic drug interactions, Food drug and drink interactions food –herb drug interaction.

I Year – I Sem M.Pharm (Pharmacology)

CLINICAL PHARMACOLOGY & PHARMACOTHERAPEUTICS

Unit-I

Principles of Pharacokinetics

A. Revision of basic concepts.
B. Clinical Pharmacokinetics.
   i) Dose – response in man
   ii) Influence of renal and hepatic disease on Pharmacokinetics
   iii) Therapeutics drug monitoring
   iv) Population Pharmacokinetics.

Unit-II

Adverse Drug Reactions, Drug Interactions and ADR monitoring.

Unit-III

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.

Unit-IV

Drug therapy in

A. Geriatrics
B. Pediatrics
C. Pregnancy & Lactation.

Unit-V

Pharmacogenetics : Inter-racial and individual variability in drugs metabolism.

I Year – I Sem M.Pharm (Pharmacology)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations
2. Simultaneous determination of combination formulations (Minimum of 04 experiments)
3. Effect of pH and solvent on UV spectrum of certain drugs
4. Experiments of Chromatography
    a. Thin layer chromatography
    b. Paper chromatography: Ascending, Descending, circular and two-dimensional techniques
5. Experiments based on HPLC and GC
6. IR, NMR and mass spectra: Interpretation for the structural elucidation of organic compounds
7. Any other relevant experiments

I Year – I Sem M.Pharm (Pharmacology)

ADVANCED PHARMACOLOGY - I LAB

Practical shall be based on theory.

I Year – II Sem M.Pharm (Pharmacology)

INTELLECTUAL PROPERTY RIGHTS & REGULATORYAFFAIRS

Unit-I

Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing and application. Patents, Copyrights, Trademarks, Salient features, international and regional agreements.

Unit-II

GATT & WTO: GATT – Historical perspective, objectives, fundamental principles, impact on developing countries. WTO – objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization, India – task and challenges, trade related aspects (TRIPS).

Unit-III

Regulatory Affairs : Indian context – requirements and guidelines of GMP, understanding of Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule N ,U & Y.

Unit-IV

Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

Unit-V

Documentation: Types related to pharmaceutical industry, protocols, harmonizing formulations, development for global filings, ANDA, NDA, CTD, dealing with post – approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended Books

1. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
2. Protection of Industrial Property rights, P. Das & Gokul Das
3. Law and Drugs, Law Publications. S.N. Katju
4. Original Laws Published By Govt. of India
5. Laws of drugs in India, Hussain
6. New Drug Approval Process, R.A.Guarino,Vol 100, Marcel Decker, NY
7. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.o

I Year – II Sem M.Pharm (Pharmacology)

SCREENING METHODS AND CLINICAL RESEARCH

Unit I

Care Handling and breeding techniques of laboratory animals, Regualtions for laboratory animals, CPCSEA guidelines, alternatives to animal studies. Good laboratory Practices .

Unit II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine , Oxytocin , Tetanus Antitoxin and Diphtheria Vaccine . Test for pyrogens.

Unit III

Toxicity tests:OECD guidelines. Determination of LD50, Acute, subacute and chronic toxicity studies.
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Unit IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological,anti-inflammatory, analgesic and anti diabetic.

Unit V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Principles of Biological standardization: Statistical treatment of model problems in the biological evaluation of drugs. Methods used in the bio-assay of vitamins, hormones, vaccines, cardiac drugs and other Pharmacopoeial preparations. Test for pyrogens.

Bioassay methods for autacoids –development of new bio-assay methods.

Toxicity tests: Determination of LD50, Acute, subacute and chronic toxicity studies – tests for undue toxicity of drugs.

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of antithypertensive, cardiac, psychopharmacological, autonomic, diuretic, anti-inflammatory, antihistamine, muscle relaxant, analgesic, anti – ulcer anti diabetic, hepatoprotective, antistress and nootropic activities. Cell culture techniques for pharmacological screening.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books.

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized Tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trails on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

I Year – II Sem M.Pharm (Pharmacology)

ADVANCED PHARMACOLOGY – II

Unit I

Autacoids : Drugs therapy of Inflammation.

A. Histamine, Bradykinin & their antagonists
B. Eicosanoids & PAF (Platelet Activating Factors)
C. Anti-inflammatory, analgesic & antipyretic agents.
D. Antiasthamatic agents.

Unit II

Drugs affecting gastro intestinal function.
A.Agents for control of acidity and antiulcer drugs.
B.Emetics & anti emetics.

Unit III

Chemotherapy of
A.Malaria
B.Microbial infections
(i) Fluoroquinolones
(ii) Cephalosporins and others newer agents.
(iii) Antifungal & antiviral drugs including anti HIV drugs.
C.Neoplastic diseases
D.Immunomodulators

Unit IV

Insulin,Oral hypoglycemic agents, Thyroid and Anti-Thyroid agents

Unit V

Estrogens, Progestins and Androgens

I Year – II Sem M.Pharm (Pharmacology)

ADVANCED SCREENING METHODS & TOXICOLOGY

Unit-I

a. Drug discovery process : Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomies robotics and economics of drug discovery, Regulations, for laboratory animal care and ethical requirements.

b.Bioassay methods for autacoids, vasopressin, oxytocin, acetylcholine, adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophine, pertussis, rabbis and plague.

Unit-II

Preclinical models employed in the screening of new drugs belonging to following categories. Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral), sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, , bronchodilators, antihistaminics, eicosanoids. Antisychotic agents, antianxiety agents, nootropic drugs , antidepressant drugs; antiparkinsonian agents, antiepileptics ; antiulcer agents; infarction; antiatherosclerotic drug; antimalarials; anthelmintics models for status epilepticus drugs/ cerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.

Unit-III

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

Unit-IV

Principles of Toxicology ,Test for mutagenicity, carcinogencity, teratogenicity , special tests.Techniques for toxicity studies in man,Toxicogenomics

Unit-V

Poison

A) Classification of Poisoning
B) Diagnosis of poisoning
C) Physical signs of poisoning
D) Principles of management of acute poisoning, treatment of poisoning
e) Common poisoning agents

I Year – II Sem M.Pharm (Pharmacology)

ADVANCES IN PHARMACEUTICAL SCIENCES

Unit-I

Pharmacokinetics approach to New Drug Discovery :
Basic concepts and Definition, importance of ADME parameters in disposition, therapeutics and development – their implications on drug discovery,

Unit-II

Overview on computer aided Drug design (CADD) including QSAR, QSPR, Combinational Chemistry, High Throughput screening (HTS)
Molecular Basis of Drugs Action.
Drug Latentiation :Basic concepts, Prodrugs of functional groups, Bio-precurssor prodrugs, chemical delivery system.

Unit-III

Biotechnology in Drug Discovery :

Cloning of DNA, Expression of cloned DNA, Manipulation of DNA sequence information, New Biological Targets for Drug Development Novel Drug Screening strategies, Novel Biological Agents, Antibodies, Antisense oligonucleotide therapy, Gene therapy.

Unit-IV

Herbal Neutraceuticals as new source for medicines.

Unit-V

Study of Advanced drugs from natural sources of following groups.
Anticancer, Anti AIDS, Hepatoprotectives, Antidiabetics, Antiarthritic, Adaptogenic, Cardiotonic, Antipyretic, antimalarials, Diuretics, Hypnotics, Brain Tonic, Urolithiasis, Antifilarial,. AntihyperlipidemicRecent trends in study of authentic and controversial drugs of above mentioned groups. Modern Phytochemical screening techniques and evaluation of Herbal. Drugs, their extracts and formulations-concept of Reverse Pharmacognosy

I Year – II Sem M.Pharm (Pharmacology)

ADVANCED PHARMACOLOGY – II LAB

Practical shall be based on theory.

I Year – II Sem M.Pharm (Pharmacology)

ADVANCED SCREENING METHODS & TOXICOLOGY LAB

Practical shall be based on theory.

BOOKS RECOMMENDED

01. Drug Discovery and Evaluation: Pharmacological Assays Ed by H.Gerhard VOGE

02. T.B.of Therapeutics: Drug & Diseases Management Ed by Eric Harfindal, Dick R Gourley

03. Drug Interaction Ivory H Stackely

04. Biopharmacutics Clinical Pharmacokinetics by Hilo Gibaldi and Donald Perrier

05. Biopharmaceutics Clinical Pharmacokinetics by E Notari

06. Drug Metabolism by Berhard Tests and Peter Jenner.

07.Principles of Drug action by Goldstein, Aranow and Kolman

08. Burger's Medicinal Chemistry and Drug Discovery by Manfred and Wolf

09. Wilson and Griswold's Organic Medicinal and Pharmaceutical Chemistry

10. Comprehensive Biotechnology Ed, Mirray Moo-Young, Pergamon Press, New york

11. Herbal Options by Chakravary T.K

12. Medicinal Natural Products – a Biosynthetic approach by Dewick Paul M

13. Herbal Drug Treatment by Agarwal

14. Supplements of Cultivation 0f Medicinal Plants by Honda, Kaur

15. Phytochemical Methods by Horbone

16. Clinical Pharmacology by D.R. Lawrence and P.N. Bennette

17. Pharmacology and Pharmacotherapeutics by R.S. Satoskar and S.D. Bhandarkar.

18.The Pharmacology basis of therapeutics, by Louis S. Goodman and Alfred Gillman.

19.Pharmacology by H.P. Rang and M.A. Dale

20. Pharmacotherapy Joiseph T Dipira & others

21 Pharmacotherapeutics F S K Barar

22. Principles of Pharmacology by H L Sharma, K.K Sharma

23. Clinical Pharmacotherapeutics by Kohli

24. Pharmacology by George M Brenner

25. Clinical Pharmacy and Therapeutics Ed. Roger Walker, Cate Whittlessea

26. Medicinal Plants by Keerthikar Basu

27. Indegenous Dugs of India by R.N. Chopra.

28. Medicinal Pharmacology by Tripati

29. Pharmacology by Battacharya

30. Comprehensive Medical Toxicology by V.V. Pillay

31. Screening methods in pharmacology by Robert A Turner

32. Biopharmaceutics &clinical pharmacokinetics by Milo Gibaldi

34. Introduction to drug Metabolism by G.Gordan Gibson & Paul Skett