JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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 specializations prescribed by the University for each programme, from time to time.

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

2.0 COURSE WORK:

2.1 A Candidate after securing admission must pursue the M.Tech. course of study for Four semesters duration.

2.2 Each semester shall be of 20 weeks duration including all examinations.

2.3 A candidate admitted to a programme should complete it within a period equal to twice the prescribed duration of the programme from the date of admission.

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

3.0 ATTENDANCE:

3.1 A candidate shall be deemed to have eligibility to write end semester examinations if he/she has put in atleast 75% of attendance on cumulative basis of all subjects/courses in the semester.

3.2 Condonation of shortage of attendance up to 10% i.e., from 65% and above and less than 75% may be given by the college on the recommendation of the Principal.

3.3 Condonation of shortage of attendance shall be granted only on genuine and valid reasons on representation by the candidate with supporting evidence.

3.4 If the candidate does not satisfy the attendance requirement he/she is detained for want of attendance and shall reregister for that semester. He/she shall not be promoted to the next semester.

4.0. EVALUATION:

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

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

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

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

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

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

4.5. For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day to day performance.

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

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

10 marks are allotted. The assessment will be made by the faculty allotted by the HOD.

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

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

4.10. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified in 4.9.) he/she 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 i.e., fourth semester. The duration of the project work 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 seminars 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.

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

Where, Ci is the number of credits of the i^{th} subject, Gi is the grade point scored by the student in the i^{th} course and n is the number 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.

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

Where 'Si' is the SGPA of the i^{th} semester, Ci is the total number of credits in that semester and n is the number 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:

8.1 A candidate shall be eligible for the award of respective degree if he/she fulfils the following academic regulations.

i. Pursues a course of study for not less than two academic years and in not more than four academic years.
ii. Registers for 78 credits and secures all 78 credits.

8.2 A candidate shall be eligible for the award of class if he/she satisfies the minimum academic requirements in every subject and secures 'satisfactory' grade report on his/her project thesis 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.**

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RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not

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

7.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the impostor is an outsider, he will be handed over to the police and a case is registered against him.
8.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or	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.

	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.

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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	**17S08104**	**Pharmaceutical Analysis Practical for Industrial Pharmacy**	**-**	**-**	**6**	**3**
6	**17S08105**	**Pharmaceutical Formulation Development Practical**	**-**	**-**	**6**	**3**
7	**17S08106**	**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 I	-	-	6	3
6	17S08206	Industrial Pharmacy Practical II	-	-	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. 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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

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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. Biorelevent 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

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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 thestudents in the area of novel drug delivery systems.

Objective

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

- 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, MucoadhesiveDDS(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 MicronCosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

3 08HrsTargeted

Drug Delivery Systems: Importance, concept,biological process and events involved in drug targeting, design,formulation& evaluation, methods in drug targeting –nanoparticles, liposomes, niosomes, pharmacosomes, resealederythrocytes, microspheres, magnetic microspheres. Specializedpharmaceutical 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. Filling of patents. Theessential 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**

(17S08104) PHARMACEUTICAL ANALYSIS PRACTICAL FOR INDUSTRIAL PHARMACY

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.

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

(17S08105) PHARMACEUTICAL FORMULATION DEVELOPMENT PRACTICAL

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.

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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 dosecalculations, dose adjustments and to apply biopharmaceutics theories inpractical problem solving. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics are provided to help the students' toclarify the concepts.

Objectives

Upon completion of this course it is expected that students will be ableunderstand,

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

THEORY **60 Hrs**

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formuulation and physicochemical factors: Dissolution rate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup andsolution) as a dosage form ,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transport model:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.

2 12hrs

Biopharmaceutic considerations in drug product designand In Vitro Drug Product Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limitingsteps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product performance, in vitro:dissolution and drug release testing, compendial methods ofdissolution,

alternative methods of dissolution testing,meetingdissolution requirements,problems of variable control in dissolutionTestingperformance of drug products. In vitro–in vivo correlation,dissolution profile comparisons, drug productstability,considerations in the design of a drug product.

3 12 hrs

Pharmacokinetics: Basic considerations, pharmacokineticmodels, compartment modeling: one compartment model- IVbolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmaxand vmax. Drug interactions: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

4 12 hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ andIn-vivo methods.generic biologics (biosimilar drugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, genericsubstitution.

5 12 hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Introduction to Pharmacokinetics andpharmacodynamic, drug interactions. Pharmacokinetics andpharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, 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. (Industrial Pharmacy)

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(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 safetyissues.

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, parentraland semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilotplant to plant scale, process scale up for tablets, capsules, liquidorals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physicallayout, 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, cleaningvalidation and vender qualification.

3 12Hrs

Equipment Qualification: Importance, IQ, OQ, PQ forequipments – autoclave, DHS, membrane filter, rapid mixergranulator, 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 andsealing, sterilization, water process systems, environmentalcontrol.

5 12Hrs

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

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 Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman,Lieberman, Marcel Dekker, NY.

7. Pharmaceutical dosage forms, Parentral 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,VallabhPrakashan,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 thestudents 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 tounderstand,

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

THEORY 60 Hrs

Improved Tablet Production: Tablet production process, unit

1. 12Hrs

operation improvements, granulation and pelletizationequipments, continuous and batch mixing, rapid mixinggranulators, 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. Problemsencountered.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Capsule Production: Production process, improved capsulemanufacturing and filling machines for hard and soft gelatincapsules. 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 &temperaturecontrol, air filtration systems, dust collectors. Water TreatmentProcess: Techniques and maintenance – RO, DM, ultra –filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, VarghesePubl, 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, Parentral 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. Chezerisionoff.

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 Industy,.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, EllisHorwoods, UK.

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

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4	0	0	4

(17S08204) ENTREPRENEURSHIP MANAGEMENT

Scope

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

Objectives:

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

- 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 inentrepreneurship development. Role of enterprise in national andglobal 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 ofmotivation. Entrepreneurial competency – Concepts. DevelopingEntrepreneurial competencies - requirements and understandingthe process of entrepreneurship development, self-awareness,interpersonal skills, creativity, assertiveness, achievement, factorsaffecting entrepreneur role.

3 12Hrs

Launching AndOrganising An Enterprise: Environmentscanning – Information, sources, schemes of assistance,problems. Enterprise selection, market assessment, enterprisefeasibility study, SWOT Analysis. Resource mobilisation -finance, technology, raw material, site and manpower. Costingand marketing management and quality control. Feedback,monitoring and evaluation.

4 12Hrs

Growth Strategies And Networking: Performance appraisal andassessment. Profitability and control measures, demands andchallenges. Need for diversification. Future Growth – Techniquesof expansion and diversification, vision strategies. Concept anddynamics. Methods, Joint venture, co-ordination and feasibilitystudy.

5 12Hrs

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.

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

(17S08205) INDUSTRIAL PHARMACY PRACTICAL - I

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 bounddrug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism

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

(17S08206) INDUSTRIAL PHARMACY PRACTICAL - II

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.

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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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personalhygiene, 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.

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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	**17S07104**	**Modern Pharmaceutical Analytical Techniques Practical**	**-**	**-**	**6**	**3**
6	**17S04104**	**Quality Control And Quality Assurance Practical**	**-**	**-**	**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**	**-**	**-**	**6**	**3**
6	**17S04208**	**Pharmaceutical Validation-Practical**	**-**	**-**	**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

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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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

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M. Pharm – I year I Sem. (PA & QA)

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(17S04101) QUALITY MANAGEMENT SYSTEMS

Scope

This course is designed to impart fundamental knowledge and concepts aboutvarious quality management principles and systems utilized in themanufacturing industry. It also aids in understanding the quality evaluation in thepharmaceutical industries.

Objectives

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

- 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 ofQuality, Dimensions of Quality, Quality as a Strategic Decision: Meaning of strategy andstrategic quality management, mission and vision statements,quality policy, Quality objectives, strategic planning andimplementation, McKinsey 7s model, Competitive analysis,Management commitment to qualityCustomer Focus: Meaning of customer and customer focus,Classification of customers, Customer focus, Customerperception of quality, Factors affecting customer perception,Customer requirements, Meeting customer needs andexpectations, 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 ofquality.

2 12Hrs

Pharmaceutical quality Management: Basics of QualityManagement, Total Quality Management (TQM), Principles of Sixsigma, ISO 9001:2008, 9001:2015, ISO 14001:2004,Pharmaceutical Quality Management – ICH Q10, Knowledgemanagement, Quality Metrics, Operational Excellence and QualityManagement Review. OSHAS guidelines, NABL certification andaccreditation, CFR-21 part 11, WHO-GMP requirements.

3 12Hrs

Six System Inspection model: Quality Management system,Production system, Facility and Equipment system, Laboratorycontrol 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 anddetermination of root cause, Corrective & Preventive Actions(CAPA), Returns and Recalls, Vendor Qualification, AnnualProduct Reviews, Batch Review and Batch Release. Concept ofIPQC, area clearance/ Line clearance.

4 16Hrs

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

5 8Hrs

Regulatory Compliance through Quality Management anddevelopment of Quality CultureBenchmarking: Definition of benchmarking, Reasons forbenchmarking, Types of Benchmarking, Benchmarking process,Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks andResults, 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: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson, 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 Materialsand 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,DukeOkes, 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 qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike cGMP, QC tests, documentation, quality certifications, GLP and regulatoryaffairs.

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 toPharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY 60 Hrs

1. 12Hrs

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

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

2. 12Hrs

cGMP guidelines according to schedule M, USFDA (inclusiveof CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnelresponsibilities, training, hygiene and personal records, drugindustry location, design, construction and plant lay out,maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and GoodWarehousing Practice. CPCSEA guidelines.

3. 12Hrs

Analysis of raw materials, finished products, packagingmaterials, in process quality control (IPQC), Developingspecification (ICH Q6 and Q3)Purchase specifications and maintenance of stores for rawmaterials. In process quality control and finished products qualitycontrol for following formulation in Pharma industry according toIndian, US and British pharmacopoeias: tablets, capsules,ointments, suppositories, creams, parenterals, ophthalmic andsurgical products (How to refer pharmacopoeias), Quality controltest for containers, closures and secondary packing materials.

4. 12Hrs

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

5. 12Hrs

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

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 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 compedium of Guide lines andRelated 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 Methodsof Analysis and Quality specification for Pharmaceutical Substances,

Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekker 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 qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware 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.

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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 inpharmaceutical industries. This subject covers the methodology involved in theauditing 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 pharmaceuticalmanufacturing environment: cGMP Regulations, Qualityassurance functions, Quality systems approach, Managementresponsibilities, Resource, Manufacturing operations, Evaluationactivities, Transitioning to quality system approach, Audit checklistfor drug industries.

3 12Hrs

Auditing of vendors and production department: BulkPharmaceutical 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 themanufacturing process, Product and process information, Generalareas of interest in the building raw materials, Water, Packagingmaterials.

5 12Hrs

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 Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. 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).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QA)

L	T	P	C
4	0	0	4

(17S07104) 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. Qunatitative 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 Spectrophtometer/ 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

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.

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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 understandissues related to different kinds of hazard and their management. Basictheoretical and practical discussions integrate the proficiency to handle theemergency situation in the pharmaceutical product development process andprovides 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 differentkinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology forprovide safe industrial atmosphere.

THEORY 60Hrs

1. 12Hrs

Multidisciplinary nature of environmental studies: NaturalResources, Renewable and non-renewable resources, Naturalresources 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 andfunction of an ecosystem. Environmental hazards: Hazardsbased on Air, Water, Soil and Radioisotopes.

2 12Hrs

Air based hazards: Sources, Types of Hazards, Air circulationmaintenance industry for sterile area and non sterilearea,Preliminary Hazard Analysis (PHA) Fire protection system: Fireprevention, types of fire extinguishers and critical Hazardmanagement 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 andhazards potential, mechanical electrical, thermal and processhazards. Safety and hazards regulations, Fire protection system:Fire prevention, types of fire extinguishers and critical Hazardmanagement system mechanical and chemical explosion,multiphase reactions, transport effects and global rates.Preventive and protective management from fires and explosionelectricitypassivation, ventilation, and sprinkling, proofing, reliefsystems -relief valves, flares, scrubbers.

5 12Hrs

Hazard and risk management: Self-protective measures againstworkplace hazards. Critical training for risk management, Processof hazard management, ICH guidelines on risk assessment andRisk management methods and ToolsFactory 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 treatmentprocedure, 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” AmericanInstitute of Chemical Industries, Centre for Chemical Process safety.

3. BharuchaErach, The Biodiversity of India, Mapin Pu blishingPvt.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 itcan be applied to industry and thus improve the quality of the products. Thesubject covers the complete information about validation, types, methodologyand application.

Objectives

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

- 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 ofpharmaceuticals

THEORY 60 Hrs

1. 10Hrs

Introduction to validation: Definition of Calibration, Qualificationand Validation, Scope, frequency and importance. Differencebetween calibration and validation. Calibration of weights andmeasures. Advantages of Validation, scope of Validation,Organization for Validation, Validation Master plan, Types ofValidation, Streamlining of qualification & Validation process andValidation Master Plan.

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

2 16Hrs

a. Qualification of manufacturing equipment: Dry PowderMixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membranefiltration, Capsule filling machine.
b. Qualification of analytical instruments: UV-Visiblespectrophotometer, 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 ofProcess Validation. Prospective, Concurrent &RetrospectiveValidation, Re validation criteria, Process Validation of variousformulations (Coated tablets, Capsules, Ointment/Creams, LiquidOrals and aerosols.), Aseptic filling: Media fill validation, USFDAguidelines on Process Validation- A life cycle approach.

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

4 10Hrs

Cleaning Validation: Cleaning Method development, Validationof 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 digitalsignature - 21 CFR Part 11 and GAMP

5 12Hrs

General Principles of Intellectual Property: Concepts ofIntellectual 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 ramification and financial implications. Filing a patentapplications; patent application forms and guidelines. Typespatent applications-provisional and non provisional, PCT andconvention patent applications; International patenting requirementprocedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patentinfringement meaning and scope. Significance of transfertechnology (TOT), IP and ethics-positive and negative aspectsof IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm 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 Internationalpublishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton&Agalloco,

5. (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 forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider

8. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, 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 byChurg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

11. Huber L. Validation and Qualification in Analytical Laboratories. InformaHealthcare

12. Wingate G. Validating Corporate Computer Systems: Good IT Practice forPharmaceutical Manufacturers. Interpharm Press

13. LeBlanc DA. Validated Cleaning Technologies for PharmaceuticalManufacturing. 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 drugproducts, in residual solvents, Elemental impurities, Impurity profiling andcharacterization of degradents, Stability testing of phytopharmaceuticalsandtheir protocol preparation. It also covers the biological testing of variousvaccines and their principle and procedure.

Objective

After completion of the course students shall 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 ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelinesImpurities in new drug products:Rationale for the reporting and control of degradation products,reporting degradation products content of batches, listing ofdegradation products in specifications, qualification of degradationproducts

Impurities in residual solvents:General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents

2 12Hrs

Elemental impurities:

Element classification, control of elemental impurities, PotentialSources of elemental Impurities, Identification of PotentialElemental 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 ofresults, concept of stability, commitment etc. Importantmechanistic and stability related information provided by results ofstudy of factors like temperature, pH, buffering species ionicstrength and dielectric constant etc. on the reaction rates. Withpractical considerations.

3 12Hrs

Impurity profiling and degradent characterization: Methoddevelopment, Stability studies and concepts of validationaccelerated stability testing & shelf life calculation, WHO and ICHstability testing guidelines, Stability zones, steps in development,practical considerations. Basics of impurity profiling anddegradent characterization with special emphasis. Photostabilitytesting 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 vaccinec. 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 generegulation, instrumentation (Principle and Procedures)

5 10Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of boundand 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.

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 Vol I , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, firstrevision, 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 theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Cell culture techniquesBasic 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 ofcells and their applications. Principles and applications of cellviability assays (MTT assays), Principles and applications of flowcytometry.

5 12Hrs

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

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.

2. Principles of Instrumental Analysis - Doglas 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 LBertholf, 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

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**

(17S04208) PHARMACEUTICAL VALIDATION-PRACTICAL

1. Qualification of Following Analytical Instruments

    a) UV-Visible Spectrophotometer

    b)FTIR

    c)HPLC

    d)LC-MS

2. Qualification of following Pharma Equipment

    a) Autoclave

    b) Hot Air Oven

    c) Powder Mixer

    d) Tablet compression Machine

3. Qualification of Pharmaceutical Testing Equipment

    a) Dissolution Testing apparatus

    b)Friability Apparatus

    c) Disintegration tester

4. Validation of an analytical method of any two drugs

5. Validation of processing area

6. Cleaning validation of one equipment

7. Design of plant layout –sterile and nonsterile area

8. Process validation of various formulations –Protocol preparation

9. Case study on application of QbD (Quality by Design)

10. Case study on application of PAT (Process Analytical technology)

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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree off reedom, 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.

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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	**17S07104**	**Modern Pharmaceutical Analytical Techniques Practical**	**-**	**-**	**6**	**3**
6	**17S04206**	**Food Analysis Practical**	**-**	**-**	**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**	**-**	**-**	**6**	**3**
6	**17S12202**	**Advanced Instrumental Analysis Practical**	**-**	**-**	**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. 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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (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 drugproducts, in residual solvents, Elemental impurities, Impurity profiling andcharacterization of degradents, Stability testing of phytopharmaceuticals andtheir protocol preparation. It also covers the biological testing of variousvaccines and their principle and procedure.

Objective

After completion of the course students shall 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 ActivePharmaceutical Ingredients and quantification of impurities as perICH guidelinesImpurities in new drug products:Rationale for the reporting and control of degradation products,reporting degradation products content of batches, listing ofdegradation products in specifications, qualification of degradationproducts

Impurities in residual solvents:General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents

2 10Hrs

Elemental impurities:

Element classification, control of elemental impurities, PotentialSources of elemental Impurities, Identification of PotentialElemental 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 ofresults, concept of stability, commitment etc. Importantmechanistic and stability related information provided by results ofstudy of factors like temperature, pH, buffering species ionicstrength and dielectric constant etc. on the reaction rates. Withpractical considerations.

3 10Hrs

Impurity profiling and degradent characterization: Methoddevelopment, Stability studies and concepts of validationaccelerated stability testing & shelf life calculation, WHO and ICHstability testing guidelines, Stability zones, steps in development,practical considerations. Basics of impurity profiling anddegradent characterization with special emphasis. Photostabilitytesting guidelines, ICH stability guidelines for biological products

4 16Hrs

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

Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccinec. 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 generegulation, instrumentation (Principle and Procedures)

5 14Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of boundand 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, JohnWiley& 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, CBSPublishers, NewDelhi, 1964.

8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, firstrevision, 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. (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 constituentsand finished food products. The course includes application of instrumentalanalysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand variousanalytical 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, Dietaryfibre, Crude fibre and application of food carbohydratesProteins: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and aminoacids, Digestion, absorption and metabolism of proteins.

2 12Hrs

Lipids: Classification, general methods of analysis, refining of fatsand oils; hydrogenation of vegetable oils, Determination ofadulteration in fats and oils, various methods used formeasurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis ofvitamins, 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, theiroccurrence and characteristic properties, permitted syntheticdyes, Non-permitted synthetic dyes used by industries, Method ofdetection of natural, permitted and non-permitted dyes.

4 12Hrs

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

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 emphasison 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 inpharmaceutical industries. This subject covers the methodology involved in theauditing 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 pharmaceuticalmanufacturing environment: cGMP Regulations, Qualityassurance functions, Quality systems approach, Managementresponsibilities, Resource, Manufacturing operations, Evaluationactivities, Transitioning to quality system approach, Audit checklistfor drug industries.

3 12Hrs

Auditing of vendors and production department: BulkPharmaceutical 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 themanufacturing process, Product and process information, Generalareas of interest in the building raw materials, Water, Packagingmaterials.

5 12Hrs

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 Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. 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).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (PA & QC)

L	T	P	C
0	0	6	3

(17S07104) 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. Qunatitative 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 Spectrophtometer/ HPLC/ GC/ FTIR

14. Cleaning validation of any one analytical equipment

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M. Pharm – I year I Sem. (PA & QC)

L	T	P	C
0	0	6	3

(17S04206) FOOD ANALYSIS PRACTICAL

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 techniquesfor identification, characterization and quantification of drugs. Instruments dealtare 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 organiccompounds
- 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, plateheight, resolution, band broadening, pumps, injector, detectors,columns, column problems, gradient HPLC, HPLC solvents,trouble shooting, sample preparation, method development, Newdevelopments in HPLC-role and principles of ultra, nanoliquidchromatography in pharmaceutical analysis. Immobilizedpolysaccharide CSP's: Advancement in enantiomericseparations,revised phase Chiral method development and HILICapproaches. HPLC in Chiral analysis of pharmaceuticals.Preparative HPLC, practical aspects of preparative HPLC.

2 12Hrs

Biochromatography: Size exclusion chromatography, ionexchange chromatography, ion pair chromatography, affinitychromatography general principles, stationary phases and mobilephases.

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 pharmaceuticalanalysis, basic configuration, CE characteristics, principles of CE,methods and modes of CE. General considerations and methoddevelopment in CE, Crown ethers as buffer additives in capillaryelectrophoresis. CE-MS hyphenation.

4 12Hrs

Mass spectrometry: Principle, theory, instrumentation of massspectrometry, different types of ionization like electron impact,chemical, field, FAB and MALD, APCI, ESI, APPI massfragmentation and its rules, meta stable ions, isotopic peaks andapplications of mass spectrometry. LC-MS hyphenation andDART MS analysis. Mass analysers (Quadrpole, 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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation andApplications 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 - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P DSethi, 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. Paviya, 5th Edition.

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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 ofanalysis 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 theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Cell culture techniquesBasic 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 ofcells and their applications. Principles and applications of cellviability assays (MTT assays), Principles and applications of flowcytometry.

5 12Hrs

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

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.

2. Principles of Instrumental Analysis - Doglas 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 LBertholf, 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

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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 qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike cGMP, QC tests, documentation, quality certifications, GLP and regulatoryaffairs.

Objectives

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

- The cGMPaspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable toPharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY 60 hrs

1. 12Hrs

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

Good Laboratory Practices: Scope of GLP, Definitions, Qualityassurance unit, protocol for conduct of non clinical testing, controlon animal house, report preparation and documentation.

2. 12Hrs

cGMP guidelines according to schedule M, USFDA (inclusiveof CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnelresponsibilities, training, hygiene and personal records, drugindustry location, design, construction and plant lay out,maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and GoodWarehousing Practice. CPCSEA guidelines.

3. 12Hrs

Analysis of raw materials, finished products, packagingmaterials, in process quality control (IPQC), Developingspecification (ICH Q6 and Q3)Purchase specifications and maintenance of stores for rawmaterials. In process quality control and finished products qualitycontrol for

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

4. 12Hrs

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

5. 12Hrs

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

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 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 compedium of Guide lines andRelated 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 Methodsof Analysis and Quality specification for Pharmaceutical Substances,

Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekker 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 qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware 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, phototoxinandmicrobial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patentlaw as applicable herbal drugs and natural products and its protocol.

3 12Hrs

Testing of natural products and drugs: Effect of herbalmedicine on clinical laboratory testing, Adulterant Screening usingmodern analytical instruments, Regulation and dispensing ofherbal drugs, Stability testing of natural products, protocol.Monographs of Herbal drugs: Study of monographs of herbaldrugs and comparative study in IP, USP, AyurvedicPharmacopoeia,

American herbal Pharmacopoeia, British herbalPharmacopoeia, Siddha and Unani Pharmacopoeia, WHOguidelines in quality assessment of herbal drugs.

4 12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines forsafety monitoring of natural medicine, Spontaneous reportingschemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges inmonitoring 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 ofpowder, density, viscosity of cosmetic raw materials and finishedproducts. Study of quality of raw materials and general methodsof analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testingof various cosmetics in finished forms such as baby careproducts, skin care products, dental products, personal hygienepreparations, lips sticks. Hair products and skin creams by theBureau 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 AshutoshKar

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'sPerfumes,Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook ofCosmetic 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

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

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, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis ofvariance, 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.

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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**	**Modern Pharmaceutical Analytical Techniques Practical**	**-**	**-**	**6**	**3**
6	**17S04206**	**Food Analysis Practical**	**-**	**-**	**6**	**3**
7	**17S07105**	**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 I**	**-**	**-**	**6**	**3**
6	**17S07206**	**Pharmaceutical Analysis Practical II**	**-**	**-**	**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 foridentification, characterization and quantification of drugs. Instruments dealt areNMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals andexcipients

- 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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (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 drugproducts, in residual solvents, Elemental impurities, Impurity profiling andcharacterization of degradents, Stability testing of phytopharmaceuticalsandtheir protocol preparation. It also covers the biological testing of variousvaccines and their principle and procedure.

Objective

After completion of the course students shall 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 ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelinesImpurities in new drug products:Rationale for the reporting and control of degradation products,reporting degradation products content of batches, listing ofdegradation products in specifications, qualification of degradationproducts

Impurities in residual solvents:General principles, classification of residual solvents, Analyticalprocedures, limits of residual solvents, reporting levels of residualsolvents

2 10Hrs

Elemental impurities:

Element classification, control of elemental impurities, PotentialSources of elemental Impurities, Identification of PotentialElemental 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 ofresults, concept of stability, commitment etc. Importantmechanistic and stability related information provided by results ofstudy of factors like temperature, pH, buffering species ionicstrength and dielectric constant etc. on the reaction rates. Withpractical considerations.

3 10Hrs

Impurity profiling and degradent characterization: Methoddevelopment, Stability studies and concepts of validationaccelerated stability testing & shelf life calculation, WHO and ICHstability testing guidelines, Stability zones, steps in development,practical considerations. Basics of impurity profiling anddegradent characterization with special emphasis. Photostabilitytesting guidelines, ICH stability guidelines for biological products

4 16Hrs

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 vaccinec. 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 generegulation, instrumentation (Principle and Procedures)

5 14Hrs

Immunoassays (IA)

Basic principles, Production of antibodies, Separation of boundand 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.

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 VolI , II & III 2007, 2010, 2014.

9. Methods of sampling and microbiological examination of water, firstrevision, 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 itcan be applied to industry and thus to improve the quality of the products. Thesubject covers the complete information about validation, types, methodologyand application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout 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 &Validationprocess and Validation Master Plan.

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

2 12Hrs

Qualification of analytical instruments: Electronic balance, pHmeter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLCQualification of Glassware: Volumetric flask, pipette, Measuringcylinder, 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 Methoddevelopment, Validation and validation of analytical method usedin cleaning. Cleaning of Equipment, Cleaning of Facilities.Cleaning in place (CIP).

4 12Hrs

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

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

5 12Hrs

General Principles of Intellectual Property: Concepts ofIntellectual 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 ramification and financial implications. Filing a patentapplications; patent application forms and guidelines. Typespatent applications-provisional and non-provisional, PCT andconvention patent applications; International patenting requirementprocedures and costs; Rights and responsibilities of a patentee;Practical aspects regarding maintaining of a Patent file; Patentinfringement meaning and scope. Significance of transfertechnology (TOT),IP and ethics-positive and negative aspectsof IPP; Societal responsibility, avoiding unethical practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm 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 Internationalpublishing.

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 forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider

7. Pharmaceutical Equipment Validation: The Ultimate QualificationHandbook, 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 byChurg 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, Dietaryfibre, Crude fibre and application of food carbohydratesProteins: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and aminoacids, Digestion, absorption and metabolism of proteins.

2 12Hrs

Lipids: Classification, general methods of analysis, refining of fatsand oils; hydrogenation of vegetable oils, Determination ofadulteration in fats and oils, various methods used formeasurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis ofvitamins, 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, theiroccurrence and characteristic properties, permitted syntheticdyes, Non-permitted synthetic dyes used by industries, Method ofdetection of natural, permitted and non-permitted dyes.

4 12Hrs

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

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 emphasison 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) 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. Qunatitative 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 Spectrophtometer/ 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

(17S04206) FOOD ANALYSIS PRACTICAL

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 techniquesfor identification, characterization and quantification of drugs. Instruments dealtare 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 organiccompounds
- 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, plateheight, resolution, band broadening, pumps, injector, detectors,columns, column problems, gradient HPLC, HPLC solvents,trouble shooting, sample preparation, method development, Newdevelopments in HPLC-role and principles of ultra, nanoliquidchromatography in pharmaceutical analysis. Immobilizedpolysaccharide CSP's: Advancement in enantiomericseparations,revised phase Chiral method development and HILICapproaches. HPLC in Chiral analysis of pharmaceuticals.Preparative HPLC, practical aspects of preparative HPLC.

2 12Hrs

Biochromatography: Size exclusion chromatography, ionexchange chromatography, ion pair chromatography, affinitychromatography general principles, stationary phases and mobilephases.

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 pharmaceuticalanalysis, basic configuration, CE characteristics, principles of CE,methods and modes of CE. General considerations and

methoddevelopment in CE, Crown ethers as buffer additives in capillaryelectrophoresis. CE-MS hyphenation.

4 12Hrs

Mass spectrometry: Principle, theory, instrumentation of massspectrometry, different types of ionization like electron impact,chemical, field, FAB and MALD, APCI, ESI, APPI massfragmentation and its rules, meta stable ions, isotopic peaks andapplications of mass spectrometry. LC-MS hyphenation andDART MS analysis. Mass analysers (Quadrpole, 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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR with reference to 13CNMR:Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-Dand 2-D NMR, NOESY and COSY techniques, Interpretation andApplications 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 - Doglas A Skoog, F. James Holler,

Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. 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. Paviya, 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 ofanalysis 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 theBioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novelsample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Cell culture techniquesBasic 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 ofcells and their applications. Principles and applications of cellviability assays (MTT assays), Principles and applications of flowcytometry.

5 12Hrs

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

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, Newyork. 1995.

2. Principles of Instrumental Analysis - Doglas 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 LBertholf, 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. (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 qualityassurance aspects of pharmaceutical industries. It covers the important aspectslike 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 cGMPaspects 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 QualityAssuranceGood Laboratory Practice, GMP, Overview of ICH Guidelines -QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Qualityassurance unit, protocol for conduct of non clinical testing, controlon animal house, report preparation and documentation.

2. 12Hrs

cGMP guidelines according to schedule M, USFDA (inclusiveof CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnelresponsibilities, training, hygiene and personal records, drugindustry location, design, construction and plant lay out,maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and GoodWarehousing Practice. CPCSEA guidelines.

3. 12Hrs

Analysis of raw materials, finished products, packagingmaterials, in process quality control (IPQC), Developingspecification (ICH Q6 and Q3)Purchase specifications and maintenance of stores for rawmaterials. In process quality control and finished products qualitycontrol for following formulation in Pharma industry according toIndian, US and British pharmacopoeias: tablets, capsules,ointments, suppositories, creams, parenterals, ophthalmic andsurgical products (How to refer pharmacopoeias), Quality controltest for containers, closures and secondary packing materials.

4. 12Hrs

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

5. 12Hrs

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

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures ofIndia, 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 compedium of Guide lines andRelated 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 Methodsof Analysis and Quality specification for Pharmaceutical Substances,

Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, MarcelDekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4thedition, Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total qualitycontrol – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturersand Their Suppliers, Sixth Edition, (Volume 1 - With Checklists andSoftware 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 betterunderstanding 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 vsConventional drugs, Efficacy of herbal medicine products,Validation of Herbal Therapies, Pharmacodynamic andPharmacokinetic issues. Herbal drug standardization: WHO andAYUSH guidelines.

2 12Hrs

Adulteration and Deterioration: Introduction, types ofadulteration/substitution of herbal drugs, Causes and Measure ofadulteration, Sampling Procedures, Determination of ForeignMatter, DNA Finger printing techniques in identification of drugs ofnatural origin, heavy metals, pesticide residues, phototoxinandmicrobial contamination in herbal formulations.Regulatory requirements for setting herbal drug industry:Global marketing management, Indian and international patentlaw as applicable herbal drugs and natural products and itsprotocol.

3 12Hrs

Testing of natural products and drugs: Effect of herbalmedicine on clinical laboratory testing, Adulterant Screening usingmodern analytical instruments, Regulation and dispensing ofherbal drugs, Stability testing of natural products, protocol.Monographs of Herbal drugs: Study of monographs of herbaldrugs and comparative study in IP, USP, AyurvedicPharmacopoeia, American herbal Pharmacopoeia, British herbalPharmacopoeia, Siddha and Unani Pharmacopoeia, WHOguidelines in quality assessment of herbal drugs.

4 12Hrs

Herbal drug-drug interaction: WHO and AYUSH guidelines forsafety monitoring of natural medicine, Spontaneous reportingschemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges inmonitoring 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 ofpowder, density, viscosity of cosmetic raw materials and finishedproducts. Study of quality of raw materials and general methodsof analysis of raw material used in cosmetic manufacture as perBIS.

Indian Standard specification laid down for sampling and testingof various cosmetics in finished forms such as baby careproducts, skin care products, dental products, personal hygienepreparations, lips sticks. Hair products and skin creams by theBureau 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 AshutoshKar

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'sPerfumes,Cosmetics and Soaps

12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook ofCosmetic 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 PRACTICAL - I

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.

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

(17S07206) PHARMACEUTICAL 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

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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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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	**17S02104**	**Pharmaceutical Analysis Practical for Pharmaceutical Chemistry**	**-**	**-**	**6**	**3**
6	**17S02105**	**Pharmaceutical Chemistry Practical I**	**-**	**-**	**6**	**3**
7	17S02106	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

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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 foridentification, characterization and quantification of drugs. Instruments dealt areNMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals andexcipients

- 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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

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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 theirapplications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of reterosynthesis
- 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, freeradicals, carbenes and nitrenes. Their method offormation, stability and synthetic applications.
2. Types of reaction mechanisms and methods ofdetermining them,
3. Detailed knowledge regarding the reactions,mechanisms and their relative reactivity and orientations.

Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 andSN2)
b) Elimination reactions (E1 & E2; Hoffman &Saytzeff'srule)
c) Rearrangement reaction

2 12Hrs

Study of mechanism and synthetic applications of followingnamed Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions,Dieckmann Reaction, Doebner-Miller Reaction, SandmeyerReaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-HaackReaction, Sharpless asymmetric epoxidation, Baeyer-Villigeroxidation, Shapiro & Suzuki reaction, Ozonolysis and Michaeladdition reaction

3 12Hrs

Synthetic Reagents & Applications:

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane,dicyclohexylcarbodimide, Wilkinson reagent, Witting 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-and1,3-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: carbamatesand amides

4 12Hrs

Heterocyclic Chemistry:

Organic Name reactions with their respective mechanism andapplication involved in synthesis of drugs containing five, sixmembered and fused hetrocyclics such as Debus-Radziszewskiimidazole synthesis, Knorr Pyrazole Synthesis Pinner PyrimidineSynthesis, CombesQuinoline Synthesis, BernthsenAcridineSynthesis, Smiles rearrangement and Traube purine synthesis.

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

5 12Hrs

Synthon approach and retrosynthesis applications

i. Basic principles, terminologies and advantages ofretrosynthesis; guidelines for dissection of molecules.Functional group interconvertion and addition (FGI and FGA)

ii. C-X disconnections; C-C disconnections – alcohols andcarbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalizedcompounds

iii. Strategies for synthesis of three, four, five and six-memberedring.

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.

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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 receptorinteractions, 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 drugsSystematic study, SAR, Mechanism of action and synthesis ofnew generation molecules of following class of drugs:

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

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

4 12Hrs

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

5 12Hrs

PeptidomimeticsTherapeutic values of Peptidomimetics, design ofpeptidomimetics by manipulation of the amino acids, modificationof the peptide backbone, incorporating conformational constraintslocally or globally. Chemistry of prostaglandins, leukotrienesandthromboxones.

REFERENCES

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2. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, 12th Edition, Lppincott Williams & Wilkins, WoltessKluwer(India) Pvt.Ltd, New Delhi.

3. Comprehensive Medicinal Chemistry – Corwin and Hansch.

4. Computational and structural approaches to drug design edited by RobertM 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, IppincottWilliams& Wilkins, Woltess 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 RichardB.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 ofmedicinal compounds from natural origin and general methods of structuralelucidation of such compounds. It also emphasizes on isolation, purification andcharacterization of medicinal compounds from natural origin.

Objectives

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

- 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 pharmaceuticalsfor the following class of drugs

a) Drugs Affecting the Central Nervous System: MorphineAlkaloids

b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, andTeniposide

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, generalmethods of structural determination of alkaloids, structuralelucidation and stereochemistry of ephedrine, morphine, ergot,emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, Generalmethods of structural determination of flavonoids; Structuralelucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiacglycosides. 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 ofstructural elucidation of Terpenoids; Structural elucidation ofdrugs belonging to mono (citral, menthol, camphor), di(retinol,Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside)carotinoids (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 discoveryrDNA technology, hybridoma technology, New pharmaceuticalsderived from biotechnology; Oligonucleotide therapy. Genetherapy: Introduction, Clinical application and recent advances ingene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used inIndigenous system Diabetic therapy – Gymnemasylvestre,Salacia reticulate, Pterocarpusmarsupiam, Swertiachirata,Trigonellafoenumgraccum; Liver dysfunction – Phyllanthusniruri;Antitumor – Curcuma longa Linn.

5 12Hrs

Structural Characterization of natural compoundsStructural characterization of natural compounds using IR,1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g.,Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalisglycosides.

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 Nostrant Rein Hld.

3. Recent advances in Phytochemistry Vol. I to IV – ScikelRuneckles,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, Chapmannstall.

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.

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

(17S02104) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACEUTICAL CHEMISTRY

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

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

(17S02105) 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

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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 techniquesfor identification, characterization and quantification of drugs. Instruments dealtare LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

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

- 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:

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α,β-carbonyl compounds and interpretation compounds 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 importantfunctional groups like alcohols, amines, carbonyl groups andalkanes, Meta stable ions, Mc Lafferty 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) CEMSg) High Performance Thin Layer chromatography h) Supercritical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

5 12Hrs

a). Thermalmethods of analysisIntroduction, principle, instrumentation and application of DSC,DTA and TGA.

b). Raman SpectroscopyIntroduction, Principle, Instrumentation and Applications.

c). Radio immunoassayBiologicalstandardization , 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 - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P DSethi, 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

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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 theirapplications 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 ofmicrowave, effects of solvents in microwave assistedsynthesis, microwave technology in process optimization, itsapplications in various organic reactions and heterocyclessynthesis

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

d. Continuous flow reactors: Working principle, advantages andsynthetic applications.

2 12Hrs

Chemistry of peptides

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOCprotocols, various solid supports and linkers: Activationprocedures, peptide bond formation, deprotectionandcleavage from resin, low and high

HF cleavage protocols,formation of free peptides and peptide amides, purification andcase studies, site-specific chemical modifications of peptides

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

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

3 12Hrs

Photochemical Reactions

Basic principles of photochemical reactions. Photo-oxidation,photo-addition and photo-fragmentation.PericyclicreactionsMechanism, Types of pericyclic reactions such as cycloaddition,electrocyclic reaction and sigmatrophic rearrangement reactionswith examples

4 12Hrs

Catalysis:

a. Types of catalysis, heterogeneous and homogenous catalysis,advantages and disadvantages

b. Heterogeneous catalysis – preparation, characterization,kinetics, supported catalysts, catalyst deactivation andregeneration, some examples of heterogeneous catalysisused in synthesis of drugs.

c. Homogenous catalysis, hydrogenation, hydroformylation,hydrocyanation, Wilkinson catalysts, chiral ligands and chiralinduction, Ziegler-Natta catalysts, some examples ofhomogenous 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, specificrotation, racemates and resolution of racemates, the Cahn,Ingold, Prelog (CIP) sequence rule, meso compounds, pseudoasymmetric centres, axes of symmetry, Fischers D and Lnotation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiralauxiliaries and catalytic asymmetric synthesis, enantiopureseparation and Stereo selective synthesis with examples.

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 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.

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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 arttechniques involved in computer assisted drug design.

Objectives

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

- 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: BasicsHistory and development of QSAR: Physicochemical parametersand methods to calculate physicochemical parameters: Hammettequation and electronic parameters (sigma), lipophilicityeffectsand parameters (log P, pi-substituent constant), steric effects(Taft steric and MR parameters) Experimental and theoreticalapproaches for the determination of these physicochemicalparameters.

2 12Hrs

Quantitative Structure Activity Relationships: ApplicationsHansch analysis, Free Wilson analysis and relationship betweenthem, Advantages and disadvantages; Deriving 2D-QSARequations.3D-QSAR approaches and contour map analysis.Statistical methods used in QSAR analysis and importance ofstatistical parameters.

3 12Hrs

Molecular Modeling and Docking

a) Molecular and Quantum Mechanics in drug design.

b) Energy Minimization Methods: comparison between globalminimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigiddocking, flexible docking and extra-precision docking.Agents acting on enzymes such as DHFR, HMG-CoAreductase and HIV protease, choline esterase (AchE&BchE)

4 12Hrs

Molecular Properties and Drug Design

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

b) De novo drug design: Receptor/enzyme-interaction and itsanalysis, Receptor/enzyme cavity size prediction, predictingthe functional components of cavities, Fragment based drugdesign.

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

5 12Hrs

Pharmacophore Mapping and Virtual ScreeningConcept of pharmacophore, pharmacophoremapping,identification of Pharmacophore features and Pharmacophoremodeling; Conformational search used in pharmacophoremapping.InSilico Drug Design and Virtual Screening TechniquesSimilarity based methods and Pharmacophore based screening,structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert MStroud 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, ElsevierPublishers.

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.

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8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, Ippincott Williams & Wilkins.

9. Comprehensive Medicinal Chemistry – Corwin and Hansch, PergamonPublishers.

10. Computational and structural approaches to drug design edited by RobertM Stroud and Janet. F Moore

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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 fromsmall quantities created in the research lab to the larger quantities that areneeded for further testing and then to even larger quantities required forcommercial production. The goal of a process chemist is to develop syntheticroutes that are safe, cost-effective, environmentally friendly, and efficient. Thesubject is designed to impart knowledge on the development and optimization ofa synthetic route/s and the pilot plant procedure for the manufacture of ActivePharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for thedrug development phase.

Objectives

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

- 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 strategyStages 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 genotoxicimpurities

2 12Hrs

Unit operations

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

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

c) Distillation: azeotropic and steam distillation

d) Evaporation: Types of evaporators, factors affectingevaporation.

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

3 12Hrs

Unit Processes - I

a) Nitration: Nitrating agents, Aromatic nitration, kineticsand mechanism of aromatic nitration, process equipmentfor technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, typesofhalogenations, catalytic halogenations. Case study onindustrial halogenation process.

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

4 12Hrs

Unit Processes - II

a) Reduction: Catalytic hydrogenation, Heterogeneousand homogeneous catalyst; Hydrogen transfer reactions,Metal hydrides. Case study on industrial reductionprocess.

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 ofcost-effective routes, reagent selection, familiesofreagents useful for scale-up.

5 12Hrs

Industrial Safety

a) MSDS (Material Safety Data Sheet), hazard labels ofchemicals 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(EnvironmentalManagement 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

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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 approachesinvolving (3 experiments)

a) Oxidationb) Reduction/hydrogenationc) Nitration

2. Comparative study of synthesis of APIs/intermediates by different syntheticroutes (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 Massspectra
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-iodotolene 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 ofselected 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.

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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, typeof significance tests, parametric tests(students “t” test, ANOVA, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis ofvariance, correlation, chi square test), null hypothesis, P values, degree offreedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence,non-maleficence, double effect, conflicts between autonomy andbeneficence/non-maleficence, euthanasia, informed consent, confidentiality,criticisms of orthodox medical ethics, importance of communication, controlresolution, 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, personalhygiene, 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 medicalresearch, and additional principles for medical research combined withmedical care.

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
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6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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 cGMPPart 210 and Part 211.EC Principles of GMP (Directive91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelinesGAMP-5; Medical device and IVDs Global Harmonization TaskForce(GHTF) Guidance docs.

2

12HrsGood Laboratory Practices: Introduction, USFDA GLPRegulations (Subpart A to Subpart K), Controlling the GLPinspection process, Documentation, Audit, goals of LaboratoryQuality Audit, Audit tools, Future of GLP regulations, relevant ISOand 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 of21CFR Part 11, Software Evaluation checklist, relevant ISO andQCI Standards.

4 12Hrs

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

5 12Hrs

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

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth EditionDrugs and the Pharmaceutical Sciences, Vol.168

2. Good Pharmaceutical Manufacturing practice, Rational and compliance byJohn Sharp, CRC Press

3. Establishing a cGMP Laboratory Audit System, A practical Guide by DavidM.Bleisner, Wiley Publication.

4. How to practice GLP by PP Sharma, Vandana Publications.

5. Laboratory Auditing for Quality and Regulatory compliance buDonaldC.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

6. Drugs & Cosmetics Act, Rules & Amendments

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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 documentationand 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: ExploratoryProduct Development Brief (EPDB) for Drug substance and Drugproduct, Product Development Plan (PDP), Product DevelopmentReport (PDR), Master Formula Record, Batch ManufacturingRecord and its calculations, Batch Reconciliation, BatchPackaging Records, Print pack specifications, Distributionrecords, Certificate of Analysis (CoA), Site Master File and DrugMaster Files (DMF).

2 12Hrs

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

3 12Hrs

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

Auditingstrategies, Preparation and conducting audit, Auditing strategies,audit analysis, audit report, audit follow up. Auditing/inspection ofmanufacturing facilities by regulatory agencies. Timelines foraudits/inspection. GHTF study group 4 guidance document.ISO 13485.

4 12Hrs

Inspections: Pre-approval inspections, Inspection ofpharmaceutical manufacturers, Inspection of drug distributionchannels, Quality systems requirements for national goodmanufacturing practice inspectorates, inspection report, modelcertificate 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 BeingEffected in 30 Days (CBE-30), Annual Report, Post marketingReporting 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. KarenGinsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London NewYork, Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality byShayne 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 andFrancis (2005).

5. Implementing Juran's Road Map for Quality Leadership: Benchmarksand 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: TheCEO Report By Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson, 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 toMaterials and Resources By Christine Avery; Diane Zabel, Routledge,1997

10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQPublications

11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and JosephA. De Feo, ASQ Publications

12. Root Cause Analysis, The Core of Problem Solving and CorrectiveAction, Duke Okes, 2009, ASQ Publications

13. International Medical Device Regulators Forum (IMDRF) MedicalDevice Single Audit Program (MDSAP)

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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 clinicaldevelopment process of drugs, pharmaceuticals and Medical Devices, phasesand conduct of clinical trials and research, regulations and guidance governingthe conduct of clinical research in India, USA and EU. It prepares the studentsto 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 andappreciate)

- 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

ClinicalResearch 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 biostatics 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 (EMEA) 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 RegulatoryComplianceBy Fay A. Rozovsky and Rodney K. Adams

2. HIPAA and Human Subjects Research: A Question and AnswerReference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD,PhD

3. Principles and Practices of Clinical Research, Second Edition Edited byJohn I. Gallin and Frederick P. Ognibene

4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PEKarlberg and Marjorie A Speers; Karlberg, Johan PetterEinar, HongKong.

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, RichardA; 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/cfcfr/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 PROPERTYRIGHTS

Scope

This course is designed to impart fundamental knowledge on regulations andlegislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals &Herbals, and Food &Nutraceuticals. It prepares the students for basicregulatory requirements in India of Drugs & Cosmetics, Medical Devices,Biologicals& Herbals, and Food &Nutraceuticals. for manufacture, import &registration, export, sale, marketing authorization, clinical trials and intellectualproperty 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 &NutraceuticalsActs and Rules (with latest amendments):

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

2. Other relevant provisions (rules schedules andguidelines for approval of Drugs & Cosmetics, MedicalDevices, Biologicals & Herbals, and Food &Nutraceuticals in IndiaOther relevant Acts: Narcotics Drugs and PsychotropicSubstances Act; Medicinal and Toilet Preparations (ExciseDuties) Act, 1955; Pharmacy Act, 1948; Drugs and MagicRemedies (Objectionable Advertisements) Act, 1955; Preventionof Cruelty to Animals Act.

2 12Hrs

Regulatory requirements and approval procedures for Drugs& Cosmetics Medical Devices, Biologicals & Herbals, andFood&NutraceuticalsCDSCO (Central Drug Standard Control Organization) and StateLicensing 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 andother relevant standards

4 12Hrs

Bioavailability and Bioequivalence data (BA &BE), BCSClassification of Drugs, Regulatory Requirements forBioequivalencestudyStability requirements: ICH and WHOGuidelines for Drug testing in animals/Preclinical StudiesAnimal testing: Rationale for conducting studies, CPCSEAGuidelines

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 PatentScenario. IPR vs Regulatory Affairs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Officeof India

2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators atrisk by James Bessen and Michael J. Meurer

3. Principles and Practice of Clinical Trial Medicine by Richard Chin andBruce Y. Lee

4. Ethical Guidelines for Biomedical Research on Human Participants byIndian Council of Medical Research New delhi 2006.

5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for thepurpose 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 forEvaluating Safety and Efficacy by CDSCO (Central Drug Standard ControlOrganisation)

8. Guidance for Industry on Requirement of Chemical &PharmaceuticalInformation 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

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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 forSolid, 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 submissionin 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.

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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 Japanof 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

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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 drugdevelopment process, regulatory requirements for approval of new drugs, drugproducts and cosmetics in regulated and semi-regulated countries. It preparesthe students to learn in detail on the regulatory requirements, documentationrequirements, and registration procedures for marketing the drug products andcosmetics 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), Historyand evolution of United States Federal, Food, Drug and CosmeticAct (FFDCA), Hatch Waxman act and Orange book, Purple book,Drug Master Files (DMF) system in US, Regulatory ApprovalProcess for Investigational New Drug (IND), New DrugApplication (NDA), Abbreviated New Drug Application (ANDA),Supplemental New Drug Application (SNDA); Regulatoryrequirements for Orphan drugs and Combination Products,Changes to an approved NDA / ANDA. Regulatory considerationsfor manufacturing, packaging and labeling of pharmaceuticals inUSA. 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 andNational Procedure). Regulatory considerations for manufacturing,packaging and labeling of pharmaceuticals in EU, Eudralexdirectives for human medicines, Variations &extensions,Compliance of European Pharmacopoeia (CEP)/ Certificate

ofSuitability (CoS), Marketing Authorization (MA) transfers, QualifiedPerson (QP) in EU. Legislation and regulations for import,manufacture, distribution and sale of cosmetics in EuropeanUnion& Australia.

3 12Hrs

Japan: Organization of the PMDA, Pharmaceutical Laws andregulations, types of registration applications, DMF system inJapan, drug regulatory approval process, Regulatoryconsiderations for manufacturing, packaging and labeling ofpharmaceuticals in Japan, Post marketing surveillance in Japan.Legislation and regulations for import, manufacture, distributionand sale of cosmetics in Japan

4 12Hrs

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

WHO: WHO, GMP, Regulatory Requirements for registration ofdrugs and post approval requirements in WHO throughprequalification 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, RegulatoryRequirements for registration of drugs and post approvalrequirements in China and South Korea & Association ofSoutheast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia,Philippines, Singapore and Thailand.

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

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

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, LeonShargel and IsaderKaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry MarcelDekker 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.185Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations ByRichardAGuarino, MD, 5th edition, Drugs and the Pharmaceutical

Sciences, Vol.190.

5. Guidebook for drug regulatory submissions / Sandy Weinberg. By JohnWiley& Sons. Inc.

6. Drugs: From Discovery to Approval, Second Edition By Rick Ng

7. New Drug Development: A Regulatory Overview, Eighth Edition ByMarkMathieu

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 ByWilliam 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, ISBN981-230-347-2

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, MarkKobayashi-Hillary, Springer

15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary,Springer Trade performance and Regional Integration of the CISCountries, Lev Freinkman,

16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0

17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's WorldByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes

18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEANby Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)

19. Doing Business in the Asean Countries, BalbirBhasin, Business ExpertPress ISBN:13:978-1-60649-108-9

20. Realizing the ASEAN Economic Community: A ComprehensiveAssessment, Michael G Plummer (Editor), Chia Siow Yue (Editor),Instute of South east asian studies, Singapore

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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 RegulatoryRequirements, Licensing and Registration, Regulation on Labelling of Biologicsin India, USA and EuropeIt prepares the students to learn in detail on Regulatory Requirements forbiologics, 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, DataRequirements for Preclinical Studies, Data Requirements forClinical Trial Application, Data Requirements for MarketAuthorization Application, Post-Market Data for Similar Biologics,Pharmacovigilance. GMP and GDP.

2 12Hrs

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

3 12Hrs

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

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

4 12Hrs

Vaccine regulations in India, US and European Union: Clinicalevaluation, Marketing authorisation, Registration or licensing,Quality assessment, Pharmacovigilance, Additional requirementsBlood and Blood Products Regulations in India, US and EuropeanUnion: Regulatory Requirements of Blood and/or Its ComponentsIncluding Blood Products, Label Requirements, ISBT(International Society of Blood Transfusion) and IHN (InternationalHaemovigilence Network)

5 12Hrs

Herbal Products: Quality, safety and legislation for herbalproducts 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; WeiWang ,Manmohan Singh ; wiley ,2013

3. Development of Vaccines: From Discovery to Clinical Testing; ManmohanSingh ,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 MarketingAuthorization in India

9. www.cdsco.nic.in

10. www.ema.europa.eu › scientific guidelines › Biologicals

11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance RegulatoryInformation (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 medicaldevices and in vitro diagnostics, basis of classification and product life cycle ofmedical devices, regulatory requirements for approval of medical devices inregulated countries like US, EU and Asian countries along with WHOregulations. It prepares the students to learn in detail on the harmonizationinitiatives, quality and ethical considerations, regulatory and documentationrequirements 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 basedclassification and Essential Principles of Medical Devices andIVDs. Differentiating medical devices IVDs and CombinationProducts from that of pharmaceuticals, History of Medical DeviceRegulation, Product Lifecycle of Medical Devices andClassification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purposeand Functions, Regulatory Guidelines, Working Groups,Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN).

2 12Hrs

Ethics: Clinical Investigation of Medical Devices, ClinicalInvestigation Plan for Medical Devices, Good Clinical Practice forClinical 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, AdverseEvent Reporting of Medical device

3 12Hrs

USA: Introduction, Classification, Regulatory approval process forMedical Devices (510k) Premarket Notification, Pre-MarketApproval (PMA), Investigational Device Exemption (IDE) and Invitro Diagnostics, Quality System Requirements 21 CFR Part 820,Labeling requirements 21 CFR Part 801, Post marketingsurveillance of MD and Unique Device Identification (UDI). Basicsof In vitro diagnostics, classification and approval process.

4 12Hrs

European Union: Introduction, Classification, Regulatoryapproval process for Medical Devices(Medical Device Directive, Active Implantable Medical DeviceDirective) 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, Regulatoryregistration procedures, Quality System requirements and clinicalevaluation and investigation.IMDRF study groups and guidance documents.

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics by Douglas J. Pisano, David Mantus.

2. Medical Device Development: A Regulatory Overview by Jonathan S.Kahan

3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, MedicalDevices by John J. Tobin and Gary Walsh

4. Compliance Handbook for Pharmaceuticals, Medical Devices andBiologics 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 RegulatoryRequirements, Registration and Labeling Regulations of Nutraceuticals in India,USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects fornutraceuticals 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 NutraceuticalRegulations, Meaning of Nutraceuticals, Dietary Supplements,Functional Foods, Medical Foods, Scope and Opportunities inNutraceutical Market.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

USA: US FDA Food Safety Modernization Act, DietarySupplement Health and Education Act. U.S. regulations formanufacture and sale of nutraceuticals and dietary supplements,Labelling

Requirements and Label Claims for DietarySupplements, Recommended Dietary Allowances (RDA) in theU.S

5 12Hrs

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

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

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspectiveby Clare M. Hasler (Wiley Online Library)

2. Nutraceutical and Functional Food Regulations in the United States andAround the World by DebasisBagchi (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

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 andIndia 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 marketauthorization
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, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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	**17S10102**	**Pharmaceutical Analysis Practical for Pharmaceutical Technology**	**-**	**-**	**6**	**3**
6	**17S10103**	**Pharmaceutical Technology Practical - I**	**-**	**-**	**6**	**3**
7	**17S10104**	**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 foridentification, characterization and quantification of drugs. Instruments dealt areNMR, 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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (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 DrugSubstance, Drug Product and analytical tests and methods, required followingcandidate drug selection to completion of technology transfer from R&D to thefirst receiving site and technology transfer related to post-marketing changes inmanufacturing 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 fromR&D to actual manufacturing by sorting out various informationobtained during R&D
- To elucidate necessary information to transfer technology of existingproducts between various manufacturing places

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

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

3 12Hrs

Pilot plant scale up: Concept, Significance, design, layout ofpilot plant scale up study, operations, large scale manufacturingtechniques (formula, equipment, process, stability and

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

4 12Hrs

Pharmaceutical packaging: Pharmaceutical dosage form andtheir packaging requirments, Pharmaceutical packaging materials,Medical device packaging, Enteral Packaging, Aseptic packagingsystems, Container closure systems, Issues facing modern drugpackaging, Selection and evaluation of Pharmaceutical packagingmaterials.

Quality control test: Containers, closures and secondarypacking materials.

5 12Hrs

Technology transfer: Development of technology by R & D,Technology transfer from R & D to production, Optimization andProduction, 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, Groupof Taylor and Francis.

2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of IndustrialPharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodmanufacturing of pharmaceuticals (A Plan for total quality control) 3rdEdition. 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 MiloGibaldi, 3rd Edn, Lea & Febriger, Philadelphia.

6. Pharmaceutical product development. Vandana V. Patrevale. John I.Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.

7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, MackPublishing company, Eastern Pennsylvania.

8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19thEdn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters KluwerCompany, Philadelphia.

9. The Pharmaceutical Sciences; the Pharma Path way ‘Pure and appliedPharmacy’ 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 thestudents in the area of novel drug delivery systems.

Objective

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

- 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 controlleddrug delivery systems (DDS), rate programmed release,activation modulated & feedback regulated DDS, effect of systemparameters in controlled drug delivery, computation of desiredrelease rate and dose for controlled release DDS,pharmacokinetic design for DDS – intermittent, zero order & firstorder release.

Carriers for Drug Delivery: Polymers / co-polymersintroduction,classification, characterization, polymerizationtechniques, application in CDDS / NDDS, biodegradable & naturalpolymers.

2 12Hrs

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

08Hrs

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

04Hrs

c. Sub-Micron Cosmeceuticals: Biology, formulation science andevaluation of various cosmetics for skin, hair, nail, eye etc. and it'sregulatory 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, resealederythrocytes, microspheres, magnetic microspheres. Specializedpharmaceutical emulsions – multiple emulsions, micro-emulsions.

4 04Hrs

Protein / Peptide Drug Delivery Systems: Concepts, deliverytechniques, formulation, stability testing, causes of proteindestabilization, stabilization methods.

06Hrs

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

5 06Hrs

New trends for Personalized Medicine: Introduction, Definition,Pharmacogenetics, Categories of Patients for PersonalizedMedicines: Customized drug delivery systems, BioelectronicMedicines, 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.

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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 thestudents to be on par with the routine of Industrial activities in drug regulatoryaffairs

Objectives

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

- 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 tobe satisfied by an invention to be patentable, Introduction topatent search. Parts of patents. Filling of patents. Theessential elements of patent; Guidelines for preparation oflaboratory 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 IndianPharmaceutical 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 andWilliams

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published byCBS 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**

(17S10102) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACEUTICAL TECHNOLOGY

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**

(17S10103) 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 dosecalculations, dose adjustments and to apply biopharmaceutics theories inpractical problem solving. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics are provided to help the students' toclarify the concepts.

Objectives

Upon completion of this course it is expected that students will be ableunderstand,

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

THEORY **60 Hrs**

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formuulation and physicochemical factors: Dissolution rate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup andsolution) as a dosage form ,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transport model:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.

2 12hrs

Biopharmaceutic considerations in drug product designand In Vitro Drug Product Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limitingsteps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product

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

3 12 hrs

Pharmacokinetics: Basic considerations, pharmacokineticmodels, compartment modeling: one compartment model- IVbolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmaxand vmax. Drug interactions: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

4 12 hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ andIn-vivo methods.generic biologics (biosimilar drugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, genericsubstitution.

5 12 hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Introduction to Pharmacokinetics andpharmacodynamic, drug interactions. Pharmacokinetics andpharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, 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 thestudents to be on scale up, technology transfer process and industrial safetyissues.

Objectives:

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

- 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, parentraland semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilotplant to plant scale, process scale up for tablets, capsules, liquidorals, semisolids, parentral, NDDS products – stress on formula,equipments, product uniformity, stability, raw materials, physicallayout, 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, cleaningvalidation and vender qualification.

3 12Hrs

Equipment Qualification: Importance, IQ, OQ, PQ forequipments – autoclave, DHS, membrane filter, rapid mixergranulator, 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 andsealing, sterilization, water process systems, environmentalcontrol.

5 12Hrs

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

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 Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman,Lieberman, Marcel Dekker, NY.

7. Pharmaceutical dosage forms, Parentral 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.

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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 thestudents 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 tounderstand,

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

THEORY 60 Hrs

Improved Tablet Production: Tablet production process, unit

1. 12Hrs

Operation improvements, granulation and pelletizationequipments, continuous and batch mixing, rapid mixinggranulators, 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. Problemsencountered.

2 12Hrs

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

3 12Hrs

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

4 12Hrs

Capsule Production: Production process, improved capsulemanufacturing and filling machines for hard and soft gelatincapsules. 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 & temperaturecontrol, air filtration systems, dust collectors. Water TreatmentProcess: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, VarghesePubl, 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, Parentral 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. Chezerisionoff.

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 Industy,.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, EllisHorwoods, 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 listedas 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'sperfumecosmeticsandSoaps, 10th edition.

3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition

4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye andH.I. Maibach. 3 rd edition

5. Cosmetic and Toiletries recent suppliers' catalogue.

6. CTFA directory.

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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

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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

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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, Correlationcoefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence,non-maleficence, double effect, conflicts between autonomy andbeneficence/non-maleficence, euthanasia, informed consent, confidentiality,criticisms of orthodox medical ethics, importance of communication, controlresolution, 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, personalhygiene, 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.

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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	**17S03104**	**Pharmaceutical Analysis Practical for Pharmaceutics**	**-**	**-**	**6**	**3**
6	**17S03105**	**Drug Delivery Systems Practical**	**-**	**-**	**6**	**3**
7	**17S03106**	**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) Practical**	**-**	**-**	**6**	**3**
6	**17S03206**	**Advanced Biopharmaceutics & Pharmacokinetics Practical**	**-**	**-**	**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 vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

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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 noveldrug delivery systems.

OBJECTIVES

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

- The various approaches for development of novel drug deliverysystems.
- The criteria for selection of drugs and polymers for the development ofdelivering 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 & biologicalapproaches for SR/CR formulation, Mechanism of Drug Deliveryfrom SR/CR formulation. Polymers: introduction, definition,classification, properties and application Dosage Forms forPersonalized Medicine: Introduction, Definition,Pharmacogenetics, Categories of Patients for PersonalizedMedicines: Customized drug delivery systems, BioelectronicMedicines, 3D printing of pharmaceuticals, Telepharmacy.

2 10hrs

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

3 10hrs

Gastro-Retentive Drug Delivery Systems: Principle, conceptsadvantages and disadvantages, Modulation of GI transit timeapproaches to extend GI transit. Buccal Drug Delivery Systems:Principle of muco adhesion, advantages anddisadvantages, Mechanism of drug permeation, Methods offormulation and its evaluations.

4 6hrs

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

10hrs

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

5 8 hrs

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

6 hrs

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

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised andexpanded,Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, MarcelDekker,Inc., New York, 1992.

3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published byWileyInterscience 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,VallabhPrakashan, 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

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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 learnvarious 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 Productdevelopment
- 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 ofdispersion and pharmaceutical Dispersion (Emulsion andSuspension, 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 techniquesin 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 ofequipments, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model,URS, DQ, IQ, OQ & P.Q. of facilities.

3 10 HRS

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

4 10 HRS

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

5 10 HRS

Study of consolidation parameters; Diffusion parameters,Dissolution parameters and Pharmacokinetic parameters, Heckelplots, Similarity factors – f2 and f1, Higuchi and Peppasplot,Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy ByLachmann and Libermann

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By LeonLachmann.

4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By LeonLachmann.

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 producersofIndia.

12.Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Easternpublishers, 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 theconcept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinical trials and submitting regulatorydocuments : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatoryimportance
- 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 tounderstand

- The Concepts of innovator and generic drugs, drug developmentprocess
- The Regulatory guidance's and guidelines for filing and approvalprocess
- Preparation of Dossiers and their submission to regulatory agencies indifferent 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
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY **60 Hrs**

1. 12 hrs

Documentation in Pharmaceutical industry: Masterformula record, DMF (Drug Master File), distribution records.Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION) ,drug product performance, in-vitro, ANDAregulatory approval process, NDA approval process, BE and drugproduct assessment, in –vivo, scale up process approvalchanges, post marketing surveillance, outsourcing BA and BE toCRO.

2.

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

3 12 hrs

CMC, post approval regulatory affairs. Regulation for combinationproducts and medical devices.CTD and ECTD format, industryand FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatoryrequirements 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. Institutionalreview board/ independent ethics committee Formulation andworking 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 ShargelandIsaderKaufer,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 AGuarino, 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, andbiologics/edited By Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to RegulatoryComplianceBy 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**

(17S03104) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACEUTICS

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

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

(17S03105) DRUG DELIVERY SYSTEMS PRACTICAL

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 balancedDDS
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.

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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 andbiological process involved in drug targeting. Tumor targeting andBrain 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 andevaluation, Monoclonal Antibodies; preparation and application,preparation and application of Niosomes, Aquasomes,Phytosomes, Electrosomes.

4 12 hrs

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

5 12 hrs

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

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised andexpanded,Marcel Dekker, Inc., New York, 1992.

2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts andadvances, VallabhPrakashan, New Delhi, First edition 2002.

3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, NewDelhi, 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 dosecalculations, dose adjustments and to apply biopharmaceutics theories inpractical problem solving. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics are provided to help the students' toclarify the concepts.

Objectives

Upon completion of this course it is expected that students will be ableunderstand,

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

THEORY **60 Hrs**

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formuulation and physicochemical factors: Dissolution rate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup andsolution) as a dosage form ,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.

2 12 hrs

Biopharmaceutic considerations in drug product designand In Vitro Drug Product Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limitingsteps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product performance, in vitro:dissolution and drug release testing, compendial methods ofdissolution, alternative methods of dissolution testing,meetingdissolutionrequirements,problems of variable control in

dissolutionTestingperformance of drug products. In vitro–in vivo correlation,dissolution profile comparisons, drug productstability,considerations in the design of a drug product.

3 12 hrs

Pharmacokinetics: Basic considerations, pharmacokineticmodels, compartment modeling: one compartment model- IVbolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmaxandvmax. Drug interactions: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

4 12 hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ andIn-vivo methods.generic biologics (biosimilardrugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, genericsubstitution.

5 12 hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Introduction to Pharmacokinetics andpharmacodynamic,druginteractions. Pharmacokinetics andpharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies,

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, 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, MarcelDekkerInc.,New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, LeaandFebiger, 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, MackPublishingCompany, 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,1stedition,Sunil S JambhekarandPhilipJBreen,pharmaceutical press, RPS Publishing,2009.

13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

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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 inte grated 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 andDevelopment: A General Overview: History of Computers inPharmaceutical Research and Development. Statistical modelingin Pharmaceutical research and development: Descriptive versusMechanistic Modeling, Statistical Parameters, Estimation,Confidence Regions, Nonlinearity at the Optimum, SensitivityAnalysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development:Introduction, ICH Q8 guideline, Regulatory and industry views onQbD, Scientifically based QbD - examples of application.

2 12 hrs

Computational Modeling Of Drug Disposition: Introduction,Modeling Techniques: Drug Absorption, Solubility, IntestinalPermeation, 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 ofoptimization, Optimization parameters, Factorial design,Optimization technology & Screening design. Computers inPharmaceutical Formulation: Development of pharmaceuticalemulsions, microemulsion drug carriers Legal Protection ofInnovative 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, Theoreticalbackground, Model construction, Parameter sensitivity analysis,Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroinvivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics andPharmacodynamics: Introduction, Computer Simulation: WholeOrganism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collectionand Management, Regulation of Computer Systems

5 12 hrs

Artificial Intelligence (AI), Robotics and Computational fluiddynamics: General overview, Pharmaceutical Automation,Pharmaceutical applications, Advantages and Disadvantages.Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development,SeanEkins, 2006, John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition,JelenaDjuris, 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 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. Soapsandsyndetbars.Perfumes;

Classification of perfumes. Perfume ingredients listedas allergens in EU regulation.Controversial ingredients: Parabens, formaldehyde liberators,dioxane.

4 12 hrs

Design of cosmeceutical products: Sun protection, sunscreensclassification and regulatory aspects. Addressing dry skin, acne,sun-protection, pigmentation, prickly heat, wrinkles, body odor.,dandruff, dental cavities, bleeding gums, mouth odor andsensitive 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 byprivate 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'sperfumecosmeticsandSoaps, 10th edition.

3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition

4. Handbook of cosmetic science and Technology A.O.Barel, M.PayeandH.I. Maibach. 3 rd edition

5. Cosmetic and Toiletries recent suppliers' catalogue.

6. CTFA directory.

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

L	T	P	C
0	0	6	3

(17S03205) NANO TECHNOLOGY & TARGETED Dds (Ntds) PRACTICAL

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

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

(17S03206) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

PRACTICAL

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 Pharmaco dynamics
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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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

I YEAR - I Semester

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

I YEAR II Semester

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

III SEMESTER

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

IV SEMESTER

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

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

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

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

Objectives

After completion of course student is able to know about,

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

THEORY **60 HOURS**

1. 11 hrs

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

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,

Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors

affecting vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

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

3. 11hrs

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

4. 11hrs

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

5 11hrs

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

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S01102) ADVANCED PHARMACOLOGY - I

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. 12Hrs

General Pharmacology

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

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

2 12Hrs

Neurotransmission

a. General aspects and steps involved in neurotransmission.

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

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

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

Systemic Pharmacology

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

Autonomic Pharmacology

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

3 12Hrs

Central nervous system Pharmacology

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

Depression, psychosis, mania, epilepsy, neurodegenerativediseases.

Narcotic and non-narcotic analgesics.

4 12Hrs

Cardiovascular Pharmacology

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

Hematinics, coagulants , anticoagulants, fibrinolytics and antiplateletdrugs

5 12Hrs

Autocoid Pharmacology

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

Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s

2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

3. Basic and Clinical Pharmacology by B.G Katzung

4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.

6. Graham Smith. Oxford textbook of Clinical Pharmacology.

7. Avery Drug Treatment

8. Dipiro Pharmacology, Pathophysiological approach.

9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company

12. KD. Tripathi. Essentials of Medical Pharmacology.

13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.

14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts andApplications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.

15. Applied bio-pharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.

16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S01103) PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. 12Hrs

Laboratory Animals

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

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

Maintenance and breeding of laboratory animals.

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

Bioassay-Principle, scope and limitations and methods

2 12Hrs

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

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

3 12Hrs

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

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

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

4

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

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

5 12Hrs

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

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

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin

2. Screening methods in Pharmacology by Robert Turner. A

3. Evaluation of drugs activities by Laurence and Bachrach

4. Methods in Pharmacology by Arnold Schwartz.

5. Fundamentals of experimental Pharmacology by M.N.Ghosh

6. Pharmacological experiment on intact preparations by Churchill Livingstone

7. Drug discovery and Evaluation by Vogel H.G.

8. Experimental Pharmacology by R.K.Goyal.

9. Preclinical evaluation of new drugs by S.K. Guta

10. Handbook of Experimental Pharmacology, SK.Kulkarni

11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.

12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition,Kluwer Academic Publishers, London, UK.

13. Screening Methods in Pharmacology, Robert A.Turner.

14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.

15. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), Ajay Prakash (Author)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S01104) CELLULAR AND MOLECULAR PHARMACOLOGY

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1. 12Hrs

Cell biology

Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2 12Hrs

Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligandgated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion,inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3 12Hrs

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

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

4 12Hrs

Pharmacogenomics

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.

Immunotherapeutics

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

5 12Hrs

a. Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M -L. Wong

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickensonet.al

5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller

6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

8. Current porotocols in molecular biology vol I to VI edited by FrederickM.Ausuvel et al.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S01105) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACOLOGY

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis-spectrophotometer

2.Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

7. Estimation of proteins by Braford/Lowry's in biological samples.

8. Estimation of RNA/DNA by UV Spectroscopy

9. Protein quantification Western Blotting.

10. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using soft wares

11. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)

12. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

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

L	T	P	C
0	0	6	3

(17S01106) PHARMACOLOGY PRACTICAL - I

1. Handling of laboratory animals.

1. Various routes of drug administration.

2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.

3. Functional observation battery tests (modified Irwin test)

4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic,anticonvulsant activity.

5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic andmiotic activity.

6. Evaluation of diuretic activity.

7. Evaluation of antiulcer activity by pylorus ligation method.

8. Oral glucose tolerance test.

9. Isolation and identification of DNA from various sources (Bacteria,Cauliflower, onion, Goat liver).

10. Isolation of RNA from yeast

11. Gene amplification by PCR.

12. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).

13. Cell viability assays (MTT/Trypan blue/SRB).

14. DNA fragmentation assay by agarose gel electrophoresis.

15. DNA damage study by Comet assay.

16. Apoptosis determination by fluorescent imaging studies.

17. Enzyme inhibition and induction activity

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

(17S01201) ADVANCED PHARMACOLOGY - II

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. 12Hrs

Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

2 12Hrs

Chemotherapy

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

3 12Hrs

Chemotherapy

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology

Cellular and biochemical mediators of inflammation and immuneresponse. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

4 12Hrs

GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy invarious diseases likecardiovascular disease, diabetes, asthma and peptic ulcer

5 12Hrs

Free radicals Pharmacology

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

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

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's

2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan et al.

3. Basic and Clinical Pharmacology by B.G -Katzung

4. Pharmacology by H.P. Rang and M.M. Dale.

5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

6. Text book of Therapeutics, drug and disease management by E T.Herfindal and Gourley.

7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and

Andrew B.C.Yu.

8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists

9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (RobbinsPathology)

10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company.

11. KD.Tripathi. Essentials of Medical Pharmacology

12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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

(17S01202) PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS-II

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory toxicology studies

3 12Hrs

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

4 12Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

5 12Hrs

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

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical researchand development (http://www.who.int/tdr/publications/documents/glphandbook.pdf).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) NewDelhi

3. Drugs from discovery to approval by Rick NG.

4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conductof Human Clinical Trials and Marketing Authorization for Pharmaceuticals(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

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

(17S01203) PRINCIPLES OF DRUG DISCOVERY

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3 12Hrs

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

4 12Hrs

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

5 12Hrs

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007Humana Press Inc.

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

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

(17S01204) CLINICAL RESEARCH AND PHARMACOVIGILANCE

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1. 12Hrs

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

2 12Hrs

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

3 12Hrs

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4 12Hrs

Basic aspects, terminologies and establishment of Pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

5 12Hrs

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

b . Pharmacoepidemiology, pharmacoeconomics, safetypharmacology

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices,Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health;2001.

2. International Conference on Harmonization of Technical requirements forregistration of Pharmaceuticals for human use. ICH Harmonized TripartiteGuideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000.Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs.Second Edition, Jan 2000, Wiley Publications.

6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. ChurchillLivingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

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 agonistusing suitable isolated tissue preparation.

3. To determine to the strength of unknown sample by matching bioassay byusing suitable tissue preparation.

4. To determine to the strength of unknown sample by interpolation bioassayby using suitable tissue preparation

5. To determine to the strength of unknown sample by bracketing bioassayby using suitable tissue preparation

6. To determine to the strength of unknown sample by multiple pointbioassay by using suitable tissue preparation.

7. Estimation of PA2 values of various antagonists using suitable isolatedtissue preparations.

8. Drug absorption studies by averted rat ileum preparation.

9. ADR reporting

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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*

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 historyinterview, Basic concept of medicine and poison informationservices, Basic concept of pharmacovigilance, Hemovigilance,Materiovigilance and AEFI, Patient medication counseling, Drugutilization evaluation, Documentation of clinical pharmacyservices, Quality assurance of clinical pharmacy services.

3 12Hrs

Patient Data Analysis:

Patient Data & Practice Skills: Patient's case history – itsstructure and significances in drug therapy management,Common medical abbreviations and terminologies used in clinicalpractice,

Communication skills: verbal and non-verbalcommunications, its applications in patient care services.

Lab Data Interpretation: Hematological tests, Renal functiontests, Liver function tests

4 12Hrs

Lab Data Interpretation: Tests associated with cardiacdisorders, Pulmonary function tests, Thyroid function tests, Fluidand electrolyte balance, Microbiological culture sensitivity tests

5 12Hrs

Medicines & Poison Information Services

Medicine Information Service: Definition and need for medicineinformation service, Medicine information resources, Systematicapproach in answering medicine information queries, Preparationof verbal and written response, Establishing a drug informationcentre.

Poison Information Service: Definition, need, organization andfunctions of poison information centre.

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and MilapNahata

2. Practice Standards and Definitions - The Society of Hospital Pharmacistsof Australia

3. Basic skills in interpreting laboratory data - Scott LT, American Society ofHealth 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 treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan 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 diseasesassociated with following systems

1. 12Hrs

Cardiovascular system: Hypertension, Congestive cardiacfailure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

2 12Hrs

Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseasesEndocrine system: Diabetes, Thyroid diseases

3 12Hrs

Gastrointestinal system: Peptic ulcer diseases, Refluxesophagitis, inflammatory bowel diseases, Jaundice & hepatitis

4 12Hrs

Gastrointestinal system: Cirrhosis, Diarrhea and Constipation,Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Druginduced hematological disorders

5 12Hrs

Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis,Gout, OsteoporosisDermatological Diseases: Psoriasis, Eczema and scabies,impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics – ChurchillLivingstone 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 andWilkins Publication

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Useof 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 Williamsand 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 topractice 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 structureHospital Pharmacy: Definition, Relationship of hospitalpharmacy department with other departments, Organizationalstructure, legal requirements, work load statistics, Infrastructuralrequirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement

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, DevelopingTherapeutic guidelines, Drug procurement process, and methodsof Inventory control, Methods of Drug distribution, Intravenousadmixtures, Hospital Waste Management

3 12Hrs

Education and training: Training of technical staff, training andcontinuing education for pharmacists, Pharmacy students,Medical staff and students, Nursing staff and students, Formaland informal meetings and lectures, Drug and therapeuticsnewsletter.

Community Pharmacy Practice: Definition, roles &responsibilities of community pharmacists, and their relationshipwith other health care providers.

Community Pharmacy management: Legal requirements tostart community pharmacy, site selection, lay out & design, drugdisplay, super drug store model, accounts and audits, Gooddispensing practices, Different softwares & databases used incommunity pharmacies. Entrepreneurship in communitypharmacy.

4 12Hrs

Prescription – Legal requirements & interpretation, prescriptionrelated problemsResponding to symptoms of minor ailments: Head ache,pyrexia, menstrual pains, food and drug allergy,OTC medication: Rational use of over the counter medicationsMedication counseling and use of patient information leafletsMedication adherence – Definition, factors influencing adherencebehavior, strategies to improve medication adherencePatient referrals to the doctorsADR monitoring in community pharmacies

5 12Hrs

Health Promotion – Definition and health promotion activities,family planning, Health screening services, first aid, prevention ofcommunicable and non-communicable diseases, smokingcessation, Child & mother careNational Health Programs- Role of Community Pharmacist inMalaria and TB control programsHome Medicines review program – Definition, objectives,Guidelines, method and outcomesResearch 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 drugdevelopment process especially the phases of clinical trials and also the ethicalissues involved in the conduct of clinical research. Also, it aims to impartsknowledge and develop skills on conceptualizing, designing, conducting andmanaging 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 todrug discovery, Investigational new drug application submissionEthics in Biomedical Research: Ethical Issues in BiomedicalResearch – Principles of ethics in biomedical research, Ethicalcommittee [institutional review board] - its constitution andfunctions, 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 andexecution of clinical trials, Various Phases of clinical trials,Bioavailability and Bioequivalence studies, Randomizationtechniques (Simple randomization, restricted randomization,blocking method and stratification), Types of research designsbased on Controlling Method (Experimental, Quasi experimental,and Observational methods) Time Sequences (Prospective andRetrospective), Sampling methods (Cohort study, case Controlstudy 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, ContractResearch Organization.

3 12Hrs

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, InformedConsent Form, Case report forms, Contracts and agreements,Dairy CardsClinical Trial Start up activities: Site Feasibility Studies,Site/Investigator selection, Pre-study visit, Investigator meeting,Clinical trial agreement execution, Ethics committee documentpreparation and submission

4 12Hrs

Investigational Product: Procurement and Storage ofinvestigation productFiling procedures: Essential documents for clinical trial, TrialMaster File preparation and maintenance, Investigator Site File,Pharmacy File, Site initiation visit, Conduct, Report and Follow upClinical Trial Monitoring and Close out:Preparation and conduct of monitoring visit: Review of sourcedocuments, CRF, ICF, IP storage, accountability andreconciliation, Study Procedure, EC communications, Safetyreporting, Monitoring visit reporting and follow-upClose-Out visit: Study related documents collection, Archivalrequirement, Investigational Product reconciliation anddestruction, Close-Out visit report.

5 12Hrs

Quality Assurance and Quality Control in Clinical Trials:Types of audits, Audit criteria, Audit process, Responsibilities ofstakeholders in audit process, Audit follow-up and documentation,Audit resolution and Preparing for FDA inspections, Fraud andmisconduct management

Data Management

Infrastructure and System Requirement for DataManagement: Electronic data capture systems, Selection andimplementation of new systems, System validation and testprocedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard OperatingProcedures, Data management plan, CRF & Data base designconsiderations, Study set-up, Data entry, CRF tracking andcorrections, Data cleaning, Managing laboratory and ADR data,Data transfer and database lock, Quality Control and QualityAssurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition.Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter DSloaierPublisher:Wiley;

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. ChurchillLivingstone

3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health.

5. International Conference on Harmonisation of Technical requirements forregistration of Pharmaceuticals for human use. ICH HarmonisedTripartiteGuideline. Guideline for Good Clinical Practice.E6; May 1996.

6. Ethical Guidelines for Biomedical Research on Human Subjects. IndianCouncil of Medical Research, New Delhi.

7. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, 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 theinclusion 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 andPrinciples of QUM, Key partners and responsibilities of thepartners, 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 evidencebased medicine, Approach and practice of evidence basedmedicine 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 druguse, Rational drug prescribing, Role of pharmacist in rational druguse.

3 12Hrs

QUM in various settings: Hospital settings, Ambulatorycare/Residential care, Role of health care professionals inpromoting the QUM, Strategies to promote the QUM, Impact ofQUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatricprescribing, Prescribing in pregnancy and lactation, Prescribing inimmune compromised and organ failure patients.

4 12Hrs

Regulatory aspects of QUM in India: Regulation includingscheduling, Regulation of complementary medicines, Regulationof OTC medicines, Professional responsibility of pharmacist, Roleof industry in QUM in medicine development.

5 12Hrs

Medication errors: Definition, categorization and causes ofmedication errors, Detection and prevention of medication errors,Role of pharmacist in monitoring and management of medicationerrors

Pharmacovigilance: Definition, aims and need forpharmacovigilance, Types, predisposing factors and mechanismof adverse drug reactions (ADRs), Detection, reporting andmonitoring 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 MilapNahata

2. Andrews EB, Moore N. Mann's Pharmacovigilance

3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A PathophysiologicApproach

4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-BasedMedicine: 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 treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan 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 variousdisease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence basedmedicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drugtherapy, and monitoring therapy (including alternatives, time- course ofclinical and laboratory indices of therapeutic response and adverseeffect/s)

THEORY 60 Hrs

1. 12Hrs

Nervous system: Epilepsy, Parkinson's disease, Stroke,Headache, Alzheimer’s disease, Neuralgias and Pain pathwaysand Pain management.

2 12Hrs

Psychiatric disorders: Schizophrenia, Depression, Anxietydisorders, Sleep disorders, Drug induced psychiatric disordersRenal system: Acute renal failure, Chronic renal failure, Renaldialysis, Drug induced renal disease

3 12Hrs

Infectious diseases: General guidelines for the rational use ofantibiotics 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, FungalinfectionsGynecological disorders: Dysmenorrhea, Hormonereplacement therapy.

5 Oncology: General principles of cancer chemotherapy,pharmacotherapy of breast cancer, lung cancer, head & neckcancer, hematological malignancies, Management of nausea andvomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics –ChurchillLivingstone 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 andWilkins Publication

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Useof 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 Williamsand 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 DRUGMONITORING

Scope

This course is designed to enable students to understand the basics principlesand applications of pharmacokinetics in designing the individualized dosageregimen, to interpret the plasma drug concentration profile in alteredpharmacokinetics, drug interactions and in therapeutic drug monitoringprocesses to optimize the drug dosage regimen. Also, it enables students tounderstand the basic concepts of pharmacogenetics, pharmacometrics formodeling 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/ hepaticimpairment
- 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 onpharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles ofpharmacometrics

THEORY 60 Hrs

1. 12Hrs

Introduction to Clinical pharmacokinetics: Compartmental andNon compartmental models, Renal and non-renal clearance,Organ extraction and models of hepatic clearance, Estimation anddeterminants of bioavailability, Multiple dosing, Calculation ofloading and maintenance dosesDesigning of dosage regimens: Determination of dose anddosing intervals, Conversion from intravenous to oral dosing,Nomograms and Tabulations in designing dosage regimen.

2 12Hrs

Pharmacokinetics of Drug Interaction: Pharmacokinetic druginteractions, Inhibition and Induction of Drug metabolism,Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism:Cytochrome P-450 Isoenzymes, Genetic Polymorphism in DrugTransport and Drug Targets, Pharmacogenetics andPharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics: Introduction to BayesianTheory, Adaptive method or Dosing with feedback, Analysis ofPopulation pharmacokinetic Data.

3 12Hrs

Non Linier Mixed Effects Modelling: The Structural or BaseModel, Modeling Random Effects, Modeling CovariateRelationships, Mixture Model, Estimation Methods, ModelBuilding Techniques, Covariate Screening Methods, Testing themodel assumptions, Precision of the parameter estimates andconfidence intervals, Model misspecification and violation of themodel assumptions, Model Validation, Simulation of dosingregimens and dosing recommendations, Pharmacometricssoftware.

4 12Hrs

Altered Pharmacokinetics: Drug dosing in the elderly, Drugdosing in the paediatrics, Drug dosing in the obese patients, Drugdosing in the pregnancy and lactation, Drug dosing in the renalfailure and extracorporeal removal of drugs, Drug dosing in the inhepatic failure.

5

Therapeutic Drug monitoring: Introduction, Individualization ofdrug dosage regimen (Variability – Genetic, age, weight, diseaseand Interacting drugs), Indications for TDM, Protocol for TDM,Pharmacokinetic/Pharmacodynamic Correlation in drug therapy,TDM of drugs used in the following conditions:

Cardiovasculardiseases: Digoxin, Lidocaine, Amiodarone;

Seizure disorders:Phenytoin, Carbamazepine, Sodium Valproate;

Psychiatricconditions: Lithium, Fluoxetine, Amitriptyline;

Organtransplantations: 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 andSimulation. Springer Publications.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans.Applied Pharmacokinetics & Pharmacodynamics: Principles of TherapeuticDrug Monitoring. Iippincott Williams & Wilkins.

4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.

5. SorayaDhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.

6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.

7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics andpharmacodynamics: concepts and applications. Iippincott Williams &Wilkins, USA.

8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society ofHealth system Pharmacists, USA.

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott 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: AmericanSociety 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-epidemiologicalmethods and their clinical applications. Also, it aims to impart knowledge onbasic concepts, assumptions, terminology, and methods associated withPharmacoeconomics and health related outcomes, and when should beappropriate Pharmacoeconomic model should be applied for a health careregimen.

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 Pharmacoeconomics.
- Identify and determine relevant cost and consequences associatedwith pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and itsapplications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to variouspharmacy settings.

THEORY 60 Hrs

1. 12Hrs

Introduction to Pharmacoepidemiology: Definition, Scope,Need, Aims & Applications; Outcome measurement: Outcomemeasures, Drug use measures: Monetary units, Number ofprescriptions, units of drug dispensed, defined daily doses,prescribed daily doses, Diagnosis and Therapy surveys,Prevalence, Incidence rate, Monetary units, number ofprescriptions, unit of drugs dispensed, defined daily doses andprescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk andrelative risk, Time- risk relationship and odds ratio

2 12Hrs

Pharmacoepidemiological Methods: Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series,Cross sectional studies, Cohort and case control studies,Calculation of Odds' ratio, Meta analysis models, Drug effectsstudy in populations:

Spontaneous reporting, Prescription eventmonitoring, Post marketing surveillance, Record linkage systems,Applications of Pharmacoepidemiology

3 12Hrs

Introduction to Pharmacoeconomics: Definition, history ofPharmacoeconomics, Need of Pharmacoeconomic studies inIndian healthcare system.

Cost categorization and resources for cost estimation: Directcosts. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanisticoutcomes; Quality Adjusted Life Years, Disability Adjusted LifeYears Incremental Cost Effective Ratio, Average Cost EffectiveRatio. Person Time, Willingness To Pay, Time Trade Off andDiscounting.

4 12Hrs

Pharmacoeconomic evaluations: Definition, Steps involved,Applications, Advantages and disadvantages of the followingPharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), CostUtility Analysis (CUA), Cost of Illness (COI), Cost ConsequencesAnalysis (COA).

5 12Hrs

Definition, Steps involved, Applications, Advantages anddisadvantages of the following:

Health related quality of life (HRQOL): Definition, Need formeasurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following:

Decision Analysis and Decision tree, Sensitivity analysis, MarkovModeling, 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 HealthEconomic Evaluation, Oxford University Press, London.

4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien andGregStoddart. Methods for the Economic Evaluation of Health CareProgrammes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes andpharmacoeconomics.

6. Graker, Dennis. Pharmacoeconomics and outcomes.

7. Walley, Pharmacoeconomics.

8. Pharmacoeconomic – ed. by Nowakowska – University of MedicalSciences, 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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

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

UNIT – IV

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

UNIT – V

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

References

1. *C.R.Kothari "Research Methodology Methods & Techniques", Second Edition, New Delhi: New Age International publisher*
2. *Pharmaceutical Statistics 5th edition by Sanford Bolton and Charles Bon.*
3. *Biostatistics by R.S. Shukla and P.S.Chandel-S.Chand.*
4. *Guidelines On The Regulation Of Scientific Experiments On Animals; Government of India June 2007*, https://www.aaalac.org/resources/SOP_CPCSEA.pdf.
5. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: http://anesthesia.gr/wp-content/uploads/2012/01/Decleration-of-Helsinki.pdf.*
6. *Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993,*