

Draft Academic Regulations - M.Tech. 2017-18 (Important Points)



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/PGET 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.

$$SGPA = \frac{\sum_{i=1}^n (C_i \times G_i)}{\sum_{i=1}^n C_i}$$

Where, C_i is the number of credits of the i^{th} subject, G_i 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.

$$CGPA = \frac{\sum_{i=1}^n (C_i \times S_i)}{\sum_{i=1}^n C_i}$$

Where 'S_i' is the SGPA of the i^{th} semester, C_i 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
	<i>If the candidate</i>	
1.	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.
(a)	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.
(b)	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
2.		

		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	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.

	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.	
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.

★★★★★★

Note: Draft M.Tech Regulations will be followed for M.Pharm also

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Industrial Pharmacy
(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	17S08101	Pharmaceutical Formulation Development	4	-	-	4
3	17S08102	Novel drug delivery systems	4	-	-	4
4	17S08103	Intellectual Property Rights	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S08104	Pharmaceutical Formulation Development Practical - I	-	-	6	3
7	17S08105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S08201	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4
2	17S08202	Scale up and Technology Transfer	4	-	-	4
3	17S08203	Pharmaceutical Production Technology	4	-	-	4
4	17S08204	Entrepreneurship Management	4	-	-	4
5	17S08205	Industrial Pharmacy Practical II	-	-	6	3
6	17S08206	Industrial Pharmacy Practical III	-	-	6	3
7	17S08207	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.	17S08301	Journal Club	1	-	-	1
3.	17S08302	Teaching Assignment	10	-	-	2
4.	17S08303	Comprehensive viva voce	-	-	-	2
5.	17S08304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S08305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S08401	Journal Club	1	-	-	1
2.	17S08402	Research work	31	-	-	16
3.	17S08403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

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,

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

THEORY

60 HOURS

1.

11Hrs

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

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

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

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

3

11Hrs

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

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- a) Paper chromatography
- b) Thin Layer chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Affinity chromatography

5

16Hrs

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) Isoelectric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

b) Immunological Assays: Radioimmunity assay (RIA), ELISA(Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08101) PHARMACEUTICAL FORMULATION DEVELOPMENT

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY

60 Hrs

1.

12Hrs

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2

12Hrs

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

3

12Hrs

Solubility: Importance, experimental determination, phasesolubilityanalysis, pH-solubility profile, solubility techniques toimprove solubility and utilization of analytical methods –cosolvency, salt formation, complexation, solid dispersion, micellarsolubilization and hydrotropy.

4

12Hrs

Dissolution: Theories, mechanisms of dissolution, in-vitrodissolution testing models – sink and non-sink. Factorsinfluencing dissolution and intrinsic dissolution studies.Dissolution test apparatus – designs, dissolution testing forconventional and controlled release products. Data handling andcorrection factor. Biorelevant media, in-vitro and in-vivocorrelations, levels of correlations.

5

12Hrs

Product Stability: Degradation kinetics, mechanisms, stabilitytesting of drugs and pharmaceuticals, factors influencing-mediaeffects and pH effects, accelerated stability studies, interpretationof kinetic data (API & tablets). Solid state stability and shelf lifeassignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Connors KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer Pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rded., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rdCBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer(India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4thInc, New York, 2005.
11. W. Grimm - Stability testing of drug products.ed., Marcel Dekker
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II., 4th2004.ed., CBS Publishers & distributors, New Delhi,
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08102) NOVEL DRUG DELIVERY SYSTEMS

Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective

On completion of this course it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY

60 Hrs

1.

12Hrs

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

2

12Hrs

a) Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

b)

08Hrs

Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

04Hrs

Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and its regulatory aspects.

3

08Hrs Targeted

Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

4

04Hrs

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

06Hrs

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

5

06Hrs

New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, MarcelDekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker,NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

L	T	P	C
4	0	0	4

(17S08103) INTELLECTUAL PROPERTY RIGHTS

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY

60 Hrs

1.

12 Hrs

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

2 Role of GATT, TRIPS, and WIPO

12 Hrs

3

12 Hrs

Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

4

12 Hrs

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

5

12 Hrs

Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

L T P C
0 0 6 3

(17S01105) MODEREN PHARMACEUTICAL ANALYSIS PRACTICAL

1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Industrial Pharmacy)

L T P C
0 0 6 3

(17S08104) PHARMACEUTICAL FORMULATION DEVELOPMENT PRACTICAL - I

1. Effect of pH on the solubility of drugs.
2. Stability testing of solution and solid dosage forms for photo degradation.
3. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH.
4. Compatibility evaluation of drugs and excipients (DSC & FTIR).
5. Preparation and evaluation of different polymeric membranes.
6. Formulation and evaluation of sustained release oral matrix tablet/ oralreservoir system.
7. Formulation and evaluation of microspheres / microcapsules.
8. Formulation and evaluation of transdermal drug delivery systems.
9. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
10. Electrophoresis of protein solution.
11. Preparation and evaluation of Liposome delivery system.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08201) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives

On completion of this course it is expected that students will be able to understand,

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY

60 Hrs

1.

12Hrs

Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

2

12Hrs

Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro-In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

3

12Hrs

Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max} . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

4

12Hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

5

12Hrs

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. P. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08202) SCALE UP AND TECHNOLOGY TRANSFER

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY

60 Hrs

1.

12Hrs

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2

12Hrs

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

3

12Hrs

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

4

12Hrs

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiley.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08203) PHARMACEUTICAL PRODUCTION TECHNOLOGY

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

On completion of this course it is expected that students will be able to understand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY

60 Hrs

Improved Tablet Production: Tablet production process, unit

1.

12Hrs

operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

2

12Hrs

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

3

12Hrs

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

4

12Hrs

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered. Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra –filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Cheremisinoff.
8. Pharmaceutical Project Management, T. Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H. Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwood, UK.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L T P C
4 0 0 4

(17S08204) ENTREPRENEURSHIP MANAGEMENT

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY

60 Hrs

1.

12Hrs

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

2

12Hrs

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

3

12Hrs

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

4

12Hrs

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

Preparing Project Proposal To Start On New EnterpriseProject work – Feasibility report; Planning, resource mobilization and implementation.

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD,New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting,Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing NewEntrepreneurs, Ahmedabad EDII.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L	T	P	C
0	0	6	3

(17S08205) INDUSTRIAL PHARMACY PRACTICAL - II

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Industrial Pharmacy)

L	T	P	C
0	0	6	3

(17S08206) INDUSTRIAL PHARMACY PRACTICAL - III

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Industrial Pharmacy)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis & Quality Assurance
(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	17S04101	Quality Management System	4	-	-	4
3	17S04102	Quality control and Quality Assurance	4	-	-	4
4	17S04103	Audit and Regulatory Compliance	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S04104	Quality Control And Quality Assurance Practical - I	-	-	6	3
7	17S04105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S04201	Hazards and safety management	4	-	-	4
2	17S04202	Pharmaceutical Validation	4	-	-	4
3	17S04203	Advanced Pharmaceutical Analysis	4	-	-	4
4	17S04204	Modern Bio analytical Techniques	4	-	-	4
5	17S04205	Hazards And Safety Management Practical - II	-	-	6	3
6	17S04206	Food Analysis Practical - II0049	-	-	6	3
7	17S04207	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.	17S04301	Journal Club	1	-	-	1
3.	17S04302	Teaching Assignment	10	-	-	2
4.	17S04303	Comprehensive viva voce	-	-	-	2
5.	17S04304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S04305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S04401	Journal Club	1	-	-	1
2.	17S04402	Research work	31	-	-	16
3.	17S04403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

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,

- 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. Spectrofluorimetry: 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. 11 hrs
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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.
3. 11 hrs
Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole 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 chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) 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 ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.

c. Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L T P C
4 0 0 4

(17S04101) QUALITY MANAGEMENT SYSTEMS

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

THEORY

60 Hrs

1.

12Hrs

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality, Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

2

12Hrs

Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Sixsigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical

Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

3

12Hrs

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self-inspection.

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

4

16Hrs

- a. Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report
- b. Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.
- c. Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

5

8Hrs

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000

2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. DeFeo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L T P C
4 0 0 4

(17S04102) QUALITY CONTROL AND QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY

60 Hrs

1.

12Hrs

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

2.

12Hrs

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

3.

12Hrs

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of

stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4.

12Hrs

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

5.

12Hrs

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L T P C
4 0 0 4

(17S04103) AUDITS AND REGULATORY COMPLIANCE

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY 60 Hrs

1. 12Hrs

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

2 12Hrs

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

3 12Hrs

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

4 12Hrs

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L T P C
4 0 0 4

(17S01105) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Calibration of UV – Visible Spectrophotometer/ HPLC/ GC/ FTIR
14. Cleaning validation of any one analytical equipment

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L T P C
0 0 6 3

(17S04104) QUALITY CONTROL AND QUALITY ASSURANCE PRACTICAL - I

1. Case studies on

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

2. Development of Stability study protocol

3. Estimation of process capability

4. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.

5. Assay of raw materials as per official monographs

6. Testing of related and foreign substances in drugs and raw materials

7. To carry out pre formulation study for tablets, parenterals (2 experiments).

8. To study the effect of pH on the solubility of drugs, (1 experiment)

9. Quality control tests for Primary and secondary packaging materials

10. Accelerated stability studies (1 experiment)

11. Improved solubility of drugs using surfactant systems (1 experiment)

12. Improved solubility of drugs using co-solvency method (1 experiment)

14. Determination of Pka and Log p of drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
4 0 0 4

(17S04201) HAZARDS AND SAFETY MANAGEMENT

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY

60Hrs

1.

12Hrs

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems,

a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem.
Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

2

12Hrs

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

3

12Hrs

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organicsolvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygendisplacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

4

12Hrs

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

5

12Hrs

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
4 0 0 4

(17S04202) PHARMACEUTICAL VALIDATION

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY

60 Hrs

1.

10Hrs

Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).

2

16Hrs

- a. Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.
- b. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

c. Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

3

12Hrs

Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

4

10Hrs

Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP

5

12Hrs

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property – patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications. Filing a patent applications; patent application forms and guidelines. Types of patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirements, procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.

2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up”, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
4 0 0 4

(17S04203) ADVANCED PHARMACEUTICAL ANALYSIS

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall be able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1.

12Hrs

Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines
Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2

12Hrs

Elemental impurities:

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3

12Hrs

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photo stability testing guidelines, ICH stability guidelines for biological products

4

14Hrs

a) Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

b) Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

5

10Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
4 0 0 4

(17S04204) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 Hrs

1.

12Hrs

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid-Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2

12Hrs

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

3

12Hrs

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4

12Hrs

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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5

12Hrs

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.

9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

10. ICH, USFDA & CDSCO Guidelines.

11. Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
0 0 6 3

(17S04205) HAZARDS AND SAFETY MANAGEMENT PRACTICAL - II

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Check list for Bulk Pharmaceutical Chemicals vendors
8. Check list for tableting production.
9. Check list for sterile production area
10. Check list for Water for injection.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QA)

L T P C
0 0 6 3

(17S04206) FOOD ANALYSIS PRACTICAL - III

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (PA & QA)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis & Quality Control
(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	17S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3	17S07103	Food Analysis	4	-	-	4
4	17S04103	Audit and Regulatory Compliance	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S07105	Food Analysis Practical-I	-	-	6	3
7	17S12101	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S07201	Advanced Instrumental Analysis	4	-	-	4
2	17S07202	Modern Bio analytical Techniques	4	-	-	4
3	17S07203	Quality Control and Quality Assurance	4	-	-	4
4	17S07204	Herbal and Cosmetic Analysis	4	-	-	4
5	17S12201	Herbal And Cosmetic Analysis Practical -II	-	-	6	3
6	17S12202	Advanced Instrumental Analysis Practical -IV	-	-	6	3
7	17S12203	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.	17S12301	Journal Club	1	-	-	1
3.	17S12302	Teaching Assignment	10	-	-	2
4.	17S12303	Comprehensive viva voce	-	-	-	2
5.	17S12304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S12305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S12401	Journal Club	1	-	-	1
2.	17S12402	Research work	31	-	-	16
3.	17S12403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

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,

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

THEORY

60 HOURS

1.

11Hrs

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

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

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

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

3

11Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole 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 chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Affinity chromatography

5

16Hrs

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

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Immunological Assays: Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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,3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson,Volume 11, Marcel Dekker Series.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L T P C
4 0 0 4

(17S07101) ADVANCED PHARMACEUTICAL ANALYSIS

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall be able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1.

10Hrs

Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines
Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2

10Hrs

Elemental impurities:

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C,H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3

10Hrs

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

4

16Hrs

Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC fingerprinting, interactions and complexity.

Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

5

14Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J.Mendham, R. C. Denney, 5th edition, ELBS, 1991.
 2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4thEdition, CBS publishers, New Delhi, 1997.
 3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, JohnWiley& Sons, 1982.
- 102
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition,Wiley – Inter science Publication, 1961.
 5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
 6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B,Volume 11, Marcel Dekker Series.
 7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBSPublishers, NewDelhi, 1964.
 8. Indian Pharmacopoeia VoII , II & III 2007, 2010, 2014.
 9. Methods of sampling and microbiological examination of water, firstrevision, BIS
 10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley & Sons.
 11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
 12. Analytical Profiles of drug substances and Excipients – Harry G Brittan,Volume 21 – 30, Elsevier, 2005.
 13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press, London.
 14. ICH Guidelines for impurity profiles and stability studies.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L T P C
4 0 0 4

(17S07103) FOOD ANALYSIS

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY

60 Hrs

1.

12Hrs

Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates
Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2

12Hrs

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3

12Hrs

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4

12Hrs

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

5

12Hrs

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L T P C
4 0 0 4

(17S04103) AUDITS AND REGULATORY COMPLIANCE

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY

60 Hrs

1.

12Hrs

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

2

12Hrs

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

3

12Hrs

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

4

12Hrs

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L T P C
0 0 6 3

**(17S01105) MODERN PHARMACEUTICAL ANALYTICAL
TECHNIQUES PRACTICAL**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Calibration of UV – Visible Spectrophotometer/ HPLC/ GC/ FTIR
14. Cleaning validation of any one analytical equipment

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L	T	P	C
0	0	6	3

(17S07105) FOOD ANALYSIS PRACTICAL -I

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
4 0 0 4

(17S07201) ADVANCED INSTRUMENTAL ANALYSIS

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60 Hrs

1.

12Hrs

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nanoliquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

2

12Hrs

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3

12Hrs

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4

12Hrs

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrupole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).

5

12Hrs

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ¹³C NMR: Spin spin and spin lattice relaxation phenomenon. ¹³C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

8. Organic Spectroscopy by Donald L. Pavia, 5th Edition.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
4 0 0 4

(17S07202) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 Hrs

1.

12Hrs

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid-Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2

12Hrs

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

3

12Hrs

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4

12Hrs

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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5

12Hrs

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.

9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

10. ICH, USFDA & CDSCO Guidelines.

11. Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
4 0 0 4

(17S07203) QUALITY CONTROL AND QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY

60 hrs

1.

12Hrs

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

2.

12Hrs

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

3.

12Hrs

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for

following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4.

12Hrs

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

5.

12Hrs

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
4 0 0 4

(17S07204) HERBAL AND COSMETIC ANALYSIS

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY

60 Hrs

1.

12Hrs

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

2

12Hrs

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3

12Hrs

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia,

American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4

12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

5

12Hrs

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lipsticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients

11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
0 0 6 3

(17S12201) HERBAL AND COSMETIC ANALYSIS PRACTICAL -II

1. Quantitative analysis of rancidity in lipsticks and hair oil
2. Determination of aryl amine content and Developer in hair dye
3. Determination of foam height and SLS content of Shampoo.
4. Determination of total fatty matter in creams (Soap, skin and hair creams)
5. Determination of acid value and saponification value.
6. Determination of calcium thioglycolate in depilatories
7. Determination of tannins
8. Determination of microorganisms in herbal products
9. Specifications for adsorbents used in TLC
10. Determination of total phenol content
11. Determination of aflatoxins
12. Determination of swelling index and foaming index
13. Quality control methods for herbal materials/ Medicinal plant materials

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (PA & QC)

L T P C
0 0 6 3

(17S12202) ADVANCED INSTRUMENTAL ANALYSIS PRACTICAL -IV

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Massspectra
7. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical methodvalidation.
11. Protocol preparation for the conduct of BA/BE studies according toguidelines.
12. In process and finished product quality control tests for tablets, capsules,parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (PA & QC)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Analysis
(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	17S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3	17S07102	Pharmaceutical Validation	4	-	-	4
4	17S07103	Food Analysis	4	-	-	4
5	17S07104	Pharmaceutical Analysis Practicals	-	-	6	3
6	17S07105	Food Analysis Practical - I	-	-	6	3
7	17S07106	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S07201	Advanced Instrumental Analysis	4	-	-	4
2	17S07202	Modern Bio-Analytical Techniques	4	-	-	4
3	17S07203	Quality Control And Quality Assurance	4	-	-	4
4	17S07204	Herbal and Cosmetic Analysis	4	-	-	4
5	17S07205	Pharmaceutical Analysis Practical II	-	-	6	3
6	17S07206	Pharmaceutical Analysis Practical III	-	-	6	3
7	17S07207	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.	17S07301	Journal Club	1	-	-	1
3.	17S07302	Teaching Assignment	10	-	-	2
4.	17S07303	Comprehensive viva voce	-	-	-	2
5.	17S07304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S07305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S07401	Journal Club	1	-	-	1
2.	17S07402	Research work	31	-	-	16
3.	17S07403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

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 Hrs

1.

10Hrs

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, Difference/ Derivative 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, Data Interpretation.

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2

10Hrs

a) 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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

10Hrs

b) Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers

of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy.

3

10Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a) Thin Layer chromatography
- b) High Performance Thin Layer Chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Ultra High Performance Liquid chromatography
- h) Affinity chromatography
- i) Gel Chromatography

4

10Hrs

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 ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5

10Hrs

a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L T P C
4 0 0 4

(17S07101) ADVANCED PHARMACEUTICAL ANALYSIS

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall be able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1.

10Hrs

Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines. Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2

10Hrs

Elemental impurities:

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3

10Hrs

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

4

16Hrs

a) Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC fingerprinting, interactions and complexity.

b) Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

5

14Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07102) PHARMACEUTICAL VALIDATION

SCOPE

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. This subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carry out validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 Hrs

1.

12Hrs

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

2

12Hrs

Qualification of analytical instruments: Electronic balance, pHmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

3

12Hrs

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

4

12Hrs

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP.

5

12Hrs

General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications. Filing a patent applications; patent application forms and guidelines. Types of patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirements, procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer of technology (TOT), IP and ethics- positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L T P C
4 0 0 4

(17S07103) FOOD ANALYSIS

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY

60 Hrs

1.

12Hrs

Carbohydrates: classification and properties of foodcarbohydrates, General methods of analysis of foodcarbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2

12Hrs

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3

12Hrs

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4

12Hrs

General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.

5

12Hrs

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L T P C
0 0 6 3

(17S07104) PHARMACEUTICAL ANALYSIS PRACTICALS

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography
13. Calibration of UV – Visible Spectrophotometer/ HPLC/ GC/ FTIR
14. Cleaning validation of any one analytical equipment

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Analysis)

L	T	P	C
0	0	6	3

(17S07105) FOOD ANALYSIS PRACTICAL - I

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Analysis of vitamin content in food products
9. Determination of density and specific gravity of foods
10. Determination of food additives
11. Determination of Aspartame in soft drinks
12. Determination of 4- imidazole in caramel
13. Determination of benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
14. UV Spectrophotometric methods for determination of sorbic acid in dairy products
15. Determination of nitrite and nitrate in food products

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L T P C
4 0 0 4

(17S07201) ADVANCED INSTRUMENTAL ANALYSIS

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60 Hrs

1.

12Hrs

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

2

12Hrs

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3

12Hrs

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and

method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4

12Hrs

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrupole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).

5

12Hrs

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ¹³C NMR: Spin spin and spin lattice relaxation phenomenon. ¹³C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Pavia, 5th Edition.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L T P C
4 0 0 4

(17S07202) MODERN BIO-ANALYTICAL TECHNIQUES

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 Hrs

1.

12Hrs

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid-Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2

12Hrs

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

3

12Hrs

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

4

12Hrs

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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5

12Hrs

Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaiach, 2nd Edition, John Wiley & Sons, New Jersey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
4	0	0	4

(17S07203) QUALITY CONTROL AND QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY

60 hrs

1.

12Hrs

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

2.

12Hrs

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

3.

12Hrs

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4.

12Hrs

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

5.

12Hrs

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L T P C
4 0 0 4

(17S07204) HERBAL AND COSMETIC ANALYSIS

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY

60 Hrs

1.

12Hrs

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

2

12Hrs

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3

12Hrs

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4

12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

5

12Hrs

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lipsticks, hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P.Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L T P C
0 0 6 3

(17S07205) PHARMACEUTICAL ANALYSIS PRACTICALS - II

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Massspectra
7. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniquesand Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalyticalmethodvalidation.
11. Protocol preparation for the conduct of BA/BE studies according toguidelines.
12. In process and finished product quality control tests for tablets, capsules,parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Analysis)

L	T	P	C
0	0	6	3

(17S07206) PHARMACEUTICAL ANALYSIS PRACTICALS - III

1. Quantitative analysis of rancidity in lipsticks and hair oil
2. Determination of aryl amine content and Developer in hair dye
3. Determination of foam height and SLS content of Shampoo.
4. Determination of total fatty matter in creams (Soap, skin and hair creams)
5. Determination of acid value and saponification value.
6. Determination of calcium thioglycolate in depilatories
7. Determination of tannins
8. Determination of microorganisms in herbal products
9. Specifications for adsorbents used in TLC
10. Determination of total phenol content
11. Determination of aflatoxins
12. Determination of swelling index and foaming index
13. Quality control methods for herbal materials/ Medicinal plant materials

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutical Analysis)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Chemistry
(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	17S02101	Advanced Organic Chemistry -I	4	-	-	4
3	17S02102	Advanced Medicinal chemistry	4	-	-	4
4	17S02103	Chemistry of Natural Products	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S02104	Pharmaceutical Chemistry Practical I	-	-	6	3
7	17S02105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S02201	Advanced Spectral Analysis	4	-	-	4
2	17S02202	Advanced Organic Chemistry -II	4	-	-	4
3	17S02203	Computer Aided Drug Design	4	-	-	4
4	17S02204	Pharmaceutical Process Chemistry	4	-	-	4
5	17S02205	Pharmaceutical Chemistry Practical II	-	-	6	3
6	17S02206	Pharmaceutical Chemistry Practical III	-	-	6	3
7	17S02207	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.	17S02301	Journal Club	1	-	-	1
3.	17S02302	Teaching Assignment	10	-	-	2
4.	17S02303	Comprehensive viva voce	-	-	-	2
5.	17S02304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S02305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S02401	Journal Club	1	-	-	1
2.	17S02402	Research work	31	-	-	16
3.	17S02403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

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 Hrs

1.

10Hrs

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, Difference/ Derivative 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, Data Interpretation.

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2

10Hrs

a) 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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

10Hrs

b) Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers

of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy.

3

10Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a) Thin Layer chromatography
- b) High Performance Thin Layer Chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Ultra High Performance Liquid chromatography
- h) Affinity chromatography
- i) Gel Chromatography

4

10Hrs

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 ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5

10Hrs

a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical

applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

L T P C
4 0 0 4

(17S02101) ADVANCED ORGANIC CHEMISTRY - I

SCOPE

The subject is designed to provide in-depth knowledge about advances inorganic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY

60 Hrs

1.

12Hrs

Basic Aspects of Organic Chemistry:

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them,
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

- a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- c) Rearrangement reaction

2

12Hrs

Study of mechanism and synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

3

12Hrs

Synthetic Reagents & Applications:

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig reagent, Osmium tetroxide, titanium chloride, diazopropane, diethylazodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris(dimethylamino) phosphoniumhexafluoro-phosphate (BOP).

Protecting groups

- a. Role of protection in organic synthesis
- b. Protection for the hydroxyl group, including 1,2- and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
- c. Protection for the Carbonyl Group: Acetals and Ketals
- d. Protection for the Carboxyl Group: amides and hydrazides, esters
- e. Protection for the Amino Group and Amino acids: carbamates and amides

4

12Hrs

Heterocyclic Chemistry:

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six-membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis, Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

5

12Hrs

Synthon approach and retrosynthesis applications

- i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
- ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
- iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", JMarch, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchartand Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers.,OxfordUniversity Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts,Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (OrientLongman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford& IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen RWilson& Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, NelsonThorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal,Narosa Publishers.
12. Organic Reaction Mechanisms IVthEdtn, VK Ahluwalia and RK Parashar,Narosa Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

L	T	P	C
4	0	0	4

(17S02102) ADVANCED MEDICINAL CHEMISTRY

SCOPE

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY

60 Hrs

1.

12Hrs

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2

12Hrs

Prodrug Design and Analog design:

a) Prodrug design: Basic concept, Carrier linked prodrugs/Bioprecursors, Prodrugs of functional group, Prodrugstoimprove patient acceptability, Drug solubility, Drugabsorption and distribution, site specific drug deliveryand sustained drug action. Rationale of prodrugdesignand practical consideration of prodrug design.

b) Combating drug resistance: Causes for drugresistance, strategies to combat drug resistance inantibiotics and anticancer therapy, Genetic principles of drug resistance.

c) Analog Design: Introduction, Classical & Non classical,Bioisosteric replacement strategies, rigid analogs,alteration of chain branching, changes in ring size, ringposition isomers, design of stereo isomers andgeometric isomers, fragments of a lead molecule,variation in inter atomic distance.

3

12Hrs

Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H₁ & H₂ receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereoselectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4

12Hrs

Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5

12Hrs

Peptidomimetics Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxanes.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, III Edition, Oxford University Press, USA.

11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B.Jaiswal II Edition, 2014, VallabhPrakashan, New Delhi.

12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarnaand Andrea Trabocchi, First edition, Wiley publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

L T P C
4 0 0 4

(17S02103) CHEMISTRY OF NATURAL PRODUCTS

SCOPE

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

60 Hrs

1.

12Hrs

Study of Natural products as leads for new pharmaceuticals for the following class of drugs

- a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d) Neuromuscular Blocking Drugs: Curare alkaloids
- e) Anti-malarial drugs and Analogues
- f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2

12Hrs

a) Alkaloids

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3

12Hrs

a) Terpenoids

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotenoids (β carotene).

b) Vitamins

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4

12Hrs

a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulata*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenum-graecum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

5

12Hrs

Structural Characterization of natural compounds Structural characterization of natural compounds using IR, ¹H NMR, ¹³C NMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V. Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrand Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.

4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmanstall.
9. Organic Chemistry of Natural Products Vol I and II by GurdeepandChatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, KrishanPrakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

L T P C
0 0 6 3

(17S01105) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL

1. Analysis of Pharmacopoeial compounds and their formulations by UV Visspectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Chemistry)

L	T	P	C
0	0	6	3

(17S02104) PHARMACEUTICAL CHEMISTRY PRACTICAL - I

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents
11. Oxidation and free radical coupling
12. Fries rearrangement
13. Perkins reaction

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L	T	P	C
4	0	0	4

(17S02201) ADVANCED SPECTRAL ANALYSIS

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60Hrs

1.

12Hrs

UV and IR spectroscopy:

Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and α,β -carbonyl compounds and interpretation of enones. ATR-IR, IR Interpretation of organic compounds.

2

12Hrs

NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

3

12Hrs

Mass Spectroscopy

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

4

12Hrs

Chromatography:

Principle, Instrumentation and Applications of the following :

- a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS g) High Performance Thin Layer chromatography h) Supercritical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

- a). Thermal methods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA.
- b). Raman Spectroscopy Introduction, Principle, Instrumentation and Applications.
- c). Radio immunoassay Biological standardization , bioassay, ELISA, Radioimmunoassay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L T P C
4 0 0 4

(17S02202) ADVANCED ORGANIC CHEMISTRY - II

Scope

The subject is designed to provide in-depth knowledge about advances inorganic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY

60 Hrs

1.

12Hrs

Green Chemistry:

a. Introduction, principles of green chemistry

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocyclic synthesis

c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2

12Hrs

Chemistry of peptides

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

3

12Hrs

Photochemical Reactions

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. Pericyclic reactions Mechanism, Types of pericyclic reactions such as cycloaddition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

4

12Hrs

Catalysis:

- a. Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages
- b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- c. Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs
- d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- f. Phase transfer catalysis - theory and applications

5

12Hrs

Stereochemistry & Asymmetric Synthesis

- a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudoasymmetric centres, axes of symmetry, Fischer's D and L notation, cis-trans isomerism, E and Z notation.
- b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.

2. "Mechanism and structure in organic chemistry", ES Gould, Hold RinchartandWinston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers.,OxfordUniversity Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal,Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar,Narosa Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L	T	P	C
4	0	0	4

(17S02203) COMPUTER AIDED DRUG DESIGN

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory

60 Hrs

1.

12Hrs

Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (σ), lipophilicity effects and parameters ($\log P$, π -substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2

12Hrs

Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

3

12Hrs

Molecular Modeling and Docking

a) Molecular and Quantum Mechanics in drug design.

b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AChE & BChE)

4

12Hrs

Molecular Properties and Drug Design

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

5

12Hrs

Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry – Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L	T	P	C
4	0	0	4

(17S02204) PHARMACEUTICAL PROCESS CHEMISTRY

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. This subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY

60 Hrs

1.

12Hrs

Process chemistry

Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process.

In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

2

12Hrs

Unit operations

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c) Distillation: azeotropic and steam distillation

d) Evaporation: Types of evaporators, factors affecting evaporation.

e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3

12Hrs

Unit Processes - I

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H₂O₂, sodium hypochlorite, Oxygen gas, ozonolysis.

4

12Hrs

Unit Processes - II

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,

ii. Vitamins: B₂ and B₁₂

iii. Statins: Lovastatin, Simvastatin

c) Reaction progress kinetic analysis

i. Streamlining reaction steps, route selection,

ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5

12Hrs

Industrial Safety

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemicalengineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: HG Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles,Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis:Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-WestPress
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim& M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II,Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L	T	P	C
0	0	6	3

(17S02205) PHARMACEUTICAL CHEMISTRY PRACTICALS – II

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
 - a) Oxidation
 - b) Reduction/hydrogenation
 - c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Chemistry)

L	T	P	C
0	0	6	3

(17S02206) PHARMACEUTICAL CHEMISTRY PRACTICALS – III

1. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizineHCl).
2. Preparation of 4-iodotoluene from p-toluidine.
3. NaBH₄ reduction of vanillin to vanillyl alcohol
4. Preparation of umbelliferone by Pechhman reaction
5. Preparation of triphenyl imidazole
6. To perform the Microwave irradiated reactions of synthetic importance(Any two)
7. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
8. Calculation of ADMET properties of drug molecules and its analysis using softwares
Pharmacophore modeling
9. 2D-QSAR based experiments
10. 3D-QSAR based experiments
11. Docking study based experiment
12. Virtual screening based experiment
13. Synthesis purification and identification of the following compounds employing some medicinal compounds.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutical Chemistry)

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, types of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Regulatory Affairs
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S11101	Good Regulatory Practices	4	-	-	4
2	17S11102	Documentation and Regulatory Writing	4	-	-	4
3	17S11103	Clinical Research Regulations	4	-	-	4
4	17S11104	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	-	-	4
5	17S11105	Regulatory Affairs Practical I	-	-	6	3
6	17S11106	Regulatory Affairs Practical II	-	-	6	3
7	17S11107	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S11201	Regulatory Aspects of Drugs& Cosmetics	4	-	-	4
2	17S11202	Regulatory Aspects of Herbal& Biologicals	4	-	-	4
3	17S11203	Regulatory Aspects of Medical Devices	4	-	-	4
4	17S11204	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4
5	17S11205	Regulatory Affairs Practical III	-	-	6	3
6	17S11206	Regulatory Affairs Practical IV	-	-	6	3
7	17S11207	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.	17S11301	Journal Club	1	-	-	1
3.	17S11302	Teaching Assignment	10	-	-	2
4.	17S11303	Comprehensive viva voce	-	-	-	2
5.	17S11304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S11305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S11401	Journal Club	1	-	-	1
2.	17S11402	Research work	31	-	-	16
3.	17S11403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11101) GOOD REGULATORY PRACTICES

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

- At completion of this course it is expected that students will be able to understand,
- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY 60 Hrs

1. 12Hrs

Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211. EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

2

12Hrs Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards

3

12Hrs

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

4

12Hrs

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

5

12Hrs

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11102) DOCUMENTATION AND REGULATORY WRITING

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

THEORY 60 Hrs

1. 12Hrs

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2 12Hrs

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

3 12Hrs

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits,

Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

4

12Hrs

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

5

12Hrs

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11103) CLINICAL RESEARCH REGULATIONS

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

Theory

60 Hrs

1.

12Hrs

Clinical Drug Development Process

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies

Key Concepts of Medical Device Clinical Evaluation

Key concepts of Clinical Investigation

2

12Hrs

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

3

12Hrs

Regulations governing Clinical Trials

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

4

12Hrs

Clinical Research Related Guidelines

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
 - E10 – Choice of Control Groups and Related Issues in Clinical Trials,
 - E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population
 - General biostatistics principle applied in clinical research

5 USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155
-

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.

5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: <http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf>
2. Code of Federal Regulations, FDA:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/cfrsearch.cfm>
3. Guidelines of International Conference on Harmonization:
<http://www.ich.org/products/guidelines.html>
4. Eudralex Guidelines: <http://www.gmpcompliance.info/euguide.htm>
5. FDA New Drug Application:
6.
<http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm>
7. Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk>
8. Central Drugs Standard Control Organization Guidance for Industry: <http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf>
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L T P C
4 0 0 4

**(17S11104) REGULATIONS AND LEGISLATION FOR DRUGS &
COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD
& NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS**

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

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

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

THEORY 60 Hrs

1. 12Hrs

Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA

2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2 12Hrs

Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing Clinical trial/ investigations

3 12Hrs

Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards

4 12Hrs

Bioavailability and Bioequivalence data (BA & BE), BCSC Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research

5 12Hrs

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials /BE studies by CDSCO

9. Guidelines for Import and Manufacture of Medical Devices by CDSCO

10. Guidelines from official website of CDSCO

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L	T	P	C
0	0	6	3

(17S11105) REGULATORY AFFAIRS PRACTICAL - I

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Regulatory Affairs)

L	T	P	C
0	0	6	3

(17S11106) REGULATORY AFFAIRS PRACTICAL - II

1. Preparation of checklist for registration of NDA as per ICH CTD format.
2. Preparation of checklist for registration of ANDA as per ICH CTD format.
3. Case studies on response with scientific rationale to USFDA Warning Letter
4. Preparation of submission checklist of IMPD for EU submission.
5. Comparison study of marketing authorization procedures in EU.
6. Comparative study of DMF system in US, EU and Japan
7. Preparation of regulatory submission using eCTD software
8. Preparation of Clinical Trial Application (CTA) for US submission
9. Preparation of Clinical Trial Application (CTA) for EU submission
10. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
11. Regulatory requirements checklist for conducting clinical trials in India.
12. Regulatory requirements checklist for conducting clinical trials in Europe.
13. Regulatory requirements checklist for conducting clinical trials in USA

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11201) REGULATORY ASPECTS OF DRUGS & COSMETICS

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives

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

- process of drug discovery and development and generic product development
- regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

Theory

60 Hrs

1.

12Hrs

USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.

2

12Hrs

European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate

of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

3

12Hrs

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan

4

12Hrs

Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

5

12Hrs

Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144

3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A. Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN 981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN: 13:978-1-60649-108-9

20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South East Asian Studies, Singapore

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11202) REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe. It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory 60 Hrs

1. 12Hrs

India : Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

2 12Hrs

USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

3 12Hrs

European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal

products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

4

12Hrs

Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements
Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

5

12Hrs

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus; Informa, 2008
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh; Wiley, 2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh, Indresh K. Srivastava; Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsc.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologics
11. [www.fda.gov/biologicsbloodvaccines/guidancecompliance](http://www.fda.gov/biologicsbloodvaccines/guidancecompliance/regulatoryinformation/biologics) Regulatory Information (Biologics)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11203) REGULATORY ASPECTS OF MEDICAL DEVICES

Scope

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives

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

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

Theory

60 Hrs

1.

12Hrs

Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

2

12Hrs

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO13485, Quality Risk Management of Medical Devices: ISO14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

3

12Hrs

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

4

12Hrs

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

5

12Hrs

ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L T P C
4 0 0 4

(17S11204) REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives

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

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Theory 60 Hrs

1. 12Hrs

Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

2. 12Hrs

Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

3. 12Hrs

India : Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

4. 12Hrs

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling

Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

5

12Hrs

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.

Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L	T	P	C
0	0	6	3

(17S11205) REGULATORY AFFAIRS PRACTICAL - III

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

L	T	P	C
0	0	6	3

(17S11206) REGULATORY AFFAIRS PRACTICAL - IV

1. Preparation of Checklist for Registration of Blood and Blood Products
2. Registration requirement comparison study in 5 emerging markets(WHO) and preparing check list for market authorization
3. Registration requirement comparison study in emerging markets(BRICS) and preparing check list for market authorization
4. Registration requirement comparison study in emerging markets(China and South Korea) and preparing check list for market authorization
5. Registration requirement comparison study in emerging markets(ASEAN) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (GCC)and preparing check list for market authorization
7. Checklists for 510k and PMA for US market
8. Checklist for CE marking for various classes of devices for EU
9. STED Application for Class III Devices
10. Audit Checklist for Medical Device Facility
11. Clinical Investigation Plan for Medical Devices

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Regulatory Affairs)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Technology
(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	17S10101	Pharmaceutical Product Development and technology Transfer	4	-	-	4
3	17S08102	Novel Drug Delivery System	4	-	-	4
4	17S08103	Intellectual Property Rights	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S10102	Pharmaceutical Technology Practical - I	-	-	6	3
7	17S10103	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S08201	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4
2	17S08202	Scale up and Technology Transfer	4	-	-	4
3	17S08203	Pharmaceutical Production Technology	4	-	-	4
4	17S10201	Cosmetics and Cosmoceuticals	4	-	-	4
5	17S10202	Pharmaceutical Technology Practical II	-	-	6	3
6	17S10203	Pharmaceutical Technology Practical III	-	-	6	3
7	17S10204	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.	17S10301	Journal Club	1	-	-	1
3.	17S10302	Teaching Assignment	10	-	-	2
4.	17S10303	Comprehensive viva voce	-	-	-	2
5.	17S10304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S10305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S10401	Journal Club	1	-	-	1
2.	17S10402	Research work	31	-	-	16
3.	17S10403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

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,

- 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. Spectrofluorimetry: 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. 11 hrs

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.
3. 11 hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers

of Quadrupole 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 chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

5 16hrs

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 ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.

c. Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

**(17S10101) PHARMACEUTICAL PRODUCT DEVELOPMENT AND TECHNOLOGY
TRANSFER**

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY

60 Hrs

1.

12Hrs

Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

2

12Hrs

Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.

3

12Hrs

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and

quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

4

12Hrs

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packaging materials.

5

12Hrs

Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febrieger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevalle. John I. Disouza. Maharukh T. Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remington's Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn. (1995) O O 2 C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.

10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S08102) NOVEL DRUG DELIVERY SYSTEMS

SCOPE

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective

On completion of this course it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY

60 Hrs

1.

12Hrs

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

2

12Hrs

a. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

08Hrs

b. Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

04Hrs

c. Sub-Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc. and its regulatory aspects.

3

08Hrs

Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting –nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

4

04Hrs

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

06Hrs

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

5

06Hrs

New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S08103) INTELLECTUAL PROPERTY RIGHTS

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY 60 Hrs

1. 12 Hrs

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

2 Role of GATT, TRIPS, and WIPO 12 Hrs

3 12 Hrs

Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

4 12 Hrs

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

5 12 Hrs

Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

L T P C
0 0 6 3

(17S01105) MODEREN PHARMACEUTICAL ANALYSIS PRACTICAL

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 / GC
4. Estimation of riboflavin/quinine sulphate by Fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)

L T P C
0 0 6 3

(17S10102) PHARMACEUTICAL TECHNOLOGY PRACTICAL-I

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
10. Electrophoresis of protein solution.
11. Preparation and evaluation of Liposome delivery system.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S08201) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hrs

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

2 12hrs

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product

performance, in vitro:dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

3

12 hrs

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

4

12 hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

5

12 hrs

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip JBreen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S08202) SCALE UP AND TECHNOLOGY TRANSFER

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY

60 Hrs

1.

12Hrs

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDSS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2

12Hrs

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

3

12Hrs

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

4

12Hrs

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiley.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S08203) PHARMACEUTICAL PRODUCTION TECHNOLOGY

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

On completion of this course it is expected that students will be able to understand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY

60 Hrs

Improved Tablet Production: Tablet production process, unit

1.

12Hrs

Operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered.

2

12Hrs

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

3

12Hrs

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

4

12Hrs

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including

finesolids dispersion, problems encountered. Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

5

12Hrs

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Cheremisinoff.
8. Pharmaceutical Project Management, T. Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H. Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
4 0 0 4

(17S10201) COSMETICS AND COSMECEUTICALS

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics andcosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals withdesired Safety, stability, and efficacy.

THEORY

60 Hrs

1. 12 hrs

Cosmetics – Regulatory: Definition of cosmetic products as perIndian regulation. Indian regulatory requirements for labeling ofcosmetics Regulatory provisions relating to import of cosmetics.,Misbranded and spurious cosmetics. Regulatory provisionsrelating to manufacture of cosmetics – Conditions for obtaininglicense, prohibition of manufacture and sale of certain cosmetics,loan license, offences and penalties.

2

12 hrs

Cosmetics - Biological aspects : Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinklesand body odor. Structure of hair and hair growth cycle. Commonproblems associated with oral cavity. Cleansing and care needsfor face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder-arm.

3

12 hrs

Formulation Building blocks: Building blocks for differentproduct formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives,their merits and demerits. Factors affecting microbial preservativeefficacy. Building blocks for formulation of a moisturizing cream,vanishing cream, cold cream, shampoo and toothpaste. Soapsand syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4

12 hrs

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5

12 hrs

Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like Cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P.P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
0 0 6 3

(17S10202) PHARMACEUTICAL TECHNOLOGY PRACTICAL-II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)

L T P C
0 0 6 3

(17S10203) PHARMACEUTICAL TECHNOLOGY PRACTICAL-III

1. DoE Using Design Expert® Software
2. Formulation data analysis Using Design Expert® Software
3. Quality-by-Design in Pharmaceutical Development
4. Computer Simulations in Pharmacokinetics and Pharmacodynamics
5. Computational Modeling of Drug Disposition
6. To develop Clinical Data Collection manual
7. To carry out Sensitivity Analysis, and Population Modeling.
8. Development and evaluation of Creams
9. Development and evaluation of Shampoo and Toothpaste base
10. To incorporate herbal and chemical actives to develop products
11. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutical Technology)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutics
(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	17S03101	Drug Delivery System	4	-	-	4
3	17S03102	Modern Pharmaceutics	4	-	-	4
4	17S03103	Regulatory Affair	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S03104	Drug Delivery Systems Practicals - I	-	-	6	3
7	17S03105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S03201	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	4	-	-	4
2	17S03202	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4
3	17S03203	Computer Aided Drug Delivery System	4	-	-	4
4	17S03204	Cosmetic and Cosmeceuticals	4	-	-	4
5	17S03205	Nano Technology & Targeted Dds (Ntds) Practicals - II	-	-	6	3
6	17S03206	Advanced Biopharmaceutics & Pharmacokinetics Practicals - III	-	-	6	3
7	17S03207	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.	17S03301	Journal Club	1	-	-	1
3.	17S03302	Teaching Assignment	10	-	-	2
4.	17S03303	Comprehensive viva voce	-	-	-	2
5.	17S03304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S03305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S03401	Journal Club	1	-	-	1
2.	17S03402	Research work	31	-	-	16
3.	17S03403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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,

- 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. Spectrofluorimetry: 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. 11 hrs

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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.
3. 11 hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole 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 chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) 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 ray diffraction 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 - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S03101) DRUG DELIVERY SYSTEMS

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

1.

10 hrs

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

2

10hrs

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

3

10hrs

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

4

6hrs

a) Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

10hrs

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

5

8 hrs

a) Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

6 hrs

b) Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York/Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L	T	P	C
4	0	0	4

(17S03102) MODERN PHARMACEUTICS

SCOPE

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 HRS

1.10 HRS

a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental –physiological and formulation consideration, Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

2.10 HRS

Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

3

10 HRS

cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

4

10 HRS

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

5

10 HRS

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f_2 and f_1 , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, student's T-test, ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S03103) REGULATORY AFFAIRS

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 Hrs

1.

12 hrs

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) , drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

2.

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

3

12 hrs

CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S, E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

4

12 hrs

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

5

12 hrs

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee. Formulation and working procedures. Informed Consent process and procedures. HIPAA - new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A. Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons, Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
0 0 6 3

(17S01105) MODERN PHARMACEUTICAL ANALYSIS PRACTICALS

1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L	T	P	C
0	0	6	3

(17S03104) DRUG DELIVERY SYSTEMS PRACTICALS - I

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L T P C
4 0 0 4

(17S03201) MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS)
(NTDS)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hrs

1. 12 hrs

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

2. 12 hrs

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

3. 12 hrs

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

4. 12 hrs

Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

5. 12 hrs

Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L T P C
4 0 0 4

(17S03202) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hrs

1.

12 hrs

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

2

12 hrs

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in

dissolution Testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

3

12 hrs

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

4

12 hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

5

12 hrs

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. P. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L T P C
4 0 0 4

(17S03203) COMPUTER AIDED DRUG DELIVERY SYSTEM

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60 Hrs

1.12 hrs

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

2

12 hrs

Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3

12 hrs

Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4

12 hrs

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro/in vivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

5

12 hrs

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James G. Boylan, Marcel Dekker Inc, New York, 1996.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L T P C
4 0 0 4

(17S03204) COSMETICS AND COSMECEUTICALS

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics andcosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticalswithdesired Safety, stability, and efficacy.

THEORY

60 Hrs

1.

12 hrs

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

2

12 hrs

Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3

12 hrs

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes;

Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4

12 hrs

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5

12 hrs

Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like Cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P.P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L	T	P	C
0	0	6	3

(17S03205) NANO TECHNOLOGY & TARGETED DDS (NTDS) PRACTICALS - II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutics)

L	T	P	C
0	0	6	3

(17S03206) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

PRACTICALS - III

1. Bioavailability studies of Paracetamol in animals.
2. Pharmacokinetic and IVIVC data analysis by WinnolineR software
3. In vitro cell studies for permeability and metabolism
4. DoE Using Design Expert® Software
5. Formulation data analysis Using Design Expert® Software
6. Quality-by-Design in Pharmaceutical Development
7. Computer Simulations in Pharmacokinetics and Pharmacodynamics
8. Computational Modeling Of Drug Disposition
9. To develop Clinical Data Collection manual
10. To carry out Sensitivity Analysis, and Population Modeling.
11. Development and evaluation of Creams
12. Development and evaluation of Shampoo and Toothpaste base
13. To incorporate herbal and chemical actives to develop products
14. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutics)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmacognosy
(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	17S06101	Advanced Pharmacognosy-1	4	-	-	4
3	17S06102	Phytochemistry	4	-	-	4
4	17S06103	Industrial Pharmacognostical Technology	4	-	-	4
5	17S06104	Pharmacognosy Practical I	-	-	6	3
6	17S06105	Pharmacognosy Practical II	-	-	6	3
7	17S06106	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S06201	Medicinal Plant biotechnology	4	-	-	4
2	17S06202	Advanced Pharmacognosy-II	4	-	-	4
3	17S06203	Indian system of medicine	4	-	-	4
4	17S06204	Herbal cosmetics	4	-	-	4
5	17S06205	Pharmacognosy Practical III	-	-	6	3
6	17S06206	Pharmacognosy Practical IV	-	-	6	3
7	17S06207	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.	17S06301	Journal Club	1	-	-	1
3.	17S06302	Teaching Assignment	10	-	-	2
4.	17S06303	Comprehensive viva voce	-	-	-	2
5.	17S06304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S06305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S06401	Journal Club	1	-	-	1
2.	17S06402	Research work	31	-	-	16
3.	17S06403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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,

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

THEORY

60 Hrs

1.

12Hrs

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, Difference/ Derivative 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, Data Interpretation.

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2

16Hrs

a. 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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

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

3

12Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a) Thin Layer chromatography
- b) High Performance Thin Layer Chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Ultra High Performance Liquid chromatography
- h) Affinity chromatography
- i) Gel Chromatography

4

10Hrs

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 ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5

10Hrs

a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications,

Derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S06101) ADVANCED PHARMACOGNOSY – I

Scope

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

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

- Advances in the cultivation and production of drugs
- Various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- Various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

THEORY

60 Hrs

1.

12Hrs

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In situ conservation of medicinal plants.

2

12Hrs

Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

3

12Hrs

Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

- a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
- b) Limonoids – i) d-Limonene ii) α – Terpineol
- c) Saponins – i) Shatavarins
- d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
- e) Phenolic acids- Ellagic acid
- f) Vitamins
- g) Tocotrienols and Tocopherols
- h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
- i) Miscellaneous

Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman.V.George Tropical Botanic Garden & Research Institute, 1995.

8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scigel Runeckles- Appleton Century Crofts.
16. Text book of Pharmacognosy, C.K. Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S06102) PHYTOCHEMISTRY

SCOPE

Students shall be equipped with the knowledge of natural product drugdiscovery and will be able to isolate, identify and extract and the phytoconstituents

OBJECTIVES

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

- Different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drugdiscovery
- Phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY

60 Hrs

1.

12Hrs

Biosynthetic pathways and Radio tracing techniques:Constituents& their Biosynthesis, Isolation, Characterization andpurification with a special reference to their importance in herbalindustries of followingphyto-pharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine,Berberine, Taxol, Vincaalkoloids.

b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides,Bacosides, Quercitin.

c) Steroids: Hecogenin, guggulosterone and withanolides

d) Coumarin: Umbelliferone.

e) Terpenoids: Cucurbitacins

2

12Hrs

Drug discovery and development: History of herbs as source ofdrugs and drug discovery, the lead structure selection process,structure development, product discovery process and drugregistration, Selection and optimization of lead compounds withsuitable examples from the following source : artemesin,andrographolides. Clinical studies emphasising on phasesofclinical trials, protocol design for lead molecules.

3

12Hrs

Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4

12Hrs

Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.

5

12Hrs

Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (¹H, ¹³C)

- a. Carvone, Citral, Menthol
- b. Luteolin, Kaempferol
- c. Nicotine, Caffeine
- d. Glycyrrhizin.

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol. II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Blatt.
7. Wilson and Gisvolds text book of Organic Medicinal and Pharmaceutical Chemistry by George. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and Seemi Siddiqui

10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, JohnWiley& Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, MeenakshiS, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Intercept Ltd., New York, 1999.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S06103) INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES

By the end of the course the student shall be able to know,

- The requirements for setting up the herbal/natural drug industry.
- The guidelines for quality of herbal/natural medicines and regulatory issues.
- The patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY

60 Hrs

1.

12Hrs

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.

2

12Hrs

Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.

Export - Import (EXIM) policy, TRIPS.

Quality assurance in herbal/natural drug products.

Concepts of TQM, GMP, GLP, ISO-9000.

3

12Hrs

Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal

pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4

12Hrs

Testing of natural products and drugs: Herbal medicines -clinical laboratory testing. Stability testing of natural products, protocols.

5

12Hrs

Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject matters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukharjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangaraj (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H. Wagner and S. Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B. Harborne, (1999), 2nd Edition, Taylor and Francis Ltd, UK.

11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal,(2004), IST Edition,

12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), EasternPublisher, New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
0 0 6 3

(17S06104) PHARMACOGNOSY PRACTICAL – I

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV-Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Estimation of quinine sulphate by fluorimetry
6. Demonstration of HPLC- estimation of glycyrrhizin
7. Methods of extraction
8. Physical evaluation of bio-drugs like determination of ash and extractive values.
9. Determination of bitterness value and foaming index.
10. Determination of moisture content, LOD and Swelling index.
11. Estimation of fibre content, total solids, FOM and the like.
12. Determination of haemolytic activity.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
0 0 6 3

(17S06105) PHARMACOGNOSY PRACTICAL – II

1. Phytochemical screening.
2. Fluorescence analysis of biodrugs.
3. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by PC & TLC/HPTLC methods.
4. Determination of leaf constants.
5. Determination of volatile oil content.
6. Monograph analysis of Volatile oil like Clove oil.
7. Monograph analysis of fixed oil like Castor oil.
8. Identification of bioactive constituents from plant extracts.
9. Estimation of bioactive constituents.
10. Formulation of different dosage forms and their standardization.
11. Preparation and standardization of simple ISM dosage forms.
12. Preparation of aromatherapy formulation.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
4 0 0 4

(17S06201) MEDICINAL PLANT BIOTECHNOLOGY

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES

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

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY

60 Hrs

1.

12Hrs

Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

2

15Hrs

Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

3

15Hrs

Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

4

13Hrs

Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5

05 Hrs

Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberdt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
4 0 0 4

(17S06202) ADVANCED PHARMACOGNOSY - II

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES

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

- Validation of herbal remedies
- Methods of detection of adulteration and evaluation techniques for the herbal drugs
- Methods of screening of herbals for various biological properties

THEORY

60 Hrs

1.

12Hrs

Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

2

12Hrs

Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.

3

12Hrs

Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

4

12Hrs

Analytical Profiles of herbal drugs: *Andrographis paniculata*, *Boswellia serata*, *Coleus forskohlii*, *Curcuma longa*, *Embellica officinalis*, *Psoralea corylifolia*.

5

12Hrs

Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V. George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K. Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangaraj, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H. Wagner and S. Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publishers, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M. Blumenthal.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
4 0 0 4

(17S06203) INDIAN SYSTEMS OF MEDICINE

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY

60 Hrs

1.

12Hrs

Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine

Different dosage forms of the ISM.

Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2

12Hrs

Naturopathy, Yoga and Aromatherapy practices

a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3

12Hrs

Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts.

Standardization, Shelf life and Stability studies of ISM formulations.

4

12Hrs

Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5

12Hrs

TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupta, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, BRITISH Herbal Medicine Association, UK.

9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.

10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.

11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.

12. Clinical Dietetics and Nutrition, F.P. Antia, Oxford University Press, Delhi.

13. Yoga - The Science of Holistic Living by V.K. Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
4 0 0 4

(17S06204) HERBAL COSMETICS

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

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

- Understand the basic principles of various herbal/natural cosmetic preparations
- Current good manufacturing practices of herbal/natural cosmetics as per the regulatory authorities

THEORY 60 Hrs

1. 12Hrs

Introduction: Herbal/natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: -License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

2 12Hrs

Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

3 12Hrs

Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

4 12Hrs

Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sunburn preparations, moisturizing creams, deodorants.

5

12Hrs

Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatherapy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
0 0 6 3

(17S06205) PHARMACOGNOSY PRACTICALS III

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Preparation of different types of tissue culture mediums
5. Sterilization methods involved in plant tissue culture.
6. Sub- culturing techniques.
7. Establishment of callus culture
8. Establishment of suspension culture
9. Immobilization technique
10. *In vitro* determination of antioxidant
11. *In vitro* determination of anti-inflammatory activity.
12. Preparation of Asavas and Aristas and their standardization.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacognosy)

L T P C
0 0 6 3

(17S06206) PHARMACOGNOSY PRACTICALS IV

1. Preparation of herbal cosmetic formulation such as lip balm and lipstick.
2. Preparation and standardization of herbal hair care and scalp care products.
3. Preparation and standardization of hair growth promoting herbal formulations.
4. Preparation and standardization of nail care products.
5. Preparation and standardization of sunscreen, UV protection cream, skin care formulations.
6. Preparation and standardization of oral hygiene products.
7. Preparation and standardization of baby care products.
8. Evaluation of herbal tablets and capsules
9. Formulation & standardization of herbal cough syrup.
10. Toxicity screening of herbal cosmetics.
11. Formulation and standardization of wound healing herbal ointments / creams.
12. Formulation of herbal nutraceuticals.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmacognosy)

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 (wilcoxon 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.

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	Modern Pharmaceutical Analytical Techniques Practical	-	-	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 Hrs**

1. 12Hrs

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, Difference/ Derivative 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, Data Interpretation.

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2 16Hrs

a. 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-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

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

3

12Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a) Thin Layer chromatography
- b) High Performance Thin Layer Chromatography
- c) Ion exchange chromatography
- d) Column chromatography
- e) Gas chromatography
- f) High Performance Liquid chromatography
- g) Ultra High Performance Liquid chromatography
- h) Affinity chromatography
- i) Gel Chromatography

4

10Hrs

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 ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

5

10Hrs

- a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.
- b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample

preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications,

derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas 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, 4th edition, 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, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

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, neurodegenerative diseases.

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 antiplatelet drugs

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 Therapy by 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 and Andrew 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 and Applications – 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 coordination, 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 and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents.

Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and 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, antiarrhythmics, 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.

Immunomodulators, 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 for pharmacology

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 and western blotting, Recombinant DNA technology and gene therapy. Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA 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 Dickenson et.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 protocols in molecular biology vol I to VI edited by FrederickM.Ausuvet et al.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
0 0 6 3

(17S01105) PRACTICAL - I: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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 Bradford/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) PRACTICAL - I: PHARMACOLOGY -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 and miotic 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 β -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 SCREENING METHODS-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), teratogenicity 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 research and 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 Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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. 2007 Humana Press Inc.
2. Darryl León. Scott Markell. 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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, pharmacoconomics, safetypharmacology

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. 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.
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 Sylvan Green, 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. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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 agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA₂ values of various antagonists using suitable isolated tissue preparations.
8. Drug absorption studies by averted rat ileum preparation.
9. ADR reporting

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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.,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmacy Practice
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S09101	Clinical Pharmacy Practice	4	-	-	4
2	17S09102	Pharmacotherapeutics-I	4	-	-	4
3	17S09103	Hospital &Community Pharmacy	4	-	-	4
4	17S09104	Clinical Research	4	-	-	4
5	17S09105	Pharmacy Practice Practical I	-	-	6	3
6	17S09106	Pharmacy Practice Practical II	-	-	6	3
7	17S09107	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S09201	Principles of Quality Use of Medicines	4	-	-	4
2	17S09202	Pharmacotherapeutics II	4	-	-	4
3	17S09203	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	-	4
4	17S09204	Pharmacoepidemiology & Pharmacoeconomics	4	-	-	4
5	17S09205	Pharmacy Practice Practical III	-	-	6	3
6	17S09206	Pharmacy Practice Practical IV	-	-	6	3
7	17S09207	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.	17S09301	Journal Club	1	-	-	1
3.	17S09302	Teaching Assignment	10	-	-	2
4.	17S09303	Comprehensive viva voce	-	-	-	2
5.	17S09304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S09305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S09401	Journal Club	1	-	-	1
2.	17S09402	Research work	31	-	-	16
3.	17S09403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09101) CLINICAL PHARMACY PRACTICE

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to :

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY 60 Hrs

1. 12Hrs

Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2 12Hrs

Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counseling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

3 12Hrs

Patient Data Analysis:

Patient Data & Practice Skills: Patient's case history – its structure and significance 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.

Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

4

12Hrs

Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

5

12Hrs

Medicines & Poison Information Services

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.

Poison Information Service: Definition, need, organization and functions of poison information centre.

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09102) PHARMACOTHERAPEUTICS-I

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY 60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. 12Hrs

Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

2 12Hrs

Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system: Diabetes, Thyroid diseases

3 12Hrs

Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, inflammatory bowel diseases, Jaundice & hepatitis

4 12Hrs

Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug-induced hematological disorders

5

12Hrs

Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis
Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug-induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09103) HOSPITAL & COMMUNITY PHARMACY

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY

60 Hrs

1.

12Hrs

Introduction to Hospitals – Definition, classification, organizational structure
Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2

12Hrs

Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

3

12Hrs

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.

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, layout & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4

12Hrs

Prescription – Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies

5

12Hrs

Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care National Health Programs- Role of Community Pharmacist in Malaria and TB control programs Home Medicines review program – Definition, objectives, Guidelines, method and outcomes Research in community pharmacy Practice

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09104) CLINICAL RESEARCH

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY

60 Hrs

1.

12Hrs

Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICHGCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

2

12Hrs

Types and Designs used in Clinical Research: 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) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3

12Hrs

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

4

12Hrs

Investigational Product: Procurement and Storage of investigation product Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of sourced documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

5

12Hrs

Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

Data Management

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Andrew. J. Flether Anthony W Fos , Peter D Sloaier Publisher: Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone

3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L	T	P	C
0	0	6	3

(17S09105) PHARMACY PRACTICE PRACTICAL – I

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. ABC Analysis of a given list of medications (one)
8. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
9. Formulation and dispensing of a given IV admixtures (one)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)

L	T	P	C
0	0	6	3

(17S09106) PHARMACY PRACTICE PRACTICAL – II

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
2. Preparation of a patient information leaflet (two)
3. Preparation of Study Protocol (one)
4. Preparation of Informed Consent Form (one)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09201) PRINCIPLES OF QUALITY USE OF MEDICINES

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY 60 Hrs

1. 12Hrs

Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

2 12Hrs

Concepts in QUM

Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings

Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list

Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

3 12Hrs

QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

4

12Hrs

Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

5

12Hrs

Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
 - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
 - <http://curriculum.racgp.org.au/statements/quality-use-of-medicines/>
 - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09202) PHARMACOTHERAPEUTICS II

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY 60 Hrs

1. 12Hrs

Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

2 12Hrs

Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders
Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

3 12Hrs

Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

4 12Hrs

Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections
Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

5 Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics –Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09203) CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Scope

This course is designed to enable students to understand the basic principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY **60 Hrs**

1. 12Hrs

Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses, Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2 12Hrs

Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

3

12Hrs

Non Linear Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

4

12Hrs

Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the hepatic failure.

5

Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions:

Cardiovascular diseases: Digoxin, Lidocaine, Amiodarone;

Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate;

Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline;

Organ transplantations: Cyclosporine;

Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin;

Antibiotics: Vancomycin, Gentamicin, Meropenem.

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Ippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer. Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Ippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Ippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. PharmaBook Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L T P C
4 0 0 4

(17S09204) PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Scope

This course enables students to understand various pharmaco-epidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoconomics and health related outcomes, and when should be appropriate Pharmaco-economic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoconomics analysis methods
- Understand the Pharmaco-economic decision analysis methods and its applications.
- Describe current Pharmaco-economic methods and issues.
- Understand the applications of Pharmacoconomics to various pharmacy settings.

THEORY

60 Hrs

1.

12Hrs

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

2

12Hrs

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations:

Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3

12Hrs

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.

Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

4

12Hrs

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

5

12Hrs

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following:

Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, WoultersKluwerLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.

3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L	T	P	C
0	0	6	3

(17S09205) PHARMACY PRACTICE PRACTICAL - III

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Interpretation of Therapeutic Drug Monitoring reports of a given patient(three)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)

L	T	P	C
0	0	6	3

(17S09206) PHARMACY PRACTICE PRACTICAL - IV

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
2. Calculation of Bioavailability and Bioequivalence from the given data (two)
3. Calculation of various Pharmacoeconomic outcome analysis for the given, data (two)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmacy Practice)

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 (wilcoxon 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for Pharm. D.
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

Pharm. D. & Pharm. D. (Post Bacalaureate) Regulations 2017

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948). (As approved by the Government of India, Ministry of Health vide, letter March, 2008 and notified by the Pharmacy No.V.13013/1/2007-PMS, dated the 13th Council of India). No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.
(2) They shall come into force from the date of their publication in the official Gazette.
2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –
 - a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –
Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.
Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.
 - b) Pharm.D. (Post Bacalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –
Phase I – consisting of First and Second academic year.
Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.
4. Minimum qualification for admission to. –
 - a) Pharm.D. Part-I Course – A pass in any of the following examinations -
 - (1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

(2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

a) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –

i)Pharm.D. Programme – 30 students.

ii)Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the pharmacyAct, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.
 (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
 (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

TABLES

First Year examination:

S.No	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70	30	100
				600			600 = 1200

Second Year examination:

S.No	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30		-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination:

S.No	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics -II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination:

S.No	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics -III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			500 = 1100

Fifth Year examination:

S.No	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship*	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis .

** 30 marks – viva-voce (oral)
70 arks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post BaccaLaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.
12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
(3) Practical examination shall also consist of a viva –voce (Oral) examination.
(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.
13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post BaccaLaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.
(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.
(3) The sessional marks in practicals shall be allotted on the following basis:-
 - (i) Actual performance in the sessional examination (20 marks);
 - (ii) Day to day assessment in the practical class work, promptness, viva- voce record maintenance, etc. (10 marks).

14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.
15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.
16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquire skills under the supervision so that he or she may become capable of functioning independently.
(2) Every student has to undergo one year internship as per Appendix-C to these regulations.
17. Approval of examinations.— Examinations mentioned in regulations 10 to 12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix-D to these regulations.
18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III **Practical training**

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
21. Objectives of project work.— The main objectives of the project work is to—
(i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

- (ii) develop the students in data collection, analysis and reporting and interpretation skills.
22. Methodology.— To complete the project work following methodology shall be adopted, namely:—
- (i) students shall work in groups of not less than two and not more than four under an authorised teacher;
 - (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
 - (ii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoconomics;
 - (iv) project work shall be approved by the institutional ethics committee;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.
23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-titles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.
24. Evaluation.— The following methodology shall be adopted for evaluating the project work—
- (i) Project work shall be evaluated by internal and external examiners.
 - (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
 - (iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
 - (iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)
 - (v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above

COURSE STRUCTURE

First Year:

S.No.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No.	Subjects codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
1.1	17T00101	Human Anatomy and Physiology	3	1	3		1.7	17T00107
1.2	17T00102	Pharmaceutics	2	1	3		1.8	17T00108
1.3	17T00103	Medicinal Biochemistry	3	1	3		1.9	17T00109
1.4	17T00104	Pharmaceutical Organic Chemistry	3	1	3		2.0	17T00110
1.5	17T00105	Pharmaceutical Inorganic Chemistry	2	1	3		2.1	17T00111
1.6	17T00106	Remedial Mathematics/ Biology	3	1	3*		2.2	17T00112*
		Total hours	16	6 = (40)	18			

* For Biology

Second Year:

S.No	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
2.1	17T00201	Pathophysiology	3	1	-	-		-
2.2	17T00202	Pharmaceutical Microbiology	3	1	3	✓	2.7	17T00207
2.3	17T00203	Pharmacognosy &Phytopharmaceuticals	3	1	3	✓	2.8	17T00208
2.4	17T00204	Pharmacology-I	3	1	-	-		-
2.5	17T00205	Community Pharmacy	2	1	-	-		-
2.6	17T00206	Pharmacotherapeutics-I	3	1	3	✓	2.9	17T00209
		Total Hours	17	6 = 32	9			

Third Year:

S.N O	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
3.1	17T00301	Pharmacology-II	3	1	3	✓	3.7	17T00307
3.2	17T00302	Pharmaceutical Analysis	3	1	3	✓	3.8	17T00308
3.3	17T00303	Pharmacotherapeutics-II	3	1	3	✓	3.9	17T00309
3.4	17T00304	Pharmaceutical Jurisprudence	2	-	-	-		-
3.5	17T00305	Medicinal Chemistry	3	1	3	✓	4.0	17T00310
3.6	17T00306	Pharmaceutical Formulations	2	1	3	✓	4.1	17T00311
		Total hours	16	5 = 36	15			

Fourth Year:

S.No.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical/ Hospital Posting	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
4.1	17T00401	Pharmacotherapeutics-III	3	1	3	✓	4.7	17T00407
4.2	17T00402	Hospital Pharmacy	2	1	3	✓	4.8	17T00408
4.3	17T00403	Clinical Pharmacy	3	1	3	✓	4.9	17T00409
4.4	17T00404	Biostatistics & Research Methodology	2	1	-	-		-
4.5	17T00405	Biopharmaceutics & Pharmacokinetics	3	1	3	✓	4.10	17T00410
4.6	17T00406	Clinical Toxicology	2	1	-	-		-
		Total hours	15	6 = 33	12			
For Pharm D Post Baccalaurate								
4.11	14T00411	Pharmacotherapeutics I & II	3	1	3	✓	4.12	14T00412
			18	7=39				

Fifth Year:

S.No.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Seminar	No. of hours of Hospital posting*
(1)	(2)	(3)	(4)	(5)	(6)
5.1	17T00501	Clinical Research	3	1	-
5.2	17T00502	Pharmacoepidemiology and Pharmacoconomics	3	1	-
5.3	17T00503	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	1	-
5.4		Clerkship*	-	1	-
5.5		Project work (Six Months)	-	-	20
		Total hours	8	4 = 32	20

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments

10. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.
11. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Bacculaureate) programme without the prior approval of the Pharmacy Council of India.
- (2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.
- (3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:
- Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.
10. Examination. – (1) Every year there shall be an examination to examine the students.
- (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

(17T00101) HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory:3 Hrs. /Week

- 1. Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
- 2. Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and the ir imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. Course materials:

Text books

- a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
- b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

- a. Guytonarthur, C. Physiology of human body. Publisher: Holtsaunders.
- b. Chatterjee,C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
- c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- d. Gray's anatomy. Publisher: Churchill Livingstone, London.

4. Lecture wise program :

Topics

- 1
 - i) Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
 - ii) Structure of cell – its components and their functions.
Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
 - i) Osseous system - structure, composition and functions of theSkeleton. (done in practical classes - 6hrs)
 - iii) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)
- 2 i) Haemopoetic System
 - a)Composition and functions of blood
 - b)Haemopoesis and disorders of blood components (definition of d isorder)

- c) Blood groups
- d) Clotting factors and mechanism
- e) Platelets and disorders of coagulation

ii) Lymph

- a) Lymph and lymphatic system, composition, formation and circulation.
- b) Spleen: structure and functions, Disorders
- c) Disorders of lymphatic system (definition only)

iii) Cardiovascular system

- a) Anatomy and functions of heart
- b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
- c) Electrocardiogram (ECG)
- d) Cardiac cycle and heart sounds
- e) Blood pressure – its maintenance and regulation
- f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

3 i) Respiratory system

- a) Anatomy of respiratory organs and functions
- b) Mechanism / physiology of respiration and regulation of respiration
- c) Transport of respiratory gases
- d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

ii) Digestive system

- a) Anatomy and physiology of GIT
- b) Anatomy and functions of accessory glands of GIT
- c) Digestion and absorption
- d) Disorders of GIT (definitions only)

iii) Nervous system

- a) Definition and classification of nervous system
- b) Anatomy, physiology and functional areas of cerebrum
- c) Anatomy and physiology of cerebellum
- d) Anatomy and physiology of mid brain
- e) Thalamus, hypothalamus and Basal Ganglia
- f) Spinal cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

4 i) Urinary system

- a) Anatomy and physiology of urinary system
- b) Formation of urine
- c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- d) Clearance tests and micturition

ii) Endocrine system

- a) Pituitary gland
- b) Adrenal gland
- c) Thyroid and Parathyroid glands
- d) Pancreas and gonads

iii) Reproductive system

- a) Male and female reproductive system
- b) Their hormones – Physiology of menstruation
- c) Spermatogenesis & Oogenesis

- d)Sex determination (genetic basis)
- e)Pregnancy and maintenance and parturition
- f)Contraceptive devices

5 i) Sense organs

- a)Eye
- b)Ear
- c)Skin
- d)Tongue & Nose

ii) Skeletal muscles

- a)Histology
- b)Physiology of Muscle contraction
- c)Physiological properties of skeletal muscle and their disorders (definitions)

iii) Sports physiology

- a)Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- b)Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- c)Drugs and athletics

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - I YEAR

(17T00107) HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson
Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.
 - (e) Digestive system.
 - (f) Urinary system.
 - (g) Nervous system.
 - (h) Special senses.
 - (i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

(17T00102) PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week

1. Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. Upon the completion of the course the student s hould be able to:
 - a. know the formulation aspects of different dosage forms;
 - b.do different pharmaceutical caluculation involved in formulation;
 - c.formulate different types of dosage forms; and
 - d.appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b.A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

1.
 - a. Introduction to dosage forms - classification and definitions
 - b.Prescription: definition, parts and handling
 - c.Posology: Definition, Factors affecting dose selection. Calculation of childrenand infant doses.
 - d. Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
2.
 - i) Development of Indian Pharmacopoeia and introduction to o ther Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
 - ii) Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
3.
 - i) Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
 - ii) Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles,mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.
4.
 - A) Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
 - B) Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.

C)Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

5. i) Pharmaceutical calculations.

ii) Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

iii) Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

Practical : 3 Hrs. /Week

List of Experiments:

1. Syrups

- a. Simple Syrup I.P
- b.Syrup of Ephedrine Hcl NF
- c.Syrup Vasaka IP
- d.Syrup of ferrous Phosphate IP
- e.Orange Syrup

2. Elixir

- a. Piperizine citrate elixir BP
- b.Cascara elixir BPC
- c.Paracetamol elixir BPC

3. Linctus

- a.Simple Linctus BPC
- b.Pediatric simple Linctus BPC

4. Solutions

- a.Solution of cresol with soap IP
- b.Strong solution of ferric chloride BPC
- c.Aqueous Iodine Solution IP
- d.Strong solution of Iodine IP
- e.Strong solution of ammonium acetate IP

5. Liniments

- a. Liniment of turpentine IP*
- b.Liniment of camphor IP

6. Suspensions*

- a.Calamine lotion
- b.Magnesium Hydroxide mixture BP

7. Emulsions*

- a.Cod liver oil emulsion
- b.Liquid paraffin emulsion

8. Powders*

- a.Eutectic powder
- b.Explosive powder
- c.Dusting powder
- d.Insufflations

9. Suppositories*

- a.Boric acid suppositories
- b.Chloral suppositories

10. Incompatibilities

a.Mixtures with Physical

b.Chemical & Therapeutic incompatibilities

*Colourless bottles required for dispensing □ Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

(17T00103) MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases
- 2. Objectives of the Subject (Know, do, appreciate) :**

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

 - a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
 - b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
 - c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
 - d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
 - e. do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- a. Harpers review of biochemistry - Martin
- b. Text book of biochemistry – D.Satyanarayana
- c. Text book of clinical chemistry- Alex kaplan&LaverveL.Szabo

Reference books (Theory)

- a. Principles of biochemistry -- Lehninger
- b. Text book of biochemistry -- Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

- 1. a. Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- b. Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 2. i) Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.
- ii) Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid

metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).

3. **i) Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

iii) Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

iv) Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

4. **Introduction to clinical chemistry:** Cell; composition; malfunction; Roll of the clinical chemistry laboratory.

The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

- a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
- b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
- c) Urine concentration test
- d) Urinary tract calculi. (stones)

Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

- a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
- Selected enzyme tests.

5. **i) Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

ii) Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

iii) Electrolytes: Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - I YEAR

(17T00109) MEDICINAL BIOCHEMISTRY (PRACTICAL)

practical: 3 Hrs. /Week

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by LibermannBurchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin- Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**
13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. Study of factors affecting Enzyme activity. (pH& Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

(17T00104) PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a very good knowledge about
 - IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - Some important physical properties of organic compounds;
 - Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - Some named organic reactions with mechanisms; and
 - Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- T.R.Morrison and R. Boyd - Organic chemistry,
- Bentley and Driver-Text book of Pharmaceutical chemistry
- I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

- Organic chemistry – J.M.Cram and D.J.Cram
- Organic chemistry- Brown
- Advanced organic chemistry- Jerry March, Wiley
- Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

- i) Structures and Physical properties:
 - Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - Acids and bases, Lowry bronsted and Lewis theories
 - Isomerism
 - ii) Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
 - iii) Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
 - iv) Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- i) Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN 2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

- ii) Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- iii) Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, Markovnikov rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- iv) Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
3. i) Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allylic cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allylic cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- ii) Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.
4. i) Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.
- ii) Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- iii) Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions.
5. i) Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- ii) Oxidation reduction reaction.
- iii) Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glycerol trinitrate, Urea, Ethylene

diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzylbenzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - I YEAR

(17T00110) PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

practical: 3 Hrs. /Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
- 8,9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenoneoxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - I YEAR

(17T00105) PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory: 2 Hrs. /Week

1. Scope and objectives: This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
2. Upon completion of the course student shall be able to:
 - a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Course materials:

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr. B. G. Nagavi
- c. Analytical chemistry principles by John H. Kennedy d. I.P. 1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise programme:

Topics

1. A. Errors
B. Volumetric analysis
C. Acid-base titrations
D. Redox titrations
2. A. Non aqueous titrations
B. Precipitation titrations
C. Complexometric titrations
D. Theory of indicators
3. A. Gravimetry
B. Limit tests
C. Medicinal gases
D. Acidifiers
4. A. Antacids
B. Cathartics
C. Electrolyte replenishers
D. Essential Trace elements
5. A. Antimicrobials
B. Pharmaceutical aids
C. Dental Products
D. Miscellaneous compounds
E. Radio Pharmaceuticals

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Pharm. D - I YEAR

(17T00111) PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)
practical: 3 Hrs. /Week

- 1. Limit test (6 exercises)**
 - a. Limit test for chlorides
 - b. Limit test for sulphates
 - c. Limit test for iron
 - d. Limit test for heavy metals
 - e. Limit test for arsenic
 - f. Modified limit tests for chlorides and sulphates

- 2. Assays (10 exercises)**
 - a. Ammonium chloride- Acid-base titration
 - b. Ferrous sulphate- Cerimetry
 - c. Copper sulphate- Iodometry
 - d. Calcium gluconate- Complexometry
 - e. Hydrogen peroxide – Permanganometry
 - f. Sodium benzoate – Nonaqueous titration
 - g. Sodium chloride – Modified Volhard's method
 - h. Assay of KI – KIO₃ titration
 - i. Gravimetric estimation of barium as barium sulphate
 - j. Sodium antimony gluconate or antimony potassium tartarate

- 3. Estimation of mixture (Any two exercises)**
 - a. Sodium hydroxide and sodium carbonate
 - b. Boric acid and Borax
 - c. Oxalic acid and sodium oxalate

- 4. Test for identity (Any three exercises)**
 - a. Sodium bicarbonate
 - b. Barium sulphate
 - c. Ferrous sulphate
 - d. Potassium chloride

- 5. Test for purity (Any two exercises)**
 - a. Swelling power in Bentonite
 - b. Acid neutralising capacity in aluminium hydroxide gel
 - c. Ammonium salts in potash alum
 - d. Adsorption power heavy Kaolin
 - e. Presence of Iodates in KI

- 6. Preparations (Any two exercises)**
 - a. Boric acids
 - b. Potash alum
 - c. Calcium lactate

d. Magnesium sulphate

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment 1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00106) REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : –**
 - a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.

3. Course materials:

Text books

- a. Differential calculus By Shantinarayan
- b. Text book of Mathematics for second year pre- university by Prof.B.M.Sreenivas

Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme :

Topics

- 1 i) **Algebra :** Determinants, Matrices
ii) **Trigonometry :** Sides and angles of a triangle, solution of triangles
- 2 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successivedifferentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 3 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 4 **Differential equations:** Definition, order, degree, variable separable,homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 5 i) **Analytical Geometry:**Points, Straight line, circle, parabola
ii) **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY :

1. **Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. Course materials:

Text books

- a. Text book of Biology by S.B.Gokhale
- b. A Text book of Biology by Dr.Thulajappa and Dr.Seetaram.

Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaranathaayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. Lecture wise programme :

Topic

PART – A

01 Introduction

General organization of plants and its inclusions

Plant tissues

Plant kingdom and its classification

Morphology of plants

Root, Stem, Leaf and Its modifications

02 Inflorescence and Pollination of flowers

Morphology of fruits and seeds

Plant physiology

03 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae

Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

04 Study of Animal cell

Study animal tissues

Detailed study of frog

05 Study of Pisces, Raptiles, Aves

General organization of mammals

Study of poisonous animals

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - I YEAR

(17T00112) BIOLOGY (PRACTICAL)

practical: 3 Hrs. /Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03	01

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

(17T00201) PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b.name the signs and symptoms of the diseases; and
 - c.mention the complications of the diseases.

Text books (Theory)

- a.Pathologic basis of disease by- Cotran, Kumar, Robbins
- b.Text book of Pathology- Harsh Mohan
- c.Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1
 - i) **Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
 - ii) **Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
-
- 2
 - i) **Diseases of Immunity**
 - a) Introduction to T and B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)
 - Amyloidosis
 - ii) Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

- 3 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 4
 - a) Types of shock, mechanisms, stages and management
 - b) Biological effects of radiation
 - c) Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 5
 - i) Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases

Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology- Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2Min.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - II YEAR

(17T00202) PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source ;
- d. do cultivation and identification of the microorganisms in the laboratory;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- a. Vanitha Kale and KishorBhusari — Applied Microbiology | Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon — Immunology and Serology in Laboratory Medicines| 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, — Text book of Pathology| 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

- a. Prescott L.M., Jarley G.P Klein D.A —Microbiology| 2nd- edition Mc Graw Hill Company Inc
- b. Rawlins E.A. |Bentley's Text Book of Pharmaceutics| B ailliereTindals 24-28 London 1988
- c. Forbisher — Fundamentals of Microbiology| Philadelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology. |2nd edition WMC Brown Publishers, Oxford. 1993
- e. War Roitt, Jonathan Brostoff, David male, — Immunology|3rd edition 1996, Mosby-year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

3. **Detailed syllabus and lecture wise schedule:**

Title of the topic

- 1 a) Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
b) Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 2 a) Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria &

- fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- b) Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 3 a) Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations .
Brief information on Validation.
- b) Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 4 a) Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) .
Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- b) Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR, Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 5 a) Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12. Standardisation of vaccines and sera.
- b) Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhoea and HIV.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - II YEAR

(17T00207) PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

practical: 3 Hrs. /Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms.
- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - II YEAR

(17T00203) PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

1. Scope and objectives: This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occur ring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

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

- a. under stand the basic principles of cultivation, collection and storage of crude drugs;
- b. know the source, active constituents and uses of crude drugs; and
- c. appreciate the applications of primary and secondary metabolites of the plant.

3. Course materials:

Text books

- a. Pharmacognosy by G.E. Trease&W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale&A.C.Purohit.

Reference books

- a. Pharmacognosy by Brady &Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah &Qadery.
- d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Topics

- 1 Introduction.
Definition, history and scope of Pharmacognosy.
Classification of crude drugs.
Cultivation, collection, processing and storage of crude drugs.
- 2 Detailed method of cultivation of crude drugs.
Study of cell wall constituents and cell inclusions.
Microscopical and powder Microscopical study of crude drugs.
- 3 Study of natural pesticides.
Detailed study of various cell constituents.
Carbohydrates and related products.
- 4 Detailed study carbohydrates containing drugs.(11 drugs)
Definition sources, method extraction, chemistry and method of analysis of lipids.
Detailed study of oils.
- 5 Definition, classification, chemistry and method of analysis of protein.
Study of plants fibers used in surgical dressings and related products.
Different methods of adulteration of crude drugs.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - II YEAR

(17T00208) PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

practical: 3 Hrs. /Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia. cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil, sesame oil, shark liver oil, bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance.

(17T00204) PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - d. correlate and apply the knowledge therapeutically.

Text books(Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4t h Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16t h edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4t h edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9t h Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher : Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.

- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Blackwell Scientific.

3. Detailed syllabus and lecture wise schedule :
Title of the topic

1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. i) Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensives
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

ii) Pharmacology of Drugs acting on Respiratory tract

- a) Bronchodilators
- b) Mucolytics
- c) Expectorants
- d) Antitussives
- e) Nasal Decongestants

4. Pharmacology of drugs acting on Central Nervous System

- a) General anesthetics
- b) Sedatives and hypnotics
- c) Anticonvulsants
- d) Analgesic and anti-inflammatory agents
- e) Psychotropic drugs
- f) Alcohol and methyl alcohol
- g) CNS stimulants and cognition enhancers
- h) Pharmacology of local anaesthetics

5. i) Pharmacology of Hormones and Hormone antagonists

- a) Thyroid and Antithyroid drugs
- b) Insulin, Insulin analogues and oral hypoglycemic agents
- c) Sex hormones and oral contraceptives
- d) Oxytocin and other stimulants and relaxants

ii) Pharmacology of autocooids and their antagonists

- a) Histamines and Antihistaminics
- b) 5-Hydroxytryptamine and its antagonists
- c) Lipid derived autocooids and platelet activating factor

(17T00205) COMMUNITY PHARMACY (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
- 2. Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

- | | |
|---|----|
| 1. Synopsis | 10 |
| 2. Major Experiment
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion) | 30 |
| 3. Minor Experiment (Ability to measure B.P/ CBG / Lung function) | 15 |
| 4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) | 15 |
| 5. Viva – Voce | 10 |

Lecture wise programme:

Topics

- 1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist
Community Pharmacy Management
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements

- d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 2 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
- Inventory control in community pharmacy**
 Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
Pharmaceutical care
 Definition and Principles of Pharmaceutical care.
- 3 **Patient counselling**
 Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels
- Patient medication adherence**
 Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- Health screening services**
 Definition, importance, methods for screening
 Blood pressure/ blood sugar/ lung function and Cholesterol testing
- 4 **OTC Medication-** Definition, OTC medication list & Counselling
- Health Education**
 WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
 Commonly occurring Communicable Diseases, causative agents,
 Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhoea and AIDS
 Balance diet, and treatment & prevention of deficiency disorders
 Family planning – role of pharmacist
- 5 **Responding to symptoms of minor ailments**
 Relevant pathophysiology, common drug therapy to,
 Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- Essential Drugs concept and Rational Drug Therapy Role of community pharmacist**
- Code of ethics for community pharmacists**

(17T00206) PHARMACOTHERAPEUTICS - I (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the Subject: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. Objectives: At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. **Detailed syllabus and lecture wise schedule :**
Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure,

Angina Pectoris, Myocardial infarction, Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

Respiratory system: Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

2. **Endocrine system:** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
3. General prescribing guidelines for
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
4. Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial
5. Introduction to rational drug use
Definition, Role of pharmacist Essential drug concept Rational drug formulations

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - II YEAR

(17T00209) PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practicals: 3 Hrs. /Week

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 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00301) PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Livingstone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.

- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

2. **Detailed syllabus and lecture wise schedule:**

Title of the topic

1. i) **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
 - ii) **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
2. **Chemotherapy**
- a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolines
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
3. i) **Immunopharmacology:** Pharmacology of immunosuppressants and stimulants
- ii) **Principles of Animal toxicology:** Acute, sub acute and chronic toxicity
4. **The dynamic cell: The structures and functions of the components of the cell**
- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
 - b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
 - c) DNA replication: General, bacterial and eukaryotic DNA replication.
 - d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
 - e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).
5. **The Gene: Genome structure and function:**
- a) Gene structure: Organization and elucidation of genetic code.
 - b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families).

- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - III YEAR

(17T00307) PHARMACOLOGY – II (PRACTICAL)

practical: 3 Hrs. /Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00302) PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

1. **Quality Assurance:**

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. **Chromatography:**

Introduction, history, classification, separation techniques, choice of methods.

The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques, Rf value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography :** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carriergases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. Absorption Spectroscopy:

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation-IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors- Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

5. a. **NMR& ESR (introduction only):** Introduction, theoretical aspects and applications.

b. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

c. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

d. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.

e. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - III YEAR

(17T00308) PHARMACEUTICAL ANALYSIS (PRACTICAL)

practical: 3 Hrs. /Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipl College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.

Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine- induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan- induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*

- 13 To study the effects of drugs on vas deferens of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

**indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15 15
Viva	02	15
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00303) PHARMACOTHERAPEUTICS – II (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives of the Subject** Upon completion of the subject student shall be able to –
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

- 1. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 4 Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - III YEAR

(17T00309) PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practicals: 3 Hrs. /Week

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.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - III YEAR

(17T00304) PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules ;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta:National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabhprakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. **Detailed syllabus and lecture wise schedule:**

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
2. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.

Constitution and Functions of DTAB,DCC,CDL. Qualification and duties –Govt. analyst and Drugs Inspector.

3. **Pharmacy Act –1948.**

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

Medicinal and Toilet Preparation Act –1955.

Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

4. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.

Study of Salient Features of Drugs and magic remedies Act and its rules.

Study of essential Commodities Act Relevant to drugs price control Order.

5. **Drug Price control Order & National Drug Policy (Current).**

Prevention Of Cruelty to animals Act-1960.

Patents & design Act-1970.

Brief study of prescription and Non-prescription Products.

4. **Assignments:**

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

(17T00305) MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti- infective agents
 - a) Local anti- infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti- infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
Antimalarials
Antibiotics
4. Antineoplastic agents
Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
5. Hypoglycemic agents
Thyroid and Antithyroid agents
Diuretics
Diagnostic agents
Steroidal Hormones and Adrenocorticoids

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Pharm. D - III YEAR

(17T00310) MEDICINAL CHEMISTRY (PRACTICAL)

Practical :3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., WellyMed.Chemistry M.E. WalfedJohnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-LedniserMitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing company, Easton, Pennsylvania.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - III YEAR

(17T00306) PHARMACEUTICAL FORMULATIONS (THEORY)

Theory :2 Hrs. /Week

1. Scope of the Subject: Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper &Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
2. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatine capsules, quality control tests for soft gelatin capsules.
3. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
4. **Ophthalmic preparations(Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
5. Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

(17T00311) PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Manufacture of Tablets
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
2. Formulation and filling of hard gelatin capsules
3. Manufacture of parenterals
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
4. Evaluation of Pharmaceutical formulations (QC tests)
 - a. Tablets
 - b. Capsules
 - c. Injections
5. Formulation of two liquid oral preparations and evaluation by assay
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
6. Formulation of semisolids and evaluation by assay
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
7. Cosmetic preparations
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
8. Tablet coating (demonstration)

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - IV YEAR

(17T00401) PHARMACOTHERAPEUTICS – III (THEORY)

Theory:3 Hrs. /Week

1. **Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, and headaches.
Evidence Based Medicine

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication

- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble
MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

(17T00407) PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical:3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, and headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00402) HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant&Dr. J.S. Qadry. Revised by R.K.Goyal& R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

1 Hospital - its Organisation and functions

Hospital pharmacy-Organisation and management

- a) Organizational structure-Staff, Infrastructure & work load statistics
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist

2 The Budget – Preparation and implementation

Hospital drug policy

- a) Pharmacy and Therapeutic committee (PTC)
- b) Hospital formulary
- c) Hospital committees
 - Infection committee
 - Research and ethical committee
- d) developing therapeutic guidelines
- e) Hospital pharmacy communication - Newsletter

3.Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
 - Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital

- i) Individual prescription method
- ii) Floor stock method
- iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

4. Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

5 Continuing professional development programs

Education and training

Radio Pharmaceuticals – Handling and packaging

Professional Relations and practices of hospital pharmacist

(17T00408) HOSPITAL PHARMACY (PRACTICAL)

Practical:3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

(17T00403) CLINICAL PHARMACY (THEORY)

Theory :3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;

- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathietal, Orient OrientLangramPvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Definitions, development and scope of clinical pharmacy
Introduction to daily activities of a clinical pharmacist
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

Patient data analysis

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

2. Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

- a. Haematological, Liver function, Renal function, thyroid function tests
- b. Tests associated with cardiac disorders
- c. Fluid and electrolyte balance
- d. Microbiological culture sensitivity tests
- e. Pulmonary Function Tests

3. Drug & Poison information

- a. Introduction to drug information resources available
- b. Systematic approach in answering DI queries
- c. Critical evaluation of drug information and literature
- d. Preparation of written and verbal reports
- e. Establishing a Drug Information Centre
- f. Poisons information- organization & information resources

4. Pharmacovigilance

- a. Scope, definition and aims of pharmacovigilance
- b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
- c. Reporting, evaluation, monitoring, preventing & management of ADRs
- d. Role of pharmacist in management of ADR.

5. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.

Pharmaceutical care concepts

Critical evaluation of biomedical literature

Medication errors

(17T00409) CLINICAL PHARMACY (PRACTICAL)

Practical:3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min

(17T00404) BIostatistics AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments,
determination of sample size to obtain a confidence interval of specified width,
power of a study
- d) Report writing and presentation of data

2. **Biostatistics**

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semi logarithmic plots

3. **Basics of testing hypothesis**

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

4. **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

5. **Computer applications in pharmacy**

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

Drug Information Retrieval & Storage:

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

(17T00405) BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
4. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open ModelNonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis- menton method of estimating parameters.
5. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.

Bioavailability and Bioequivalence.

- a. Introduction.
- b. Bioavailability study protocol.
- c. Methods of Assessment of Bioavailability

(17T00410) BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical:3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half- life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B.Jaiswal, VallabhPrakashanPitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylean, Marcel Dekker Inc, New York 1996.

(17T00406) CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. General principles involved in the management of poisoning
Antidotes and the clinical applications.
Supportive care in clinical Toxicology.
Gut Decontamination.
Elimination Enhancement.
Toxicokinetics.
2. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti- inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
3. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
4. Plants poisoning. Mushrooms, Mycotoxins.
Food poisonings
. Envenomations – Arthropod bites and stings.
- 5. Substance abuse:**
Signs and symptoms of substance abuse and treatment of dependence
 - a) CNS stimulants: amphetamine
 - b) Opioids
 - c) CNS depressants
 - d) Hallucinogens: LSD
 - e) Cannabis group
 - f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V VPillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Theory:

3Hrs/week

- **Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases.**

1. **13 hrs**
Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
2. **14 hrs**
Respiratory system: Introduction to Pulmonaryfunction test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
3. **13 hrs**
General prescribing guidelines for
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding**Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations
Dermatology: Psoriasis, Scabies, Eczema, Impetigo.
4. **18 hrs**
Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
5. **17hrs**
Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
Renal system: Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - IV YEAR

(17T00412) PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

Practicals:

3 Hrs./Week

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 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03 hrs	04 hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - V YEAR

(17T00501) CLINICAL RESEARCH (THEORY)

Theory:3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.

3.

1. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
2. Challenges in the implementation of guidelines
3. Ethical guidelines in Clinical Research
4. Composition, responsibilities, procedures of IRB / IEC

4.

1. Overview of regulatory environment in USA, Europe and India.
2. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority

5.

1. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
2. Informed consent Process
3. Data management and its components
4. Safety monitoring in clinical trials.

References:

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications,2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - V YEAR

(17T00502) PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory :3 Hrs. /Week

1. Pharmacoepidemiology:

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

2. Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

3. Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

4. Phrmacoeconomics:

Definition, history, needs of pharmaco-economic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

5. Applications of Pharmacoeconomics

Software and case studies

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Pharm. D - V YEAR

(17T00503) CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory :2 Hrs. /Week

1. Introduction to Clinical pharmacokinetics.

Design of dosage regimens:

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

2. Pharmacokinetics of Drug Interaction:

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

3. Therapeutic Drug monitoring:

- a. Introduction
- b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
- c. Indications for TDM. Protocol for TDM.
- d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
- e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

4. Dosage adjustment in Renal and hepatic Disease.

- a. Renal impairment
- b. Pharmacokinetic considerations
- c. General approach for dosage adjustment in Renal disease.
- d. Measurement of Glomerular Filtration rate and creatinine clearance.
- e. Dosage adjustment for uremic patients.
- f. Extracorporeal removal of drugs.
- g. Effect of Hepatic disease on pharmacokinetics.

5. Population Pharmacokinetics.

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feed back.
- c. Analysis of Population pharmacokinetic Data.

Pharmacogenetics

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations