



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

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

1.0 ELIGIBILITY FOR ADMISSIONS:

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

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

2.0 COURSE WORK:

- 2.1 A Candidate after securing admission must pursue the M.Tech. course of study for Four semesters duration.
- 2.2 Each semester shall be of 20 weeks duration including all examinations.
- 2.3 A candidate admitted to a programme should complete it within a period equal to twice the prescribed duration of the programme from the date of admission.
- 2.4 The medium of instruction shall be English for all theory and practical courses, examinations, Seminar, Teaching Assignments, Comprehensive Viva-Voce and project thesis/dissertation reports.

3.0 ATTENDANCE:

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

4.0 EVALUATION:

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

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

- 4.2. Two Internal Examinations shall be held during the semester for 20 marks. First internal examination shall be conducted for half of the syllabus and second internal examination shall be conducted for remaining half of the syllabus. In each internal exam, a student shall answer all three questions in 2 hours of time without seeking any choice. Final Internal marks for a total of 20 marks shall be arrived at by considering the marks secured by the student in both the internal examinations with 70% weightage to the better internal exam and 30% to the other.
- 4.3. For the remaining 20 marks in internal evaluation, the University shall conduct one online examination.
- 4.4. The following pattern shall be followed in the End Examination.
 - a) Five questions shall be set from each of the five units with either/or type for 12 marks each.
 - b) All the questions have to be answered compulsorily.
 - c) Each question may consist of one, two or more bits.
- 4.5. For practical subjects, 60 marks shall be for the End Semester Examinations and 40 marks will be for internal evaluation based on the day to day performance.
- 4.6. For **Comprehensive Viva-Voce** and **Seminar** there will be an internal evaluation of 100 marks in each. A candidate has to secure a minimum of 50% (in each) to be declared successful. The assessment will be made by a board consisting of HOD and two senior internal experts at the end of **III** semester instruction.
- 4.7. For **Teaching Assignments** there will be an internal evaluation of 100 marks. A candidate has to secure a minimum of 50% to be declared successful. Student has to teach 10 Hours in his/her interesting subject/subjects in the entire III Semester instruction period for his juniors at PG level or Under Graduate students who are available on the campus. For each teaching hour maximum of 10 marks are allotted. The assessment will be made by the faculty allotted by the HOD.
- 4.8. Mandatory MOOCs course is introduced in III Semester as an elective without any credits. A student can choose any subject of his/her choice that has more than 30 hours duration from any MOOCs provider and should obtain satisfactory certificate. An Open Elective is introduced in III semester.
- 4.9. A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified above) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.
- 4.10. In case the candidate does not secure the minimum academic requirement in any of the subjects (as specified in 4.9.) he has to reappear for the Semester Examination either supplementary or regular in that subject, or repeat the course when next offered or do any other specified subject as may be required.

5.0 RE-REGISTRATION FOR IMPROVEMENT OF INTERNAL EVALUATION MARKS:

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

- 5.1 The candidate should have completed the course work and obtained examinations results for **I, II and III** semesters.
- 5.2 He should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%.
- 5.3 Out of the subjects the candidate has failed in the examination due to Internal Evaluation marks secured being less than 50%, the candidate shall be given one chance for each Theory subject and for a maximum of **three** Theory subjects for Improvement of Internal evaluation marks.
- 5.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.
- 5.5 For each subject, the candidate has to pay a fee equivalent to one third of the semester tuition fee and the amount is to be remitted in the form of D.D. in favour of the Registrar, JNTUA payable at Ananthapuramu along with the requisition through the Principal of the respective college.
- 5.6 In the event of availing the Improvement of Internal evaluation marks, the internal evaluation marks as well as the End Examinations marks secured in the previous attempt(s) for the reregistered subjects stand cancelled.

6.0 EVALUATION OF PROJECT WORK:

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

- 6.1 **Registration of Project work:** A candidate is permitted to register for the project work after satisfying the attendance requirement of all the courses (theory and practical courses of I & II Semester)
- 6.2 An Internal Departmental Committee (I.D.C) consisting of HOD, Supervisor and one internal senior expert shall monitor the progress of the project work.
- 6.3 The **first phase of the project work** on the project shall be initiated in the third semester and **second phase of the project work will be** continued in the final semester. The duration of the project is for two semesters. The candidate can submit Project thesis with the approval of I.D.C. after 36 weeks from the date of registration at the earliest and one calendar year from the date of registration for the project work. Extension of time within the total permissible limit for completing the programme is to be obtained from the Head of the Institution.
- 6.4 The student must submit status report by giving seminar in three different phases (**one in III semester and another two in IV semester**) during the project work period. These seminar reports must be approved by the I.D.C before submission of the Project Report.
- 6.5 A candidate shall be allowed to submit the thesis/dissertation only after obtaining plagiarism report with less than 30% and passing in all the prescribed subjects (both theory and practical), and then take viva-voce examination of the project. The viva-voce examination may be conducted once in two months for all the candidates submitted during that period.
- 6.6 Three copies of the Thesis/Dissertation certified in the prescribed format by the supervisor & HOD shall be presented to the HOD. One copy is to be forwarded to the University and one copy to be sent to the examiner.
- 6.7 The college shall submit a panel of three experts for a maximum of **five** students at a time. However, the thesis/dissertation will be adjudicated by one examiner nominated by the University.

6.8 If the report of the examiner is favorable viva-voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the examiner who adjudicated the thesis/dissertation. The board shall jointly report candidates work as:

- | | |
|---------------------|---------|
| 1. Satisfactory | Grade A |
| 2. Not satisfactory | Grade B |

If the report of the viva-voce is not satisfactory (Grade B) the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination he will not be eligible for the award of the degree unless the candidate is permitted to revise and resubmit the thesis.

7.0 GRADING

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

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

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

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

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

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

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

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

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

Where 'Si' is the SGPA of the ith semester, Ci is the total number of credits in that semester and n is the no. of semesters.

Both SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts.

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

Grade Point: It is a numerical weight allotted to each letter grade on a 10-point scale.

Letter Grade: It is an index of the performance of students in a said course. Grades are denoted by letters as mentioned in the above table.

8.0 AWARD OF DEGREE AND CLASS:

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

Class Awarded	CGPA Secured
First class with Distinction	≥ 8
First class	≥ 7 and < 8
Second class	≥ 5 and < 7

9.0 WITH – HOLDING OF RESULTS:

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

10.0 TRANSITORY REGULATIONS:

Candidates who have discontinued or have been detained for want of attendance or who have failed after having undergone the course in earlier regulations and wish to continue the course are eligible for admission into the unfinished semester from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to 4.10 and 2.3 sections. Whereas they continue to be in the academic regulations they were first admitted.

11.0 GENERAL:

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

RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

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

		examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
6.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
7.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the impostor is an outsider, he will be handed over to the police and a case is registered against him.
8.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that

	<p>person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.</p>	<p>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.</p>
9.	<p>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.</p>	<p>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.</p> <p>Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.</p>
10.	<p>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.</p>	<p>Cancellation of the performance in that subject.</p>
11.	<p>Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.</p>	<p>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.</p>
12.	<p>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.</p>	

Malpractices identified by squad or special invigilators

1. Punishments to the candidates as per the above guidelines.
2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
 - (i) A show cause notice shall be issued to the college.
 - (ii) Impose a suitable fine on the college.
 - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-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 vibrational frequencies and Applications of IR spectroscopy
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. 11hrs
NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.
3. 11hrs
Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy
4. 11hrs
Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography
5. 11hrs
a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

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

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

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L T P C
4 0 0 4

(17S03101) DRUG DELIVERY SYSTEMS

SCOPE

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

OBJECTIVES

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

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

THEORY

60 Hrs

1.

10 hrs

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

2

10hrs

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

3

10hrs

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

4

6hrs

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

10hrs

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

5

8 hrs

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

6 hrs

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

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, 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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

L	T	P	C
4	0	0	4

(17S03102) MODERN PHARMACEUTICS

SCOPE

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

Objectives

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

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

THEORY

60 HRS

1. 10 HRS
a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.
b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation
2. 10 HRS
Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.
3. 10 HRS
cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.
4. 10 HRS
Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.
5. 10 HRS
Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f₂ and f₁, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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(17S03103) REGULATORY AFFAIRS

SCOPE

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

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

Objectives:

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

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

THEORY

60 Hrs

1.

12 hrs

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

2.

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

3

12 hrs

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

4

12 hrs

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

5

12 hrs

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

REFERENCES

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

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

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**(17S03104) PHARMACEUTICAL ANALYSIS PRACTICAL FOR
PHARMACEUTICS**

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

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

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(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 balanced DDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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

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(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. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 hrs
2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. 12 hrs
3. Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 hrs
4. Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 hrs
5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 hrs

REFERENCES

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

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

L T P C
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(17S03202) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

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

Objectives

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

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

THEORY

60 Hrs

1.

12 hrs

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

2

12 hrs

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

3

12 hrs

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

4

12 hrs

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

5

12 hrs

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

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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(17S03203) COMPUTER AIDED DRUG DELIVERY SYSTEM

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60 Hrs

1.12 hrs

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

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

2

12 hrs

Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

3

12 hrs

Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4

12 hrs

a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro/in vivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

5

12 hrs

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

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James G. Boylan, Marcel Dekker Inc, New York, 1996.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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(17S03204) COSMETICS AND COSMECEUTICALS

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and Cosmeceuticals 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 and cosmeceuticals
- Scientific knowledge to develop cosmetics and Cosmeceuticals with desired Safety, stability, and efficacy.

THEORY

60 Hrs

1.

12 hrs

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

2

12 hrs

Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3

12 hrs

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4

12 hrs

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

5

12 hrs

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

REFERENCES

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

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(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)

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**(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 Pharmacodynamics
8. Computational Modeling Of Drug Disposition
9. To develop Clinical Data Collection manual
10. To carry out Sensitivity Analysis, and Population Modeling.
11. Development and evaluation of Creams
12. Development and evaluation of Shampoo and Toothpaste base
13. To incorporate herbal and chemical actives to develop products
14. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutics)

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(17S01301) RESEARCH METHODOLOGY & BIostatISTICS

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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