JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Draft Academic Regulations for the Award of Full Time M.Tech. P.G. Degree
(WITH EFFECT FROM THE ACADEMIC YEAR 2017-18 ONWARDS)

The Jawaharlal Nehru Technological University Anantapur shall confer M. Tech. Post Graduate degree to candidates who are admitted to the Master of Technology Programs and fulfill all the requirements for the award of the degree.

1.0 ELIGIBILITY FOR ADMISSIONS:

Admission to the above programmes shall be made subject to the eligibility, qualifications and specialization prescribed by the University for each Programme, from time to time.

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.Tech. 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.

2.4 The medium of instruction shall be English for all theory and practical courses, examinations, Seminar, Teaching Assignments, Comprehensive Viva-Voce and project thesis/dissertation reports.

3.0 ATTENDANCE:

3.1 A candidate shall be deemed to have eligibility to write end semester examinations if he/she has put in atleast 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/she 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 program shall be evaluated subject wise, with a maximum of 100 marks for theory and 100 marks for practical examination, on the basis of Internal Evaluation and End Examination.

4.1. There shall be five units in each of the theory subjects. For the theory subjects 60% of the marks will be for the End Examination and 40% of the marks will be for Internal Evaluation.

4.2. Two Internal Examinations shall be held during the semester for 20 marks. First internal examination shall be conducted for half of the syllabus and second internal examination shall be conducted for remaining half of the syllabus. In each internal exam, a student shall answer all three questions in 2 hours of time without seeking any choice. Final Internal marks for a total of 20 marks shall be arrived at by considering the marks secured by the student in both the internal examinations with 70% weightage to the better internal exam and 30% to the other.

4.3. For the remaining 20 marks in internal evaluation, the University shall conduct one online examination.

4.4. The following pattern shall be followed in the End Examination.

a) Five questions shall be set from each of the five units with either/or type for 12 marks each.
b) All the questions have to be answered compulsorily.
c) Each question may consist of one, two or more bits.

4.5. 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.

4.6. For **Comprehensive Viva-Voce** and **Seminar** there will be an internal evaluation of 100 marks in each. A candidate has to secure a minimum of 50% (in each) to be declared successful. The assessment will be made by a board consisting of HOD and two senior internal experts at the end of **III** semester instruction.

4.7. For **Teaching Assignments** there will be an internal evaluation of 100 marks. A candidate has to secure a minimum of 50% to be declared successful. Student has to teach 10 Hours in his/her interesting subject/subjects in the entire III Semester instruction period for his juniors at PG level or Under Graduate students who are available on the campus. For each teaching hour maximum of 10 marks are allotted. The assessment will be made by the faculty allotted by the HOD.

4.8. Mandatory MOOCs course is introduced in III Semester as an elective without any credits. A student can choose any subject of his/her choice that has more than 30 hours duration from any MOOCs provider and should obtain satisfactory certificate. An Open Elective is introduced in III semester.

4.9. 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. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified above) 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.

4.10. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified in 4.9.) 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 and III** 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 **three** 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 Ananthapuramu 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 evaluation 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 Semester)

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 **first phase of the project work** on the project shall be initiated in the third semester and **second phase of the project work will be** 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 from the Head of the Institution.

6.4 The student must submit status report by giving seminar in three different phases **(one in III semester and another two in IV semester)** during the project work period. These seminar 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 obtaining plagiarism report with less than 30% and 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 format by the supervisor & HOD shall be presented to the HOD. One copy is to be forwarded to the University and one copy to be sent to the examiner.

6.7 The college shall submit a panel of three experts for a maximum of **five** 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. Satisfactory Grade A
2. Not satisfactory Grade B

If the report of the viva-voce is not satisfactory (Grade B) 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 the thesis.

7.0 GRADING

After each subject is evaluated for 100 marks, the marks obtained in each subject will be converted to a corresponding letter grade as given below, depending on the range in which the marks obtained by the student fall.

Letter Grade	Marks Range	Grade Point
S	91-100	10
A	81-90	9
B	70-80	8
C	60-69	7
D	55-59	6
E	50-54	5
F	<50	0
Absent	Ab (Absent)	0

A student obtaining Grade F shall be considered failed and will be required to reappear for that subject when the next supplementary examination offered.

Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA):

The Semester Grade Point Average (SGPA) is the ratio of sum of the product of the number of credits with the grade points scored by a student in all the courses taken by a student and the sum of the number of credits of all the courses undergone by a student, i.e.

$$\text{SGPA} = \sum_{i=1}^{n}(\text{Ci} \times \text{Gi}) / \sum_{i=1}^{n} \text{Ci}$$

Where, Ci is the number of credits of the i^{th} subject, Gi is the grade point scored by the student in the i^{th} course and n is the no. of subjects.

The Cumulative Grade Point Average (CGPA) will be computed in the same manner taking into account all the courses undergone by a student over all the semesters of a program, i.e.

$$\text{CGPA} = \sum_{i=1}^{n}(\text{Ci} \times \text{Si}) / \sum_{i=1}^{n} \text{Ci}$$

Where 'Si' is the SGPA of the i^{th} semester, Ci is the total number of credits in that semester and n is the no. of semesters.
Both SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

While computing the SGPA the subjects in which the student is awarded Zero grade points will also be included.

Grade Point: It is a numerical weight allotted to each letter grade on a 10-point scale.
Letter Grade: It is an index of the performance of students in a said course. Grades are denoted by letters as mentioned in the above table.

8.0 AWARD OF DEGREE AND CLASS:

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

Class Awarded	**CGPA Secured**
First class with Distinction	>= 8
First class	>= 7 and < 8
Second class	>= 5 and < 7

9.0 WITH – HOLDING OF RESULTS:

If the candidate has not paid dues to the university or if any case of in-discipline 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.

10.0 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 4.10 and 2.3 sections. Whereas they continue to be in the academic regulations they were first admitted.

11.0 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 places 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 rolls with effect from the dates notified by the University.**

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	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

	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.	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-Pharmacology
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	*17S01101*	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2	*17S01102*	Advanced Pharmacology-I	4	-	-	4
3	*17S01103*	Pharmacological and Toxicological Screening Methods-I	4	-	-	4
4	*17S01104*	Cellular and Molecular Pharmacology	4	-	-	4
5	***17S01105***	**Pharmaceutical Analysis Practical for Pharmacology**	**-**	**-**	**6**	**3**
6	*17S01106*	Pharmacology Practical I	-	-	6	3
7	*17S01107*	Seminar/Assignment	-	-	7	4
		Total	16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	*17S01201*	Advanced Pharmacology II	4	-	-	4
2	*17S01202*	Pharmacological and Toxicological Screening Methods-II	4	-	-	4
3	*17S01203*	Principles of Drug Discovery	4	-	-	4
4	*17S01204*	Clinical Research and Pharmacovigilance	4	-	-	4
5	*17S01205*	Pharmacology Practical II	-	-	6	3
6	*17S01206*	Pharmacology Practical III	-	-	6	3
7	*17S01207*	Seminar/Assignment	-	-	7	4
		Total	16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	*17S01301*	Research Methodology and Biostatistics	4	-	-	4
2.	*17S01302*	Journal Club	1	-	-	1
3.	*17S01303*	Teaching Assignment	10	-	-	2
4.	*17S01304*	Comprehensive viva voce	-	-	-	2
5.	*17S01305*	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	*17S01306*	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	*17S01401*	Journal Club	1	-	-	1
2.	*17S01402*	Research work	31	-	-	16
3.	*17S01403*	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01101) **MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1. 11 hrs

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. 11hrs

NMR spectroscopy: Quantum numbers and their role in NMR,Principle, Instrumentation, Solvent requirement in NMR,Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applicationsof NMR spectroscopy.

3. 11hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4.

11hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a)Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography d) Column chromatographye) Gas chromatography f) High Performance Liquidchromatographyg) Affinity chromatography

5 11hrs

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
b. X ray Crystallography: Production of X rays, Different X raydiffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of Xray diffraction.
c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

***(17S01102)* ADVANCED PHARMACOLOGY - I**

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to :

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1. 12Hrs

General Pharmacology

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Proteinbinding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2 12Hrs

Neurotransmission

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system(Detailed study about neurotransmitters- Adrenaline and Acetylcholine).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3 12Hrs

Central nervous system Pharmacology

General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerativediseases.

Narcotic and non-narcotic analgesics.

4 12Hrs

Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics,drugs for heart failure and hyperlipidemia.

Hematinics, coagulants , anticoagulants, fibrinolytics and antiplateletdrugs

5 12Hrs

Autocoid Pharmacology

The physiological and pathological role of Histamine, Serotonin,Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts andApplications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied bio-pharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)

L	T	P	C
4	0	0	4

***(17S01103)* PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I**

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY 60 Hrs

1. 12Hrs

Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals.

CPCSEA guidelines to conduct experiments on animals and Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

2 12Hrs

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3 12Hrs

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD andanti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyreticagents.

Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrhealand laxatives.

4

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.Anti cancer agents. Hepatoprotective screening methods.

5 12Hrs

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition,Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), Ajay Prakash (Author)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01104) CELLULAR AND MOLECULAR PHARMACOLOGY

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable forpharmacology

THEORY 60 Hrs

1. 12Hrs

Cell biology : Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

2 12Hrs

Cell signaling Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligandgated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion,inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3 12Hrs

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA andwestern blotting, Recombinant DNA technology and gene therapy. Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinantDNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4 12Hrs

Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics. Immunotherapeutics

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

5 12Hrs

a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry

b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M - L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickensonet.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by FrederickM.Ausuvel et al.

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M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01105) **PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACOLOGY**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis-spectrophotometer
2.Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Estimation of proteins by Braford/Lowry's in biological samples.
8. Estimation of RNA/DNA by UV Spectroscopy
9. Protein quantification Western Blotting.
10. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using soft wares
11. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
12. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01106) **PHARMACOLOGY PRACTICAL - I**

1. Handling of laboratory animals.
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic,anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic andmiotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria,Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Gene amplification by PCR.
12. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
13. Cell viability assays (MTT/Trypan blue/SRB).
14. DNA fragmentation assay by agarose gel electrophoresis.
15. DNA damage study by Comet assay.
16. Apoptosis determination by fluorescent imaging studies.
17. Enzyme inhibition and induction activity

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01201) **ADVANCED PHARMACOLOGY - II**

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1. 12Hrs

Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

2 12Hrs

Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

3 12Hrs

Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immuneresponse. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

4 12Hrs

GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy invarious diseases likecardiovascular disease, diabetes, asthma and peptic ulcer

5 12Hrs

Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T.Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (RobbinsPathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

***(17S01202)* PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS-II**

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY 60 Hrs

1. 12Hrs

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH,EPA and Schedule YOECD principles of Good laboratory practice (GLP). History, concept and its importance in drug development.

2 12Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

3 12Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)In vivo carcinogenicity studies

4 12Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

5 12Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical researchand development (http://www.who.int/tdr/publications/documents/glphandbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) NewDelhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conductof Human Clinical Trials and Marketing Authorization for Pharmaceuticals(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01203) **PRINCIPLES OF DRUG DISCOVERY**

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY 60 Hrs

1. 12Hrs

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Proteinmicro-arrays, Antisense technologies, siRNAs, antisenseoligo nucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2 12Hrs

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3 12Hrs

Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

4 12Hrs

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

5 12Hrs

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug

absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01204) **CLINICAL RESEARCH AND PHARMACOVIGILANCE**

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY 60 Hrs

1. 12Hrs

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2 12Hrs

Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3 12Hrs

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4 12Hrs

Basic aspects, terminologies and establishment of Pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory

terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

5 12Hrs

a. Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, Vigi Flow, Statistical methods for evaluating medication safety data.

b . Pharmacoepidemiology, pharmacoeconomics, safetypharmacology

REFERENCES

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

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01205) **PHARMACOLOGICAL PRACTICAL - II**

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonistusing suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay byusing suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassayby using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassayby using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple pointbioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolatedtissue preparations.
8. Drug absorption studies by averted rat ileum preparation.
9. ADR reporting

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01206) **PHARMACOLOGY PRACTICALS-III**

1. To study the effects of various drugs on isolated heart preparations
2. Recording of rat BP, heart rate and ECG.
3.. Recording of rat ECG
4. Acute oral toxicity studies as per OECD guidelines.
5. Acute dermal toxicity studies as per OECD guidelines.
6. Repeated dose toxicity studies- Serum biochemical, haematological, urineanalysis, functional observation tests and histological studies.
7. Drug mutagenicity study using mice bone-marrow chromosomal aberrationtest.
8.. Protocol design for clinical trial.(3 Nos.)
9. Design of ADR monitoring protocol.
10. In-silico docking studies. (2 Nos.)
11. In-silico pharmacophore based screening.
12. In-silico QSAR studies.

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbalchoudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists.,

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M. Pharm – III Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

General Research Methodology: Research, objective, requirements ,practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.