

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR ACADEMIC REGULATIONS FOR THE AWARD OF FULL TIME M. Pharm. DEGREE (WITH EFFECT FROM THE ACADEMIC YEAR 2009-10)

The Jawaharlal Nehru Technological University Anantapur shall confer M.Pharm. Post Graduate degree to candidates who are admitted to the Master of Pharmacy Programs 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 for each programme, from time to time.

1.1. Admissions shall be made either on the basis of merit rank obtained by the qualified candidates at an Entrance Test conducted by the University or on the basis of GATE / PGECET score, subject to reservations prescribed by the University or Government policies from time to time.

#### 2.0 COURSE WORK:

- 2.1 A Candidate after securing admission must pursue the M.Pharm.course of study for Four Semesters duration.
- 2.2 Each semester shall be of 20 weeks duration including all examinations.
- 2.3 A candidate admitted to a programme should complete it within a period equal to twice the prescribed duration of the programme from the date of admission.

#### 3.0 ATTENDANCE

- 3.1 A candidate shall be deemed to have eligibility to write end semester examinations if he has put in at least 75% of attendance on cumulative basis of all subjects/courses in the semester.
- 3.2 Condonation of shortage of attendance up to 10% i.e., from 65% and above and less than 75% may be given by the college on the recommendation of the Principal.
- 3.3 Condonation of shortage of attendance shall be granted only on genuine and valid reasons on representation by the candidate with supporting evidence.
- 3.4 If the candidate does not satisfy the attendance requirement he is detained for want of attendance and shall reregister for that semester. He / she shall not be promoted to the next semester.

#### 4.0. 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.

- 4.1 For the theory subjects 60% of the marks will be for the External End Examination. While 40% of the marks will be for Internal Evaluation, based on the better of the marks secured in the two Mid Term-Examinations held, one in the middle of the Semester (I-IV units) and another immediately after the completion of instruction (V-VIII) units with Three questions to be answered out of four in 2 hours, evaluated for 40 marks.
- \*Note: All the Questions shall have equal weightage of 10 marks and the marks obtained for 3 questions shall be extrapolated to 40 marks, any fraction rounded off to the next higher mark
- 4.2 For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day to day performance.
- 4.3 For mini project there will be an internal evaluation of 50 marks. The candidate has to secure a minimum of 50% to be declared successful. The assessment will be made by a board consisting H.O.D. and two internal staff members/experts.
- 4.4 For Seminar there will be an internal evaluation of 50 marks. A candidate has to secure a minimum of 50% to be declared successful. The assessment will be made by a board consisting of HOD and two internal experts at the end of IV semester instruction.
- 4.5 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.
- 4.6 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 4.5.) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.

#### 5.0 RE-REGISTRATION FOR IMPROVEMENT OF INTERNAL EVALUATION MARKS:

Following are the conditions to avail the benefit of improvement of internal evaluation marks.

- 5.1 The candidate should have completed the course work and obtained examinations results for I & II semesters.
- 5.2 He should have passed all the subjects for which the Internal evaluation marks secured are more than 50%.
- 5.3 Out of the subjects the candidate has failed in the examination due to Internal evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of two Theory subjects for Improvement of Internal evaluation marks.
- 5.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.
- 5.5 For each subject, the candidate has to pay a fee equivalent to one third of the semester tuition fee and the amount is to be remitted in the form of D.D. in favour of the Registrar,

- JNTUA payable at Anantapur along with the requisition through the Principal of the respective college.
- 5.6 In the event of availing the Improvement of Internal evaluation marks, the internal marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

#### **6.0 EVALUATION OF PROJECT WORK:**

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the college/ institute.

- 6.1 Registration of Project work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the courses (theory and practical courses of I & II Sem)
- 6.2 An Internal Departmental Committee (I.D.C) consisting of HOD, Supervisor and one internal senior expert shall monitor the progress of the project work.
- 6.3 The work on the project shall be initiated in the penultimate semester and continued in the final semester. The duration of the project is for two semesters. The candidate can submit Project thesis with the approval of I.D.C. after 36 weeks from the date of registration at the earliest and one calendar year from the date of registration for the project work. Extension of time within the total permissible limit for completing the programme is to be obtained form the Head of the Institution.
- 6.4 The student must submit status report at least in three different phases during the project work period. These reports must be approved by the I.D.C. before submission of the Project Report.
- 6.5 A candidate shall be allowed to submit the thesis / dissertation only after passing in all the prescribed subjects (both theory and practical) and then take viva voce examination of the project. The viva-voce examination may be conducted once in two months for all the candidates submitted during that period.
- 6.6 Three copies of the Thesis / Dissertation certified in the prescribed from by the supervisor & HOD shall be presented to the University.
- 6.7 The college shall submit a panel of three experts for a maximum of 5 students at a time. However, the thesis / dissertation will be adjudicated by one examiner nominated by the University.
- 6.8 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 / dissertation. The board shall jointly report candidates work as:

1.	Very Good	Grade	A
2.	Good	Grade	В
3.	Satisfactory	Grade	$\mathbf{C}$
4	Not satisfactory	Grade	D

If the report of the viva-voce is not satisfactory (Grade D) 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 unless the candidate is permitted to revise and resubmit thesis.

#### 7.0 AWARD OF DEGREE AND CLASS:

A candidate shall be eligible for the award of respective degree if he satisfies the minimum academic requirements in every subject and secures 'satisfactory' or higher grade report on his thesis/dissertation and viva-voce. Based on overall percentage of marks obtained, the following class is awarded.

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

#### 9.0 TRANSITORY REGULATIONS:

Candidates who have discontinued or have been detained for want of attendance or who have failed after having undergone the course in earlier regulations and wish to continue the course are eligible for admission into the unfinished semester from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to 4.6 and 2.3 sections. Whereas they continue to be in the academic regulations they were first admitted.

#### 10.0 GENERAL:

- i. The academic regulations should be read as a whole for purpose of any interpretation.
- ii. Disciplinary action for Malpractice/improper conduct in examinations is appended.
- iii. There shall be no place transfer within the constituent colleges and affiliated colleges of Jawaharlal Nehru Technological University Anantapur.
- iv. Where the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".
- v. In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- vi. The University may change or amend the academic regulations or syllabi at any time and the changes or amendments shall be made applicable to all the students on roles with effect from the dates notified by the University.

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# RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / 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)				
(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.	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 project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.			

Smuggles in the Answer book or additional Expulsion from the examination hall and sheet or takes out or arranges to send out the cancellation of performance in that subject question paper during the examination or and all the other subjects the candidate has answer book or additional sheet, during or already appeared including practical after the examination. 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 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. Expulsion from the examination hall and Leaves the exam hall taking away answer cancellation of performance in that subject script or intentionally tears of the script or any part thereof inside or outside the and all the other subjects the candidate has examination hall. already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. 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. Possess any lethal weapon or firearm in the Expulsion from the examination hall and examination hall. 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 for the remaining examinations of the subjects of that semester/year. candidate is also debarred and forfeits the seat.

7. Impersonates any other candidate connection with the examination.

The candidate who has impersonated shall be expelled from examination hall. 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 consecutive semesters from class work and University examinations. continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. impostor is an outsider, he will be handed over to the police and a case is registered against him.

Refuses to obey the orders of the Chief 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.

In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(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.

9. I	If student of the college, who is not a	Student of the colleges expulsion from the
C	candidate for the particular examination or	examination hall and cancellation of the
a	any person not connected with the college	performance in that subject and all other
i	indulges in any malpractice or improper	subjects the candidate has already appeared
C	conduct mentioned in clause 6 to 8.	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 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. U	Uses objectionable, abusive or offensive	Cancellation of the performance in that
1	language in the answer paper or in letters to	subject.
t	the examiners or writes to the examiner	
	requesting him to award pass marks.	
		Cancellation of the performance in that
	evidence, such as, during valuation or	subject and all other subjects the candidate
C	during special scrutiny.	has appeared including practical
		examinations and project work of that
		semester/year examinations.
	If any malpractice is detected which is not	
	covered in the above clauses 1 to 11 shall	
	be reported to the University for further	
2	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 centre from the college to another college for a specific period of not less than one year.

# Course Structure and Syllabi for M. Pharm- Pharmacology for affiliated Pharmacy Colleges 2009-10

### I YEAR I SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1.	9S01101	Modern Pharmaceutical Analysis	4		4
2.	9S01102	Biostatistics, Intellectual property rights and regulatory affairs	4		4
3.	9S01103	Advanced Pharmacology	4		4
4.	9S01104	Advanced Pharmacology & Toxicology	4		4
5.	9S01105	Modern Pharmaceutical Analysis -Practical		6	4
6.	9S01106	Advanced Pharmacology & Toxicology - Practical		6	4
7.	9S01107	Mini-project- I		3	2
		contact periods/week	16	15	26
			Total	31	20

# I YEAR II SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1.	9S01201	Biopharmaceutics and Pharmacokinetics	4		4
2.	9S01202	Cell and Molecular biology	4		4
3.	9S01203	Clinical Pharmacology & Pharmacotherapeutics	4		4
4.	9S01204	Screening methods in Pharmacology and	4		4
		clinical research			
5.	9S01205	Clinical Pharmacology & Molecular Biology		6	4
6.	9S01206	Screening Methods in Pharmacology & Clinical		6	4
		Research (Practical)			
7.	9S01207	Mini-project- II		3	2
		contact periods/week	16	15	
			Total	31	26

# II YEAR (III & IV Semesters)

S. No	Course code	Subject	credits
1	9S01401	Seminar	2
2	9S01402	Project work	16

#### M.Pharm I year I semester Pharmacology

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#### (9S01101) MODERN PHARMACEUTICAL ANALYSIS

- 1. UV-VISIBLE SPECTROSCOPY: Brief review of electromagnetic spectrum, UV-Visual range, energy, wavelength and color relationships. Interaction of electromagnetic radiation (UV-visible) with matter and its effects. Chromophores and their interactions with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs. Shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc) Quantitative estimations, Modern instrumentation.
- 2. a) INFRARED SPECTROSCOPY: Nature of Infra-red radiation.

Interaction of I.R. radiation with I.R molecules and effects on bonds. Molecular Infrared Spectra. Brief outline of classical I.R instrumentation and practical details of obtaining spectra, including sample preparation for spectroscopy, quantitative interpretation of I.R spectroscopy including FT-IR, ATR.

- **b) OPTICAL ROTATORY DISPERSION:**Fundamental principles of ORD, cotton effect curves, their characteristics and interpretation. Octant rule and its application with examples. Circular dichroism and its relation to ORD.
- 3. NMR SPECTROSCOPY: Fundamental principles of NMR (Magnetic properties of nuclei, applied field and precession; absorption and transition; frequency). Chemical shifts concept: Isotopic nuclei, Reference standards: Proton magnetic spectra, their characteristics, presentation terms used in describing spectra and their interpretation (Signal No., Position and Intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomenon in high resolution PMR. Spin-spin coupling. Application of Signal split and coupling constant data to interpretation of spectra. De-coupling and shift reagent methods. Brief outline of principles of FT-NMR with reference to 13CNMR. Spin-spin and spin-lattice relaxation phenomenon. Free induction decay (FID) proton noise de-coupling signal, average time domain and frequency domain signals nuclear overhauser enhancement 13CNMR spectra, their presentation; characteristics, interpretation, examples and applications. Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments. Introduction to 2-D NMR techniques.
- **4. MASS SPECTROSCOPY:** Basic principles and brief outline of instrumentation. Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization Mass Spectroscopy. GC-MS, other recent advances in MS. Fast atom bombardment mass spectrometry. LC-MS, LC MS-MS.

- **5. CHROMATOGRAPHIC TECHNIQUES:** Classification of chromatographic methods based on mechanism of separation. Column chromatography, column materials, merits and demerits. Paper chromatography; techniques and applications. Thin Layer Chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC. Preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC detection methods, quantitative methods in TLC. Programmed multiple development techniques.
- **6. GAS CHROMATOGRAPHY:** Instrumentation packed and open tubular column, Column efficiency parameters, the Vandeemeter equation, Resolution, liquid stationary phase, derivatization methods of GC including acylation, perfloro acylation, alkylation and esterification. Detectors: FID, ECD, TCD, NPDA. Critical comparison of sensitivity, selectivity and field of applications of these detectors. Examples of GC applications in pharmaceutical analysis.
- 7. LIQUID CHROMATOGRAPHY: Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and micro bore columns, normal and reversed phase packing materials, reverse phase HPLC, Column selection, Mobile phase selection, Efficiency parameters, resolution, detectors in HPLC refractive index, photometric and electrochemical. Comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC-instrumentation and applications.
- **8. ELECTROPHORESIS:** Moving boundary electrophoresis, Zone electrophoresis, Iontophoresis, PAGE, Isotacophoresis and applications in pharmacy.

**X-ray Diffraction methods:** introduction, generation of X-rays, elementary crystallography, Miller Indices, X-rays diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffraction data. Principle, instrumentation and application of the following: Differential Scanning Colorimetry (DSC), DTA &TGA in analysis of pharmaceuticals.

- 1. Instrumental methods of chemical analysis by Chatwal. K, Anand, 5/e.
- 2. Vogel's text book of quantitative chemical analysis by G.H.Jeffery, J.Bassett, J.Mendhan, R.C.Denny.
- 3. Instrumental methods of analysis by Willard, Merit, Dean, Settle.
- 4. Organic spectroscopy by Y.R.Sharma.
- 5. Spectrometric identification of organic compounds by Silverstein, Webster.
- 6. Spectroscopy by B.K.Sharma
- 7. Fundamentals of analytical chemistry by Skoog
- 8. Instrumental methods of analysis by Skoog.

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# (9S01102) BIO-STATISTICS, INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

#### I. BIO-STATISTICS

- 1. **An introduction** to statistics and biostatistics-collection and organization of data, graphical, pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, Coefficient of variation, mean error, relative error, precision and accuracy
- 2. **Tests of significance**: Testing hypotheses Principles and applications of Z, t, F-ratio and chi-square tests in pharmaceutical and medical research. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.
- 3. **Design of Experiments**: Principles of randomization, replication and local control; CRD, RBD, LSD their applications and analysis of data; Factorial Experiments Principles and applications; Probit analysis: Dose effect relationships, calculation of  $LD_{50}$ ,  $ED_{50}$ .

**Statistical quality control**: Meaning and uses, Construction of  $\overline{X}$ , R, P,  $\eta p$  and C chart-s.

# II. INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

- 1. 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.
- 2. 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).
- 3. 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.

- 4. a) Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.
  - **b)** 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.

- 1. 'Biostatistics', KS Negi, AITB Publishers, Delhi.
- 2. 'Fundamentals of Biostatistics', Irfan Alikhan, Ukaaz Publications
- 3. 'Biostatistics for Pharmacy', Khan and Khanum, Ukaaz Publications'
- 4. 'Basic statistics and Pharmaceutical applications', J.E, Demuth, Mercel & Dekker.
- 5. 'Applied statistics' by S.C.Gupta & V.K.Kapoor
- 6. 'Fundamentals of mathematical statistics' by S.C.Gupta & V.K.Kapoor
- 7. 'Good Manufacturing Practices for Pharmaceuticals', S.H.Wiling, Vol.78, Marcel Decker.
- 8. 'Protection of Industrial Property rights', P. Das & Gokul Das
- 9. 'Law and Drugs', S.N. Katju, Law Publications.
- 10. 'Original Laws' Published By Govt. of India
- 11. 'Laws of drugs in India', Hussain
- 12. 'New Drug Approval Process', R.A.Guarino, Vol 100, Marcel Decker, NY
- 13. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org

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#### (9S01103) ADVANCED PHARMACOLOGY

- 1. Receptor Pharmacology: Drug receptor interaction theory, occupation theory and rate theory. Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors. Receptor characterization method: Pharmacological characterization methods, radio ligand methods, monoclonal antibodies, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor sub classification. Receptor down regulation and upregulation.
- **2.** Structural activity relationships, Pharmacodynamic and pharmacokinetic aspects of chiral drugs, allo-steric binding, thermodynamics of drug interactions with the receptors.
- 3. Neurotransmitter receptor mechanism, ion channel and G-protein linked receptors, secondary messenger systems: receptor expression and regulation with specific emphasis and adrenergic, dopaminergic, cholinergic, seratonergic, histaminenargic, GABA/BZ and excitatory aminoacid receptors, opioid receptors, purinoceptors and their sub types with agonists and antagonists. Isolation and their characterization of receptors.
- **4.** Mediators of inflammation and allergy: Autacoids (histamine, bradykinins, PAF, eicosanoide, prostaglandins, thrombaxanes, leukotrienes and related compounds), nitric oxide/EDRF and vascular substances, oxygen free radicals, their scavengers. Cytokinins and their actions Cox-I, Cox-II inhibitors and their load in inflammatory process, anti-inflammatory agents, asthma and COPD.
- **5.** Immuno-modulators (immunosuppressant and immunostimulants), AIDS and Rheumatoid arthritis.
- **6.** Theoretical aspects of drug action
- **7.** Microbial conversions as tools in the preparation of drugs: introduction, practical aspects of microbial transformation, some theoretical aspects of microbial transformation, conversion by microorganisms.
- **8.** Prodrug design: various aspects governing prodrug design.

- 1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8<sup>th</sup> edition
- 2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
- 3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10<sup>th</sup> edition
- 4. Pharmacology by K.D.Tripati.
- 5. Pharmacology by Sathoshkar

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#### (9S01104) ADVANCED PHARMACOLOGY AND TOXICOLOGY

1. Drugs acting on central nervous system

General Anaesthetics, anxiolytics and hypnotics, anti-psychotics, anti-depressants anti-epileptics, analgesics, anti-migraine agents and anti-parkinsonism agents.

2. Drugs acting on autonomic nervous system

Sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and neuro muscular junction blockers.

**3.** Drugs acting on cardiovascular system:

Anti-hypertensive, cardiotonics, anti-arrhythmics, anti-anginal, hypolipidemics and anti-atherosclerotic agents.

**4.** Drugs acting on hormones

Pitutary, thyroid, parathyroid, pancreatic, adrenal. male and female sex hormones, Diabeties Mellitus.

5. Drugs acting on GIT, respiratory and kidney

GIT-GERD and Anti-ulcer agents, emetics and anti-emetics, laxatives and purgatives, anti-tussives, expectorants, Inflammatory bowel disease, anti-asthmatics, cough and pneumonia, diuretics and anti-diuretics.

- **6.** Recent developments in chemotherapeutic agents, mechanism of multi drug resistance (MDR), anti-bacterial, anti-viral, anti-protozoal and anti-helmenthic, cancer chemotherapy.
- 7. Toxicology: Definition, scope and general principles of toxicology, dose-response relationship, factors influencing toxicity, evaluation safety, biotransformation and toxico-kinetics, target organ toxicity, neuronal and behavioral toxicity, kidney, pulmonary, hepatic, cutaneous, oto-toxicity. Haemato-toxicity, mutagenecity, carcinogenicity, reproductive toxicity, environmental and industrial toxicology, management of toxicity reactions in humans.

**8.** Pharmacotherapy of alcohol, barbiturate, opoid, organophosphorus, paracetamol, heavy metal, snake bite.

- 1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001  $8^{th}$  edition
- 2. Pharmacology by Rang H.P, Dale MM and Ritter JM. Churchill lingston, London, 4 th edition, 1999
- 3. Goodman and Gilman's The pharmacological basis of therapeutes (International edition) Mc Graw Hill, USA 2001 10<sup>th</sup> edition
- 4. Pharmacology by K.D.Tripati.
- 5. Pharmacology by Sathoshkar
- 6. General and applid toxixology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
- 7. Clinical Pharmacy by Dr.Laurence , PN Bennet and MJ.Brown, 8 th edition, Churchil Livingston.
- 8. Harrison's principles of internal medicine two Vols, 2001 by Braunwald, Fauci, Kasper, Hauser, Longo Jameson, Mc Graw Hill, Newyork 15<sup>th</sup> edition



#### M.Pharm I year I semester Pharmacology

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#### (9S01105) MODERN PHARMACEUTICAL ANALYSIS - PRACTICAL

- 1. Simultaneous estimation of Paracetamol and Ibuprofen, Rifampicin and INH, Aspirin and Caffeine.
- 2. UV-Visible spectrum scanning of certain organic compounds- absorption and corelation of structures, comparisons.

Ex: a. Chloramphenicol b. Sulphadiazine c. Analgin

- 3. Effect of pH and solvent on UV spectrum of certain drugs.
- 4. Two dimensional paper chromatography and TLC.
- 5. Gradient elution and other techniques in column chromatography.
- 6. Separation by electrophoresis.(PAGE and agarose Gel electrophoresis)
- 7. Experiments based on HPLC and GC.
- 8. IR, NMR and Mass spectroscopy of compound each.
- 9. DSC/XRD curves of a sample and mixture to understand polymorphism.
- 10. Determination of insulin / any other hormones by ELISA method.



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#### (9S01106) ADVANCED PHARMACOLOGY AND TOXICOLOGY LAB

- 1. Common laboratory animals: breeding, maintenance, handling and CPCSEA regulations.
- 2. Effect of various drugs on isolated mammalian heart preparation using Langendorff's setup.
- 3. Effect of various drugs on rat / rabbit thoracic aorta (with and without endothelium).
- 4. Effect of various drugs on rat phrenic nerve diaphragm preparation.
- 5. Anti-arrhythmic activity in rats using ECG.
- 6. Effect of various autonomic drugs on rabbit blood pressure.
- 7. Effect of various drugs on rabbit jejunum preparation.
- 8. Determination of  $LD_{50}$  and  $ED_{50}$  of some drugs (mice).
- 9. Estimation of insulin by ELISA.
- 10. Serum estimation of SGOT, SGPT, AST, glucose, bilirubin, cholesterol, HDL, LDL, VLDL, catalase, SOD, lipid peroxidation.

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# (9S01107) Mini-project- I

The mini projects can be taken up as industrial visit/training and report submission.

Or

A suitable project shall be carried out in the college.



### M. Pharm I year II semester Pharmacology

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#### (9S01201) BIO PHARMACEUTICS AND PHARMACOKINETICS

- **1. Bioavailability and Bioequivalence studies:** Designing of bioavailability and bioequivalence studies and interpretation of results. Tests of significance test ANOVA.
- 2. Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexation, polymorphism and techniques of enhancing dissolution rate.
- **3.** Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
- **4. Basic concepts of pharmacokinetics:** compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to
  - a. Absorption: (wherever applicable) absorption rate constant, absorption half-life, lag time and extent of absorption, AUC.
  - b. Distribution: Apparent volume of distribution and its determination.
  - c. Metabolism: Metabolic rate constant
  - d. Elimination: Over all apparent elimination rate constant, and half life.

All the above under the following conditions:

- 1. Intravenous bolus injection
- 2. Intravenous infusion
- 3. Single dose oral administration
- 4. Multiple dose injections
- 5. Multiple dosage oral administration
- e. Noninvasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary compartments
- f. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.
- g. Concept of loading dose, maintenance dose, accumulation index, dosage adjustment in renal and hepatic impairment, individualization of therapeutic drug monitoring.
- **5. Non-linear pharmacokinetics:** Concepts of linear and non-liner pharmacokinetics, Michaelis-Menten Kinetics characteristics. Basic Kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.
- **6.** Non compartmental pharmacokinetics.
- 7. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency, Chronopharmacokinetics.
- **8.** Clinical pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver and renal disease states.

- Bio Pharmaceutics And Pharmacokinetics by Leon Shargel, 3<sup>rd</sup> edition, Williams and Wilkins1997
- 2. Bio Pharmaceutics And Pharmacokinetics by Madan
- 3. Fundamentals of experimental pharmacology by MN.Ghosh, Scientific book agency, 2<sup>nd</sup> edition, Calcutta 1984.
- 4. Screening methods in pharmacology Academic press, Newyork and London 1965.
- 5. Drug Discovery and evaluation Pharmacological assays by H.Gerhard.Vogel, 2<sup>nd</sup> edition, Springer verlag, Berlin, Heidelberg.



# M. Pharm I year II semester Pharmacology

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#### (9S01202) CELL AND MOLECULAR BIOLOGY

- 1. The cell, cell cycle, cellular aging and death, transformation of cell-metastasis, tumour gland part animal cell culture.
- 2. Structure and functions of plasma membrane: Chemical composition of membrane, integral membrane proteins, peripheral membrane proteins, lipid anchored membrane proteins, restriction on protein and lipid mobility, study of RBC, defects in ion channels and transporters as a cause of inherited disease.
- 3. Cell signaling: Communication between cells and their environment, ion channels, organization of signal transduction pathways, third messengers, biosensors.
- 4. Role of gene in cells, elucidation of genetic code, gene expression, genetic elements that control gene expression.
- 5. r-DNA Biotechnological aspects, cloning of DNA, Expression of cloned DNA, manipulation of DNA sequence information, now biological targets of drugs development, novel drug screening stragies, novel biological agents, antibodies, antisense oligonucleotide therapy, gene therapy.
- **6**. Recombinant and human genetics: DNA sequencing, mapping and cloning of human disease genes, DNA based diagnosis of genetic diseases.
- 7. Pharmacokinetics and pharmacodynamics of peptide and protein drugs: elimination, distribution, pharmacodynamics and immunogenecity of protein therapeutics.
- 8. Cancer: Basic properties of a cancer cell, causes of cancer, the genetics of caner, oncogenes, tumour-suppressor genes, new strategies for combating cancer, inhibiting the activity of cancer promoting proteins, Angiogenesis.

- 1. The Cell by Cooper.
- 2. Cell and Molecular Biology by Gerald Karp., Wiley International student version, 5/e.
- 3. Cell and Molecular Biology by De Robertis and De Robertis.
- 4. The Cell by Albert.
- 5. The World of the Cell by W.M. Becker.
- 6. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e,1999
- 7. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001, 10<sup>th</sup> edition

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#### (9S01203) CLINICAL PHARMACOLOGY & PHARMACOTHERAPEUTICS

- 1. Principles of Pharmacokinetics
  - a. Revision of basic concepts.
  - b. Clinical Pharmacokinetics.
    - i. Dose response in man.
    - ii. Influence of renal and hepatic disease on Pharmacokinetics.
    - iii. Therapeutic drug concentration monitoring.
    - iv. Population Pharmacokinetics.
- 2. Adverse Drug Reactions, Drug Interactions and ADR monitoring.
- **3.** Pathophysiology and drug therapy of the following disorders.
  - a. Schizophrenia, anxiety, depression, epilepsy, Parkinson's, Alzheimer's diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infraction,
- **4.** TB, leprosy, leukemia, solid tumours, lymphomas, psoriasis, respiratory, urinary, GI tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.
- **5.** Drug therapy in Geriatrics.
- **6.** Drug therapy in Pediatrics, Pregnancy & Lactation.
- 7. Pharmacogenetics: Inter-racial and individual variability in drugs metabolism.
- **8.** Orphan diseases and its management.

- 1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8<sup>th</sup> edition
- 2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4 th edition, 1999
- 3. Goodman and Gilman's The pharmacological basis of therapeutes (International edition) Mc Graw Hill, USA 2001 10<sup>th</sup> edition
- 4. Pharmacology by K.D.Tripati.
- 5. Pharmacology by Sathoshkar
- 6. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
- 7. Clinical Pharmacy by Dr.Laurence , PN Bennet and MJ.Brown, 8 th edition, Churchil Livingston.
- 8. Harrison's principles of internal medicine two Vols, 2001 by Braunwald, Fauci, Kasper, Hauser, Longo Jameson, Mc Graw Hill, Newyork 15<sup>th</sup> edition

#### M. Pharm I year II semester Pharmacology

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# (9S01204) SCREENING METHODS IN PHARMACOLOGY AND CLINICAL RESEARCH

- 1. Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations, for laboratory animal care and ethical requirements.
- 2. Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vaccines and sera, vasopressin, oxytocin, acetylcholine, adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophin, pertussis, rabies and plague.
- 3. Preclinical models employed in the screening of new drugs belonging to following categories-I
  - Anti-fertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral), sedatives, hypnotics, anti-arrhythmic agents, anti hypertesnsive, cardiac stimulants, cardiotonic agents, bronchodilators, anti-histaminics, eicosanoids.
- **4.** Preclinical models employed in the screening of new drugs belonging to following categories-II
  - Anti-psychotic agents, anti-anxiety agents, nootropic drugs, antidepressant drugs; anti-parkinsonian agents, anti-epileptics; analgesics and anti-inflammatory agents; antiulcer agents; myocardial infarction; anti-atherosclerotic drug, hepatoprotective;
- 5. Preclinical models employed in the screening of new drugs belonging to following categories-III
  - antimalarials; anti-helmintics anti-diabetics; models for status epilepticus drugs/cerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.
- **6.** Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques.
- **7.** Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).
- **8.** Drug development process, clinical trials, safety evaluation, preparation IND/NDAs, statistical design in clinical trials, data analysis technique and presentation skills.

#### JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm I year II semester Pharmacology

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#### (9S01205) CLINICAL PHARMACOLOGY AND MOLECULAR BIOLOGY

- 1. Monitoring of concentration of drugs in saliva/urine.
- 2. Determination of concentration of drugs in blood of children, adults, following oral administration of a safe drug.
- 3. Drug mutagenicity studies using mice bone-marrow chromosomal aberration tests.
- 4. Drug mutagenicity studies using mice bone-marrow micro nucleus tests.
- 5. Transformation of bacteria.
- 6. Isolation of plasmid DNA containing resistant gene ( $p^{BR322}$ ).
- 7. Establishing of Breast cancer cell line and testing the anti cancer activity of a drug
- 8. Preparation of antibody (polyclonal) from rabbit.
- 9. Study of possible drug interactions from prescription of local doctors (10-20 prescriptions are to be collected).

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# (9S01206) SCREENING METHODS IN PHARMACOLOGY AND CLINICAL RESEARCH (Practical)

- 1. Bioassay of acetylcholine/histamine using guinea pig ileum preparation.
- 2. Bioassay of oxytocin using rat uterine preparation.
- 3. Bioassay of 5-HT using rat fungus preparation.
- 4. PA-2 values of various antagonists using suitable isolated tissue preparations.
- 5. Screening of anxiolytic drugs.
- 6. Screening of anti-depressant drugs.
- 7. Screening of anti-ulcer drugs.
- 8. Screening of anti-inflammatory, analgesic and antipyretic activity.
- 9. Ames test for mutagenicity.

# MINIMUM EQUIPMENTS FOR PHARMOCOLOGY

#### List of equipment:

- 1. Student physiograph ----3No.s
- 2. Auto analyzer ----1 No
- 3. Langendorf's heart perfusion apparatus ---- 3No.s
- 4. Students organ bath (Temperature controlled) ----10 No.s
- 5. Elevated plus Maze ----1No
- 6. Condon's manometer (for rat B.P) ----3No.s
- 7. Bio Pac----01 No

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# M. Pharm I year II semester Pharmacology

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# (9S01207) Mini Projects-II:

The mini projects can be taken up as industrial visit/training and report submission.

Or

A suitable project shall be carried out in the college.

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(9S01401) SEMINAR

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR M. Pharm IV semester Pharmacology

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# (9S01402) PROJECT WORK

The Project Work should be on a contemporary topic relevant to the core subjects of the course. It should be original work of the candidate.

