JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
ANANTAPUR-515002 (A.P) INDIA

ACADEMIC REGULATIONS
COURSE STRUCTURE
AND
DETAILED SYLLABI

MASTER OF PHARMACY

PHARMACY PRACTICE

M.Pharm Regular Two Years P.G. Degree Course
(Applicable for the batches admitted from 2011-12)

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 form 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 B
3.	Satisfactory	Grade 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)	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.	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.

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 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.
5.	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 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 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.
6.	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 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.

7.	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 impostor is an outsider, he will be handed over to the police and a case is registered against him.
8.	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.	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 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.	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.
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 centre from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Course Structure and Syllabi for

M. Pharm- Pharmacy Practice

for affiliated Pharmacy Colleges 2011-12

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.	9S09101	Pharmacotherapeutics-I	4		4
4.	9S09102	Hospital and Community Pharmacy	4		4
5.	9S01105	Modern Pharmaceutical Analysis- Lab		6	4
6.	9S09103	Hospital And Community Pharmacy - Lab		6	4
7.	9S09104	Mini-project- I		3	2
		contact periods/week	16	15	26
			Total 31		

I YEAR II SEMESTER

S. No	Course code	Subject	Theory	Lab.	Credits
1.	9S01201	Biopharmaceutics and Pharmacokinetics	4		4
2.	9S09201	Pharmacotherapeutics-II	4		4
3.	9S09202	Clinical Pharmacy Practice	4		4
4.	9S09203	Clinical Research and Development	4		4
5.	9S09204	Pharmacotherapeutics-II Lab		6	4
6.	9S09205	Clinical Pharmacy Practice Lab		6	4
7.	9S09206	Mini-project- II		3	2
		contact periods/week	16	15	26
			Total 31		

II YEAR (III & IV Semesters)

S. No	Course code	Subject		credits
1	9S09401	Seminar		2
2	9S09402	Project work		16

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M.Pharm I year I semester (Pharmacy Practice)

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(9S01101) MODERN PHARMACEUTICAL ANALYSIS

1. **UV-Visible Spectroscopy**: Brief review of electromagnetic spectrum, UV-Visible 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. **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.
   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, 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. 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 Vandeemer equation, Resolution, liquid stationary phase, derivitazation 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 microbore 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, 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 diffractometer, obtaining and interpretation of X-ray powder diffraction data. Principle, instrumentation and application of the following: Differential Scanning Colorimetry (DSC), DTA &TGA in analysis of pharmaceuticals.

Recommended Books

1. Instrumental methods of chemical analysis by **chatwal. K, anand,** 5th edition, 2008 Himalaya Publication India.
2. Vogel's text book of quantitative chemical analysis by **G.H.Jeffery, J.Bassett, J.Mendhan, R.C.Denny.** Pearson Education 2007.
3. Instrumental methods of analysis by **Willard, Merit**, Dean, Settle. 7th edition CBS Publisher 2007.
4. Organic spectroscopy by **Y.R.Sharma.** S.Chand & Co New Delhi. 2008
5. Spectrometric identification of organic compounds by **silverstein,** Webster. John Wiley & Sons 2005.
6. Spectroscopy by **B.K.Sharma** Pub by Krishna "2007" Prakashan
7. Fundamentals of analytical chemistry by **Skoog,** 6th edition Thomson Brooks, 2007
8. Instrumental methods of analysis by **Skoog.** 6th edition, Thomson Brooks, 2007
9. Text book of pharmaceutical analysis by **S.Ravishankar.**
10. Organic spectroscopy by **William and Kemp** 3rd edition, Palgrave, N.Y.2006
11. Spectroscopic methods in Organic chemistry by **Dudley William and Ian Flemming,** Tata Mc Graw Hill 6th edition 2008.

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

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}.

4. Statistical quality control: Meaning and uses, Construction of $\bar{X}$, R, P, ηp and $\dot{C}$ charts.

Intellectual Property Rights & Regulatory Affairs

5. 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.

6. 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).

7. 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.

8. 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.

Recommended Books

1. Bio-statistics by **Dr. K Balaji and AVS Raghavaiah**. IK International Publishing House Bangalore. 2010
2. 'Biostatistics' by **KS Negi** AITB Publishers, Delhi. 2002
3. 'Fundamentals of Biostatistics' by **Irfan Alikhan** Ukaaz Publications 2nd edition, 1994
4. 'Biostatistics for Pharmacy' by **Khan and Khanum** Ukaaz Publications vol:16, 2nd edition ill, Chapman & Hall / CRC 2006
5. 'Basic statistics and Pharmaceutical applications' by **J.E, Demuth** Mercel & Dekker vol: 16
6. Applied statistics by **S.C.Gupta & V.K.Kapoor S.Chand,** 3rd edition, 1996
7. Fundamentals of mathematical statistics by **S.C.Gupta & V.K.Kapoor** S.Chand, 10th edition 2000
8. Good Manufacturing Practices for Pharmaceuticals, by **S.H. Wiling**, Vol. 78, Marcel Decker N.Y.
9. Protection of Industrial Property rights, by **P. Das & Gokul Das**
10. Law and Drugs, by **S.N. Katju** Law Publications. Delhi law House, 2002 4th edition.
11. Original Laws Published By **Govt. of India**
12. Laws of drugs in India, **Hussain**
13. New Drug Approval Process, **R.A.Guarino,Vol 100**, Marcel Decker, NY 1992
14. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org

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M.Pharm I year I semester (Pharmacy Practice)

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(9S09101) Pharmacotherapeutics-I (Theory)

Pathophysiology and pharmacotherapy of diseases associated with following systems/diseases and special references to the drug of choice in conditions like pregnancy, lactation, geriatrics and paediatrics.

1. **Haematological diseases:** Blood and body fluids, complications of blood transfusion and blood substitutes, anemia, Drug induced haematological disorder
2. **Immunology:** Immune disease – pathogenesis, immunoglobulins, mechanism of action of drugs, immunosuppressive actions in tissue as well as organ transplantation, auto-immunity, mechanism of autoimmune disease, pathogenesis of autoimmunity.
3. **Pain management:** Pathophysiology of inflammation and repair, pain pathways, analgesics and NSAIDs, opiates, local anaesthetics, neuralgia and skeletal muscle relaxants.
4. **Bone and joint Disorders:** Osteoporosis, rheumatoid arthritis, osteoarthritis, gout, Paget's disease of bones.
5. **Endocrine system:** Diabetes, thyroid diseases, liver disorders, disorders of pituitary gland and hormone replacement therapy.
6. **Gastrointestinal system:** Classification and pathogenesis of different types of ulcer diseases and its management, inflammatory bowel diseases, diarrhoea and constipation.
7. **Nervous system:** Epilepsy, Parkinson's and Alzheimer's diseases, stroke and transient ischaemic attacks, headache and migraine.
8. **Psychiatric disorders:** Schizophrenia, mania and depression, anxiety disorders and sleep disorders

Recommended Books

1. Clinical Pharmacy and therapeutics- by **Roger Walker &** cate whittels, Churchill Livingstone 4th edition publication. 2011
2. Pharmacotherapy : A Patho-physiological approach- by **Joseph T**. Dipiro et al. 6th edition McGraw hill Publication. 2011
3. Pathologic basis of diseases- by **Robins SL, W.B**.Saunders publication 5th edition. 2004
4. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. Russell Russell, 3rd edition, Pharmaceutical Press, 2008.
5. Pathology and Theapeutics for Pharmaeists: A Basis for Clinical Practice-Green and Harris, Chapman & Hall. 1994 illustrated edition.
6. Clinical Pharmacy and therapeutics- **Eric Herfindal**, Williams and Wilkins Publication. 5th edition, 1992.
7. Applied Therapeutics: the clinical use of drugs. **Lloyd Young and Koda**-Kimble MA [ISBN 0 333-65881-7]. 3rd edition, 1983.
8. Avery's drug treatment, by T.M. Speight, NH Holford, Wiley-Black well, 4th edition, 1997, Adis international Limited. Auckland, Newzealand.

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(9S09102) Hospital and Community Pharmacy (Theory)

1. The role of the hospital pharmacy department and its relationship to other hospital departments and staff. Hospital drug policy, Drug Committees, Pharmacy & Therapeutics committee, Infection Control committee and Formulary development.

2. **Hospital Pharmacy Management:** Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and planning, Infrastructure requirements (building, furniture and fittings, specialised equipment, maintenance and repairs), Workload statistics.

3. **Organisation of Hospital Pharmacy Services:** Drug distribution, Purchasing, Warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking, drug recalls), Drug distribution methods (ward stock, individual patient dispensing, unit dose), Specific requirements for inpatients, outpatients, Casualty/Emergency, Operation Theatres, ICU/CCU, Drugs of dependence, Hospital waste management, Drug stores management, organization of Drug Store, Purchase and Procurement, Inventory control (Principles, methods of inventory control) and stores management.

4. The role of the community pharmacy and its relationship to other local health care providers and services to nursing homes and clinics. Prescribed medication order - interpretation and legal requirements. Communication skills - communication with prescribers and patients.

5. Over-the-counter (OTC) sales, Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)

6. **Primary Health Care in Community Pharmacy:** Family planning, First aid, Smoking cessation, Health Screening programs

7. **Community Pharmacy Management:** Financial materials, staff, infrastructure requirements, drug information resources, computers

8. **Education and Training:** Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, formal and informal meetings and lectures, Drug and therapeutics newsletter.

Recommended Books

1. Hospital Pharmacy - **Hassan WE**. Lec and Febiger publication. 5th illustrated edition 1986.
2. J.T.Fell, Textbook of Hospital Pharmacy - **Allwood MC,** Blackwell Scientific Publications: (1980)
3. Avery's drug treatment, by T.M. Speight, NH Holford, Wiley-Black well, 4th edition, 1997, Adis international Limited. Auckland, Newzealand.
4. Remington Pharmaceutical Sciences, Carless, J.E. 13th edition.Lippin cott & Wilkins 2010.
5. Relevant review articles from recent medical and pharmaceutical literature.

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(9S01105) MODERN PHARMACEUTICAL ANALYSIS - PRACTICALS

1. Simultaneous estimation of Paracetamol, Ibuprofen, Rifampicin and INH,aspirin and caffeine.
2. UV-Visible spectrum scanning of certain organic compounds- absorption and co- relation of structures, comparisons.
   a.Chloramphenicol
   b. Sulphadiazine
   c. Analgin
3. Effect of pH and solvent and 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.
7. Experiments based on HPLC and GC.
8. IR, NMR and Mass spectroscopy on 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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(9S09103) Hospital and Community Pharmacy (Practicals)

1. Critical study of two community pharmacies in the neighborhood for schedule M compliance.
2. Comparison of prescription handling in two community pharmacies.
3. Audit of OTC sales over a 24 hour period in a local community pharmacy
4. Social awareness programmes like health education, family planning, first aid, smoking cessation, screening programmes, immunisation, etc. and report.
5. Critical study of two community pharmacies in large hospitals.
7. Summation of the advice and recommendations at the community pharmacy.
8. Report on the establishment of a drug information center in a multispeciality hospital.
9. Report on hospitals drug and therapeutic committee and its role.
10. Layout and workflow patterns in the dispensary.
11. Preparations of Inventory for the following drugs and surgicals, based on ABC and VED Analysis.
    a) Injection ASV b) Injection Deriphylline
    c) Tablet Erythromycin d) Vitamin tablets
    e) Bandage cloth, vasofix
12. Data on procurements and storage of vaccine, sera and biological preparations
13 Counseling to in-patients suffering from asthma, hypertension, diabetes, tuberculosis, peptic ulcer, anemia and AIDS
14. Development of patient information leaflets.

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(9S09104) Mini Projects-I:

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

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(9S01201) Bio-Pharmaceutics and Pharmacokinetics (Theory)

1. **Bioavailability:** Designing of bioavailability and bioequivalence studies and interpretation of results. Tests of significance - 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 like tablets, capsules, parenterals, liquid orals and topical dosage forms. Methods of assessing bioavailability, *In- vivo* methods

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, AUMC.
    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. **Time dependent pharmacokinetics**: Introduction, classification, physiologically induced time dependency, Chronopharmacokinetics.

7. **Clinical pharmacokinetics**: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver and renal disease states.

8. **Bioequivalence**: Regulations, Criteria for establishing a bioequivalence requirements, Types of bioequivalence requirements, bioequivalence testing, study design, assessment of bioequivalence, *In-vitro* dissolution studies, Qualification and Validation, *In - vitro – In -vivo* comparison, Dissolution limits, Controversies and concerns in bioequivalence.

Recommended Books

1. Biopharmaceutics & Cliwcal Pharmacoinetics **Gibaldi M.,** 54 Pharma book syndicate 4th edition vol II edition:1982
2. Dissolution, Bioavailability and bioequivalence, **Abtou, H.M.,**Mack publishing Co, Easton, PA. 2006, Sep 18. 1st edition, 1989
3. Text book of Biopharmaceutical Analysis, **Smith, RV & Stewart JT,**Lea and Febiger, Philadelphia. Sep 21, 2006.
4. Fundamentals of Clinical Pharmacokinetics, **Wagner JG,** Drug intelligence Pub. Hamilton, 111, 1975.
5. Pharmaceutical Bioequivalence, **Welling, P.G., Tse, FIS & Dighe, S.V. (eds),** Marcel & Decker Vol.48 Inc, New York. 1981 vol.48
6. Clinical Pharmacokinetics- **Rowland, M & Tozer, T.N.** Concept and Applications, Lea & febiger, USA. Mar 8, 2011. Lippin cott Wiliams & Wilkins, 2011.
7. Applied Biopharmaceutics & Pharmacokinetics, **Shargel, L & Yu, ABC,** Appleton and Lange, Connecticut, USA. Mc Graw hill Publications 4th edition.
8. Biopharmaceutics and Clinical Pharmacokinetics, **Notari, RE,** Marcel Dekker Inc, New York and Basel. 4th edition 1988 (revised & expanded)
9. Computer applications in Pharmaceutical research and development **Seaqn Ekins** Wily Interscience 2006

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(9S09201) Pharmacotherapeutics-II

Pathophysiology and pharmacotherapy of diseases associated with following systems/diseases and special references to the drug of choice in conditions like pregnancy, lactation, geriatrics and paediatrics.

1. **Cardiovascular system:**
   Hypertension, Congestive cardiac failure, Ischaemic Heart disease, Myocardial infarction, Arrhythmias, Hyperlipidaemias.

2. **Respiratory system:**
   Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

3. **Oncology:**
   General principles of cancer chemotherapy, commonly used cytotoxic drugs, Chemotherapy of lung cancer, haematological malignancies, Management of nausea and vomiting.

4. **Renal system:**
   Acute and Chronic renal failure, Renal dialysis and transplantation, Drug induced renal disease.

5. **Ophthamology:**
   Glaucoma, Eye infections

6. **Infectious diseases:**
   General guidelines for the rational use of antibiotics, Meningitis, Respiratory tract infections, Gastroenteritis, Septicemia, Otitis media, Urinary tract infections, Tuberculosis, Malaria, Helmenthiasis, Fungal infections,

7. **Skin and sexually transmitted diseases:**
   Psoriasis, Eczema and scabies, HIV and opportunistic infections, Syphillis and Gonorrhoea, Drug related skin reactions

8. **General Prescribing Guidelines:**
   Pediatric and geriatric patients. Pregnancy and breast feeding.

Recommended Books

1. Clinical Pharmacy and therapeutics- by **Roger Walker &** cate whittels, Churchill Livingstone 4th edition publication. 2011
2. Pharmacotherapy : A Patho-physiological approach- by **Joseph T**. Dipiro et al. 6th edition McGraw hill Publication. 2011
3. Pathologic basis of diseases- by **Robins SL, W.B**.Saunders publication 5th edition. 2004
4. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. Russell Russell, 3rd edition, Pharmaceutical Press, 2008.
5. Pathology and Theapeutics for Pharmaeists: A Basis for Clinical Practice-Green and Harris, Chapman & Hall. 1994 illustrated edition.
6. Clinical Pharmacy and therapeutics- **Eric Herfindal**, Williams and Wilkins Publication. 5th edition, 1992.
7. Applied Therapeutics: the clinical use of drugs. **Lloyd Young and Koda**-Kimble MA [ISBN 0 333-65881-7]. 3rd edition, 1983.
8. Avery's drug treatment, by T.M. Speight, NH Holford, Wiley-Black well, 4th edition, 1997, Adis international Limited. Auckland, Newzealand.

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(9S09202) Clinical Pharmacy Practice

1. **Definitions, development and scope of clinical pharmacy:**

2. **Clinical Pharmacy Services:**
   Introduction to daily activities of a clinical pharmacist, Pharmaceutical care, Ward round participation**,** Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)**,** Medication history**,** Patient counseling**,** Drug information and poison information**,** Adverse drug reaction management**,** Drug utilization evaluation (DUE) and review (DUR)**,** Quality assurance of clinical pharmacy services.

3. **Patient Data & Practice Skills*:*** Patient's case history - its structure and significances in drug therapy management. Common medical abbreviations and terminologies used in clinical practice. Communication skills: Verbal and non-verbal communications, its applications in patient care services, medication history interview and presentation of cases.

4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results:**
   Haematological tests, Renal function tests, Liver function tests, Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, and microbiological culture sensitivity tests

5. **Pharmacoepidemiology:**
   Definitions and scope, Methods [Sources of data, study design, drug utilisation studies, Meta-analysis] Social, cultural and economic factors influencing drug use. Systems for monitoring drug effects, advantages and disadvantages of pharmacoepidemiology.

6. **Drug & Poison information:**
   Introduction to drug information and Drug Information resources, Systematic approach in answering DI queries, Critical evaluation of drug information and literature, Preparation of written and verbal reports, Establishing a Drug Information Centre, Poison information- organization & information resources.

7. **Pharmacoeconomics:**
   Definitions and scope, types of economic evaluation, cost models and cost effectiveness Analysis

8. **Therapeutic Drug Monitoring:**
   Theoretical basis for TDM service and its applications

Recommended Books

1. Clinical Pharmacy and therapeutics- by **Roger Walker &** cate whittels, Churchill Livingstone 4th edition publication. 2011
2. Pharmacotherapy : A Patho-physiological approach- by **Joseph T**. Dipiro et al. 6th edition McGraw hill Publication. 2011
3. Pathologic basis of diseases- by **Robins SL, W.B**.Saunders publication 5th edition. 2004
4. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice. Russell Russell, 3rd edition, Pharmaceutical Press, 2008.
5. Pathology and Theapeutics for Pharmaeists: A Basis for Clinical Practice-Green and Harris, Chapman & Hall. 1994 illustrated edition.
6. Clinical Pharmacy and therapeutics- **Eric Herfindal**, Williams and Wilkins Publication. 5th edition, 1992.
7. Applied Therapeutics: the clinical use of drugs. **Lloyd Young and Koda**-Kimble MA [ISBN 0 333-65881-7]. 3rd edition, 1983.
8. Avery's drug treatment, by T.M. Speight, NH Holford, Wiley-Black well, 4th edition, 1997, Adis international Limited. Auckland, Newzealand.

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(9S09203) Clinical Research and Development (Theory)

1. Introduction to Clinical Research:
Definitions and terminology used in clinical trials, Historical development in clinical research practice.

2. **Drug development process:**
Investigational new drug development and Hatch Waxman Act

3. Ethics in Biomedical Research:
Ethical Issues in Biomedical Research – Principles of ethics in biomedical research
Ethical committee [institutional review board], its constitution and functions,

4. **Guidelines for Good Clinical Practices:**
[ICH GCP guidelines, Schedule Y (CDSCO regulations), EMEA, MHRA, and USFDA guidelines in the conduct of clinical trials]

5. **Safety Monitoring in Clinical Trails (ICH E2):**
Adverse event and serious adverse event reporting in clinical trials, emphasis on SUSAR's and managing and reporting of events.

6. **Research Design Methods:**
Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, 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)

7. 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

8. Analysis and reporting of clinical trials (ICH E3 and ICH E9).
   Monitoring and auditing of clinical trials
   Trial report generation
   Site closure
   Medical Writing and Ethics of publication
   Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Recommended Books

1. Handbook of clinical research. **Julia Lloyd and Ann Raven Ed**. Churchill Livingstone c. Elsevier, 2010. 1994 2nd edition
2. Principles of Clinical Research edited by **Giovanna di Ignazio**, Di Giovanna and Haynes. Aug 8, 2010.
3. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines For Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
4. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. **ICH Harmonized Tripartite Guideline.** Guideline for Good Clinical Practice.E6; May 1996.
5. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
6. Textbook of Clinical Trials edited by **David Machin**, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
7. Clinical Data Management edited by **R K Rondels, S A Varley, C F Webbs.** Second Edition, Jan 2000, Wiley Publications.

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(9S09204) Pharmacotherapeutics-II (Practicals)

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 15 cases should be presented and recorded covering most common
diseases. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in their practical records following SOAP [Subjective, Objective, Assessment, and Plan] technique.

1. Hypertension
2. CCF
3. Hypothyroidism
4. Hyperthyroidism
5. Acute renal failure
6. Chronic renal failure
7. Asthma
8. Depression
9. Anxiety
10. Epilepsy
11. Parkinson's disease
12. Stroke
13. Infectious diseases [any five]

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(9S09205) Clinical Pharmacy Practice (Practicals)

1. The students should be trained in the following aspects of services provided at the hospital and should be assessed for their performance on the same. The students are required to submit a record of activities (1-5) performed, which includes the strategies used.
2. Patient Medication Interviews
3. Answering Drug Information Queries.
4. Patient Medication Counselling .
5. Literature Evaluation .
6. Therapeutic Drug Monitoring (Any two drugs)
7. Problem solving in Clinical Pharmacokinetics .
8. Ward Round Participation.
9. Medication order review.
10. Detection and assessment of adverse drug reactions and their documentation .

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(9S09206) Mini Project-II:

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

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(9S09401) Seminar

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(9S09402) Project Work

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The project work should be on a contemporarary topic relevant to the core subjects of the course. It should be the original work of the candidate.