JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

Academic Regulations of M.Pharmacy (Full Time) Programme

(Effective for the students admitted into I year from the Academic Year 2021-22 and onwards)

Jawaharlal Nehru Technological University Anantapur (JNTUA) offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M.Pharm.) Post Graduate Degree programme, under Choice Based Credit System (CBCS) with different specializations at its constituent unit, OTPRI and non-autonomous affiliated colleges.

The Jawaharlal Nehru Technological University Anantapur shall confer M.Pharm. degree on candidates who are admitted to the programme and fulfill all the requirements for the award of the degree.

1. **Award of the M.Pharm. Degree**
   A student will be declared eligible for the award of the M.Pharm. degree if he/she fulfils the following:
   1.1 Pursues a course of study for not less than two academic years and not more than four academic years.
   1.2 Registers for 95 credits and secures all 95 credits.

2. Students, who fail to fulfil all the academic requirements for the award of the degree within four academic years from the year of their admission, shall forfeit their seat in M.Pharm. course and their admission stands cancelled.

3. **Programme of Study:**
   The following M.Pharm. specializations are offered at its constituent (non-autonomous) unit, OTPRI & affiliated (non-autonomous) colleges:

S.No.	Discipline	Name of the Specialization	Code
1	Master of Pharmacy	Pharmacology	
2		Pharmaceutical Chemistry	
3		Pharmaceutics	
4		Pharmaceutical Analysis and Quality Assurance	
5		Pharmacognosy	
6		Industrial Pharmacy	
7		Pharmaceutical Technology	
8		Pharmaceutical Analysis	
9		Pharmacy Practice	
10		Pharmaceutics-Drug Regulatory Affairs	
11		Pharmaceutical Quality Assurance	

and any other specializations as approved by AICTE/PCI/University from time to time.

4. **Eligibility for Admissions**:
   4.1 Admission to the M.Pharm. programme shall be made subject to the eligibility, qualifications and specialization prescribed by the A.P. State Government/University for each programme, from time to time.
   4.2 Admissions shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant qualifying GPAT Examination / the merit rank obtained by the qualified student in an entrance test conducted by A.P. State Government (APPGECET) for M.Pharm. programmes/an entrance test conducted by university/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.
5. **Programme related terms:**
   5.1 ***Credit:*** A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (Lecture/Tutorial) or two hours of practical work/field work per week.
   Credit definition:

1 Hr. Lecture (L) per week	1 credit
1 Hr. Tutorial (T) per week	1 credit
1 Hr. Practical (P) per week	0.5 credit

   5.2 ***Academic Year:*** Two consecutive (one odd + one even) semesters constitute one academic year.
   5.3 ***Choice Based Credit System (CBCS):*** The CBCS provides choice for students to select from the prescribed courses.
6. **Programme Pattern:**
   6.1 Total duration of the of M.Pharm. programme is two academic years
   6.2 Each academic year of study is divided into two semesters.
   6.3 Each Semester shall be of 22 weeks duration (inclusive of Examinations), with a minimum of 90 instructional days per semester.
   6.4 The student shall not take more than four academic years to fulfill all the academic requirements for the award of M.Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M.Pharm. programme.
   6.5 The medium of instruction of the programme (including examinations and project reports) will be in English only.
   6.6 All subjects/courses offered for the M.Pharm. programme are broadly classified as follows:

S.No.	Broad Course Classification	Course Category	Description
1.	Core Courses	Foundational & Professional Core Courses (PC)	Includes subjects related to the parent discipline

2.	Elective Courses	Electives	Includes elective subjects related to the parent discipline/inter-disciplinary subjects or subjects in an area outside the parent discipline which are of importance in the context of special skill development
3.	Research	Research methodology & IPR	To understand importance and process of creation of patents through research
		Seminar	Ensures preparedness of students to undertake major projects/Dissertation, based on core contents related to specialization
		Cocurricular Activities/Journal Club	Attending conferences, scientific presentations and other scholarly activities
		Dissertation	Major Project
4.	Audit Courses	Mandatory noncredit courses	Covering subjects of developing desired attitude among the learners is on the line of initiatives such as Unnat Bharat Abhiyan, Yoga, Value education etc.

6.7 The college shall take measures to implement Virtual Labs (https://www.vlab.co.in) which provide remote access to labs in various disciplines of science and will help student in learning basic and advanced concept through remote experimentation. Student shall be made to work on virtual lab experiments during the regular labs.

6.8 A faculty advisor/mentor shall be assigned to each specialization to advise students on the programme, its Course Structure and Curriculum, Choice of Courses, based on his competence, progress, pre-requisites and interest.

6.9 Preferably 25% course work for the theory courses in every semester shall be conducted in the blended mode of learning.

7. Attendance Requirements:

7.1 A student shall be eligible to appear for the University external examinations if he/she acquires i) a minimum of 50% attendance in each course and ii) 75% of attendance in aggregate of all the courses.

7.2 Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester may be granted by the College Academic Committee.

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

7.4 Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examination of that class.

7.5 A stipulated fee shall be payable towards condonation of shortage of attendance.

7.6 A student will not be promoted to the next semester unless he satisfies the attendance requirements of the present semester. They may seek re-admission into that semester when offered next.

7.7 If any candidate fulfils the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

7.8 If the learning is carried out in blended mode (both offline & online), then the total attendance of the student shall be calculated considering the offline and online attendance of the student.

8. Evaluation – Distribution and Weightage of Marks:

The performance of a student in each semester shall be evaluated subject - wise (irrespective of credits assigned), for a maximum of 100 marks for theory and 100 marks for practical, based on Internal Evaluation and End Semester Examination.

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

8.2 Two Internal Examinations shall be conducted for 30 marks each, one in the middle of the Semester and the other immediately after the completion of instruction. First mid examination shall be conducted for I & II units of the syllabus and second mid examination for III, IV & V units. Each mid exam shall be conducted for a total duration of 120 minutes with 3 questions (without choice) each question for 10 marks. Final Internal marks for a total of 30 marks shall be arrived at by considering the marks secured by the student in both the internal examinations with 80% weightage to the better internal exam and 20% to the other. There shall be an online examination (TWO) conducted during the respective mid examinations by the college for the remaining 10 marks with 20 objective questions.

8.3 The following pattern shall be followed in the End Examination:

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

8.4 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.

The internal evaluation based on the day-to-day work-10 marks, record- 10 marks and the remaining 20 marks to be awarded by conducting an internal laboratory test. The end examination shall be conducted by the examiners, with a breakup mark of Procedure-10, Experimentation-25, Results-10, Viva-voce-15.

8.5 There shall be a **Seminar/Assignment** for internal evaluation of 100 marks. A student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report form and shall make an oral presentation before the Project Review Committee consisting of Head of the Department, supervisor/mentor and two

other faculty members of the department. The student has to secure a minimum of 50% of marks, to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when supplementary examinations are conducted. The seminar shall be conducted anytime during the semester as per the convenience of the Project Review Committee and students. There shall be no external examination for Technical Seminar.

8.6 For Teaching Practice/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 Undergraduate 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.

8.7 There shall be Mandatory **Audit courses** for zero credits. There is no external examination for audit courses. However, attendance shall be considered while calculating aggregate attendance and student shall be declared to have passed the mandatory course only when he/she secures 50% or more in the internal examinations. In case, the student fails, a re-examination shall be conducted for failed candidates for 40 marks every six months/semester satisfying the conditions mentioned in item 1 & 2 of the regulations.

8.8 There shall be **Comprehensive Viva–Voce** in III semester**.** This will test the student's learning and understanding during the course of their specialization. The Comprehensive viva-voce will be conducted by the committee consisting of Head of the Department and two faculty members related to the specialization. The Comprehensive Viva-Voce shall be evaluated for 100 marks by the committee. There are no internal marks for the Comprehensive Viva-Voce. A student shall acquire 2 credits assigned to the Comprehensive Viva–voce when he/she secures 50% or more marks for the total of 100 marks. In case, if a student fails in Comprehensive Viva–voce he/she shall reappear as and when III semester supplementary examinations are conducted.

8.9 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.

8.10 In case the candidate does not secure the minimum academic requirement in any of the subjects 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.

8.11 The laboratory records and mid semester test papers shall be preserved for a minimum of 3 years in the respective institutions as per the University norms and shall be produced to the Committees of the University as and when the same are asked for.

9. **Credit Transfer Policy**

As per University Grants Commission (Credit Framework for Online Learning Courses through SWAYAM) Regulation, 2016, the University shall allow up to a maximum of 40% of the total courses being offered in a particular Programme in a semester through the Online Learning courses through SWAYAM.

9.1 The University shall offer credit mobility for MOOCs and give the equivalent credit weightage to the students for the credits earned through online learning courses through SWAYAM platform.

9.2 The online learning courses available on the SWAYAM platform will be considered for credit transfer. SWAYAM course credits are as specified in the platform

9.3 Student registration for the MOOCs shall be only through the institution, it is mandatory for the student to share necessary information with the institution

9.4 The institution shall select the courses to be permitted for credit transfer through SWAYAM. However, while selecting courses in the online platform institution would essentially avoid the courses offered through the curriculum in the offline mode.

9.5 The institution shall notify at the beginning of semester the list of the online learning courses eligible for credit transfer in the forthcoming Semester.

9.6 The institution shall also ensure that the student has to complete the course and produce the course completion certificate as per the academic schedule given for the regular courses in that semester

9.7 The institution shall designate a faculty member as a Mentor for each course to guide the students from registration till completion of the credit course.

9.8 The university shall ensure no overlap of SWAYAM MOOC exams with that of the university examination schedule. In case of delay in SWAYAM results, the university will re-issue the marks sheet for such students.

9.9 Student pursuing courses under MOOCs shall acquire the required credits only after successful completion of the course and submitting a certificate issued by the competent authority along with the percentage of marks and grades.

9.10 The institution shall submit the following to the examination section of the university:

a) List of students who have passed MOOC courses in the current semester along with the certificates of completion.

b) Undertaking form filled by the students for credit transfer.

9.11 The university shall resolve any issues that may arise in the implementation of this policy from time to time and shall review its credit transfer policy in the light of periodic changes brought by UGC, SWAYAM, NPTEL and state govt.

Note: Students shall also be permitted to register for MOOCs offered through online platforms other than SWAYAM NPTEL. In such cases, credit transfer shall be permitted only after seeking approval of the University at least three months prior to the commencement of the semester.

10. **Re-registration for Improvement of Internal Evaluation Marks**:

A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and has failed in the end examination

10.1 The candidate should have completed the course work and obtained examinations results for **I, II and III** semesters.

10.2 The candidate should have passed all the subjects for which the Internal Evaluation marks secured are more than 50%.

10.3 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.

10.4 The candidate has to re-register for the chosen subjects and fulfill the academic requirements.

10.5 For reregistration the candidates have to apply to the University through the college by paying the requisite fees and get approval from the University before the start of the semester in which re-registration is required

10.6 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.

11. Evaluation of Project/Research Work:

The Project work shall be initiated at the beginning of the III Semester and the duration of the Project is of two semesters. Evaluation of Project work is for 300 marks with 200 marks for internal evaluation and 100 marks for external evaluation. Internal evaluation of the Project Work – I & Project work – II in III & IV semesters respectively shall be for 100 marks each. External evaluation of final Project work viva voce in IV semester shall be for 100 marks.

A Project Review Committee (PRC) shall be constituted with the Head of the Department as Chairperson, Project Supervisor and one faculty member of the department offering the M.Pharm. programme.

11.1 A candidate is permitted to register for the Project Work in III Semester after satisfying the attendance requirement in all the subjects, both theory and laboratory (in I & II semesters).

11.2 A candidate is permitted to submit Project dissertation with the approval of PRC. The candidate has to pass all the theory, practical and other courses before submission of the Thesis.

11.4 Project work shall be carried out under the supervision of teacher in the parent department concerned.

11.5 A candidate shall be permitted to work on the project in an industry/research organization on the recommendation of the Head of the Department. In such cases,one of the teachers from the department concerned would be the internal

guide and an expert from the industry/ research organization concerned shall act as co-supervisor/ external guide. It is mandatory for the candidate to make full disclosure of all data/results on which they wish to base their dissertation. They cannot claim confidentiality simply because it would come into conflict with the Industry's or R&D laboratory's own interests. A certificate from the external supervisor is to be included in the dissertation.

11.6 Continuous assessment of Project Work - I and Project Work – II in III & IV semesters respectively will be monitored by the PRC.

11.7 The candidate shall submit status report by giving seminars in three different phases (two in III semester and one in IV semester) during the project work period. These seminar reports must be approved by the PRC before submission of the Project Thesis.

11.8 After registration, a candidate must present in Project Work Review - I, in consultation with his Project Supervisor, the title, objective and plan of action of his Project work to the PRC for approval within four weeks from the commencement of III Semester. Only after obtaining the approval of the PRC can the student initiate the project work.

11.9 The Project Work Review - II in III semester carries internal marks of 100. Evaluation should be done by the PRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and PRC will examine the Problem Definition, Objectives, Scope of Work, Literature Survey in the same domain and progress of the Project Work.

11.10 A candidate has to secure a minimum of 50% of marks to be declared successful in Project Work Review - II. Only after successful completion of Project Work Review – II, candidate shall be permitted for Project Work Review – III in IV Semester. The unsuccessful students in Project Work Review - II shall reappear for it as and when supplementary examinations are conducted.

11.11 The Project Work Review - III in IV semester carries 100 internal marks. Evaluation should be done by the PRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The PRC will examine the overall progress of the Project Work and decide whether or not eligible for final submission. A candidate has to secure a minimum of 50% of marks to be declared successful in Project Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for Project Work Review - III after a month.

11.12 For the approval of PRC the candidate shall submit the draft copy of dissertation to the Head of the Department and make an oral presentation before the PRC.

11.13 After approval from the PRC, the students are required to submit a report showing that the plagiarism is within 30%. The dissertation report will be accepted only when the plagiarism is within 30%, which shall be submitted along with the dissertation report.

11.14 Research paper related to the Project Work shall be published in conference proceedings/UGC recognized journal. A copy of the published research paper shall be attached to the dissertation.

11.15 After successful plagiarism check and publication of research paper, three copies of the dissertation certified by the supervisor and HOD shall be submitted to the College.

11.16 The dissertation shall be adjudicated by an external examiner selected by the University. For this, the Principal of the College shall submit a panel of three examiners as submitted by the supervisor concerned and department head for each student. However, the dissertation will be adjudicated by one examiner nominated by the University.

11.17 If the report of the examiner is not satisfactory, the candidate shall revise and resubmit the dissertation, in the time frame as decided by the PRC. If report of the examiner is unfavorable again, the thesis shall be summarily rejected. The candidate has to reregister for the project and complete the project within the stipulated time after taking the approval from the University

11.18 If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Project Viva voce exam.

11.19 The Project Viva voce examinations shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who has adjudicated the dissertation. For Dissertation Evaluation (Viva voce) in IV Sem. there are external marks of 100 and it is evaluated by external examiner. The candidate has to secure a minimum of 50% marks in Viva voce exam.

11.20 If he fails to fulfill the requirements as specified, he will reappear for the Project Viva voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree.

12. Credits for Co-curricular Activities

The credits assigned for co-curricular activities shall be given by the principals of the colleges and the same shall be submitted to the University.

A Student shall earn 02 credits under the head of co-curricular activities, viz., attending Conference, Scientific Presentations and Other Scholarly Activities.

Following are the guidelines for awarding Credits for Co-curricular Activities

Name of the Activity	Maximum Credits / Activity
Participation in National Level Seminar/ Conference / Workshop /Training programs (related to the specialization of the student)	1
Participation in International Level Seminar / Conference / workshop/Training programs held outside India (related to the specialization of the student)	2
Academic Award/Research Award from State Level/National	1

Agencies	
Academic Award/Research Award from International Agencies	2
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	1
Research / Review Publication in International Journals with Editorial board outside India (Indexed in Scopus / Web of Science)	2

Note:

i) Credit shall be awarded only for the first author. Certificate of attendance and participation in a Conference/Seminar is to be submitted for awarding credit.

ii) Certificate of attendance and participation in workshops and training programs (Internal or External) is to be submitted for awarding credit. The total duration should be at least one week.

iii) Participation in any activity shall be permitted only once for acquiring required credits under cocurricular activities

13. Grading:

As a measure of the student's performance, a 10-point Absolute Grading System using the following Letter Grades and corresponding percentage of marks shall be followed:

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

Structure of Grading of Academic Performance

Range in which the marks in the subject fall	Grade	Grade points Assigned
≥ 90	S (Superior)	10
≥ 80 < 90	A (Excellent)	9
≥ 70 < 80	B (Very Good)	8
≥ 60 < 70	C (Good)	7
≥ 50 < 60	D (Pass)	6
< 50	F (Fail)	0
Absent	Ab (Absent)	0

i) A student obtaining Grade 'F' or Grade 'Ab' in a subject shall be considered failed and will be required to reappear for that subject when it is offered the next supplementary examination.

ii) For noncredit audit courses, "Satisfactory" or "Unsatisfactory" shall be indicated instead of the letter grade and this will not be counted for the computation of SGPA/CGPA/Percentage.

Computation of 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.,

$$SGPA = \Sigma (C_i \times G_i)/\Sigma C_i$$

where, C_i is the number of credits of the i^{th} subject and G_i is the grade point scored by the student in the i^{th} course.

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

$$CGPA = \Sigma (C_i \times S_i)/ \Sigma C_i$$

where "S_i" is the SGPA of the i^{th} semester and C_i is the total number of credits up to that semester.

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

iii) 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 S, A, B, C, D and F.

14. Award of Class:

After a student has satisfied the requirements prescribed for the completion of the program and is eligible for the award of M. Pharm. Degree, he shall be placed in one of the following three classes:

Class Awarded	Percentage of Marks to be secured
First Class with Distinction	≥70%
First Class	< 70% ≥ 60%
Pass Class	< 60% ≥ 50%

15. **Exit Policy:** The student shall be permitted to exit with a PG Diploma based on his/her request to the university through the respective institution at the end of first year subject to passing all the courses in first year.

The University shall resolve any issues that may arise in the implementation of this policy from time to time and shall review the policy in the light of periodic changes brought by UGC, PCI, AICTE and State government.

16. Withholding of Results:

If the candidate has any case of in-discipline 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.

17. **Transitory Regulations**

Discontinued, detained, or failed candidates are eligible for readmission as and when the semester is offered after fulfilment of academic regulations. Candidates who have been detained for want of attendance or not fulfilled academic requirements or who have failed after having undergone the course in earlier regulations or have discontinued 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 Section 2 and they will follow the academic regulations into which they are readmitted.

18. General:

17.1 The academic regulations should be read as a whole for purpose of any interpretation.

17.2 Disciplinary action for Malpractice/improper conduct in examinations is appended.

17.3 There shall be no places transfer within the constituent colleges and affiliated colleges of Jawaharlal Nehru Technological University Anantapur.

17.4 Where the words “he”, “him”, “his”, occur in the regulations, they include “she”, “her”, “hers”.

17.5 In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.

17.6 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 MALPRACTICES / 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.	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 for four 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. 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 four consecutive semesters from class work and all University examinations if his involvement is established. Otherwise, the candidate is 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 imposter is an outsider, he will be handed over to the police and a case is registered against him.

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.	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 only.
6.	Refuses to obey the orders of the Chief Superintendent /Assistant - Superintendent /any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. If the candidate physically assaults the invigilator/ officer-in-charge of the Examinations, then the candidate is also debarred and forfeits his/her seat. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	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.
8.	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.
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.	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.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject only or in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester / year examinations, depending on the recommendation of the committee.
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.	

1. Malpractices identified by squad or special invigilators
2. Punishments to the candidates as per the above guidelines.
3. Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
4. A show cause notice shall be issued to the college.
5. Impose a suitable fine on the college.
6. Shifting the examination center from the college to another college for a specific period of not less than one year.

Note:

Whenever the performance of a student is cancelled in any subject/subjects due to Malpractice, he has to register for End Examinations in that subject/subjects consequently and has to fulfil all the norms required for the award of Degree.

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

SEMESTER – I

S. No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S07101	Advanced Pharmaceutical Analysis	4	-	-	4
3.	21S07102	Pharmaceutical and Food Analysis	4	-	-	4
4.	21S07103	Quality Control And Quality Assurance	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S07104	Pharmaceutical and Food Analysis Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.		Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S07201	Advanced Instrumental Analysis	4	-	-	4
2.	21S07202	Modern Bio-Analytical Techniques	4	-	-	4
3.	21SOE301a	Pharmaceutical Validation	4	-	-	4
4.	21S07203	Herbal and Cosmetic Analysis	4	-	-	4
5.	21S07204	Advanced Instrumental Analysis Lab	-	-	6	3
6.	21S07205	Modern Bio-Analytical Techniques Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S07206	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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SEMSTER - III

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
2.	 21SOE301d 21SOE301f 21SOE301e	**Open Electives** Biological Screening methods Stability of Drugs and Dosage forms Pharmacoepidemiology and Pharmacoeconomics	3	-	-	3
3.	21S07301	Teaching Practice/Assignment	-	-	4	2
4.	21S07302	Comprehensive viva voce	-	-	4	2
5.	21S07303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S07401	Co-Curricular Activities	2			2
2.	21S07402	Research Work - II	3		30	18
		Total	5		30	20

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Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
21S01101		4	0	0	4
	Semester	**I**			

Course Objectives:

The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcomes (CO): Student will be able to

- Modern Analytical Techniques and can apply the theories in analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments
- Apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT - I

UV-Visible spectroscopy

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

UNIT - II

IR spectroscopy

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

UNIT - III

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

UNIT – IV

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.

UNIT – V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography

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COURSE STRUCTURE & SYLLABI

g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Textbooks:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

Reference Books:

4. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
5. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,T imothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
8. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
9. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
10. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
11. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

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Course Code	ADVANCED PHARMACEUTICAL ANALYSIS	L	T	P	C
21S07101		4	0	0	4
	Semester	**I**			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

- 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

UNIT - I

Impurity and stability studies

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

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

UNIT - II

Elemental impurities

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

Stability testing protocols

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

UNIT – III

Impurity profiling and degradent characterization

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

UNIT – IV

Stability testing of phytopharmaceuticals

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

Biological tests and assays of the following

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

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UNIT – V		

Immunoassays (IA)

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

Reference Books:

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, John Wiley& Sons, 1982.102.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi,3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia VolI , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2ndedition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20,Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2ndedition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS	L	T	P	C
21S07102		4	0	0	4
	Semester	**I**			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT - I

Carbohydrates
Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates.

Proteins
Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT - II

Lipids
Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

Vitamins
Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT – III

Probiotics
Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT – IV

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

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

UNIT – V

Milk (constituents and milk products)
General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

- Analysis of fermentation products like wine, spirits, beer and vinegar.

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COURSE STRUCTURE & SYLLABI

- Pesticides Analysis in food like organophosphorus and organochlorine
- And also student shall have knowledge in food regulations and legislations

Textbooks:

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
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

Reference Books:

1. Indian Pharmacopoeia 2012
2. Remington's Pharmaceutical Sciences by Alfonso and Gennaro

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COURSE STRUCTURE & SYLLABI

Course Code	QUALITY CONTROL AND QUALITY ASSURANCE	L	T	P	C
21S07103		4	0	0	4
	Semester	**I**			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT - I

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

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

UNIT - II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

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Reference Books:

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

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Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

List of Experiments

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. Preparation of Master Formula Record.
14. Preparation of Batch Manufacturing Record.

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL AND FOOD ANALYSIS LAB	L	T	P	C
21S07104		0	0	6	3
	Semester	**I**			

List of Experiments

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 benzoic acid by titrimetric analysis in beverages/ sauces/ ketchup/ jam
11. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
12. Assay of any two Antihistamines (API & dosage forms) official in IP
13. Assay of any two Diuretics (API & dosage forms) official in IP

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED INSTRUMENTAL ANALYSIS		L	T	P	C
21S07201			4	0	0	4
Pre-requisite		Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT - I

HPLC

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

UNIT - II

Biochromatography

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

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

High performance Thin Layer chromatography

Principles, instrumentation, pharmaceutical applications.

UNIT – III

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications

Capillary electrophoresis:

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

UNIT – IV

Mass spectrometry

Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (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.

UNIT – V

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

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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 and Applications of NMR spectroscopy. LC-NMR hyphenations.

Reference Books:

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.

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES	L	T	P	C
21S07202		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT – I

Extraction of drugs and metabolites from biological matrices

General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

Bioanalytical method validation: USFDA and EMEA guidelines

UNIT – II

Biopharmaceutical Consideration

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

UNIT – III

Pharmacokinetics and Toxicokinetics:

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

UNIT – IV

Cell culture techniques

Cell culture techniques Basic equipment's used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

UNIT – V

Metabolite identification

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

Reference Books:

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M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

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. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will 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

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

Analytical method validation
General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

UNIT – V

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

positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

Reference Books:

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

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COURSE STRUCTURE & SYLLABI

Course Code	HERBAL AND COSMETIC ANALYSIS	L	T	P	C
21S07203		4	0	0	4
	Semester	II			

Course Objectives:

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.

Course Outcomes (CO): Student will be able to

- 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.

UNIT – I

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

UNIT – II

Adulteration and Deterioration:

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

UNIT – III

Testing of natural products and drugs

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

UNIT – IV

Herbal drug-drug interaction

General principles, Validation of analytical method as per ICH guidelines and USP.
Computerized system validation: Electronic records and digitalsignificance-21 CFR part 11 and GAMP.

UNIT – V

Evaluation of cosmetic products:

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished

forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards

Reference Books:

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

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED INSTRUMENTAL ANALYSIS LAB	L	T	P	C
21S07204		0	0	6	3
	Semester	II			

List of Experiments

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 Mass spectra
7. Testing of related and foreign substances in drugs and raw materials
8. Assay of raw materials as per official monographs
9. Calibration of UV – Visible Spectrophtometer/ HPLC/ GC/ FTIR
10. Cleaning validation of any one analytical equipment

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN BIO-ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S07205		0	0	6	3
	Semester	II			

List of Experiments

1. Protocol preparation and performance of bioanalytical method validation
2. Protocol preparation for the conduct of BA/BE studies according to guidelines
3. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques
4. Isolation of analgesics from biological fluids (blood serum and urine)
5. Identification of anti-histaminics drug in urine by TLC
6. Extraction of drugs and metabolites from biological matrices by SPE/LLE
7. HPLC separation of modern drug from plasma and its formulations (Diclofenac)
8. Stability indicating method development by HPLC of any API
9. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis
10. Quality control methods for herbal materials/ Medicinal plant materials

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COURSE STRUCTURE & SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	**III**			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Research Problem
Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT – II

Literature review
Effective literature studies approaches, analysis, Plagiarism, Research ethics.

UNIT – III

Report writing
Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT – IV

Nature of Intellectual Property
Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT – V

Patent Rights:
Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

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COURSE STRUCTURE & SYLLABI

Textbooks:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

Reference Books:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

AUDIT COURSE-I

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COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II		Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III		Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV		Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V		Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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COURSE STRUCTURE & SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes,Volcanisms,Cyclones,Tsunamis,Floods,DroughtsandFamines,Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering ADisasteror Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

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COURSE STRUCTURE & SYLLABI

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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COURSE STRUCTURE & SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science &technology can be understood
- Being a logical language will help to develop logic in students

UNIT - I		
Alphabets in Sanskrit,		
UNIT - II		
Past/Present/Future Tense, Simple Sentences		
UNIT - III		
Order, Introduction of roots		
UNIT - IV		
Technical information about Sanskrit Literature		
UNIT - V		
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics		

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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AUDIT COURSE-II

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M.PHARM. PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof

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3. Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, ‘learning to read’campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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COURSE STRUCTURE & SYLLABI

Course Code	**STRESSMANAGEMENT BY YOGA**	**L**	**T**	**P**	**C**
21DAC201b		**2**	**0**	**0**	**0**
	Semester	**II**			

Course Objectives: This course will enable students:

- To achieve overall health of body and mind
- To overcome stres

Course Outcomes (CO): Student will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT - I		
Definitions of Eight parts of yog.(Ashtanga)		
UNIT - II		
Yam and Niyam.		
UNIT - III		
Do`sand Don't'sin life. i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan		
UNIT - IV		
Asan and Pranayam		
UNIT - V		
i)Variousyogposesand theirbenefitsformind &body ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam		

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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M.PHARM. IN PHARMACEUTICAL ANALYSIS

COURSE STRUCTURE & SYLLABI

Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam- Holistic development of personality
Verses-19,20,21,22(wisdom)
Verses-29,31,32(pride &heroism)
Verses-26,28,63,65(virtue)

UNIT - II

Neetisatakam- Holistic development of personality
Verses-52,53,59(dont's)
Verses-71,73,75,78(do's)

UNIT - III

Approach to day to day work and duties.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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OPEN ELECTIVE

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COURSE STRUCTURE & SYLLABI

Course Code	BIOLOGICAL SCREENING METHODS	L	T	P	C
21SOE301d	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcomes (CO): Student will be able to know

- How to handle animals
- About various techniques for screening of drugs for different pharmacological activities
- Guidelines and regulations for screening new drug molecules on animals.

UNIT – I

Drug discovery process:
Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations. Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques.

UNIT – II

Bioassays:
Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization.

UNIT – III

Toxicity Evaluations
Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).
Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity.

UNIT – IV

Screening of drugs
Screening of different classes of drugs using micro-organisms. Vitamin and antibiotic assays.
Screening methods involved in toxins and pathogens.

UNIT – V

Enzymatic screening methods
α-glucosidase, α- amylase, DNA polymerase, nucleases, L-asparginase, lipases and peptidases.

Reference Books:

1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8th edition
2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10th edition.
4. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
5. Drug Discovery by Vogel's
6. Drug Discovery and evaluation – Pharmacological assays by H.Gerhard.Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.
7. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.

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COURSE STRUCTURE & SYLLABI

Course Code	STABILITY OF DRUGS AND DOSAGE FORMS	L	T	P	C
21SOE301f	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes (CO): Student will be able to

- Evaluation of stability of solutions, solids and formulations against adverse conditions.
- Suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT – I

Drug decomposition mechanisms

1. Hydrolysis and acyl transfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT – II

Solid state chemical decomposition

Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT – III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT – IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards

UNIT – V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

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COURSE STRUCTURE & SYLLABI

b) Interaction of containers & closure Compatibility Testing.

Reference Books:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A.H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
4. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
5. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
7. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
8. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
10. Drug stability: Principles and practices by Jens T. Carstensen
11. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACOEPIDEMIOLOGY &	L	T	P	C
21SOE301e	PHARMACOECONOMICS (Elective-I)	3	0	0	3
	Semester	III			

Course Objectives:

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcomes (CO): Student will be able to

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT – I

Introduction to Pharmacoepidemiology

Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk:

Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT – II

Pharmacoepidemiological Methods

Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT – III

Introduction to Pharmacoeconomics

Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT – IV

Pharmacoeconomic evaluations

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

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UNIT – V		

Health related quality of life (HRQOL)

Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics

Reference Books:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott 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 Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

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SEMESTER – I

S. No.	Course codes	Course Name	Hours per			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S03101	Advanced Physical Pharmaceutics	4	-	-	4
3.	21S03102	Modern Pharmaceutics-I	4	-	-	4
4.	21S03103	Advanced Biopharmaceutics & Pharmacokinetics	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques lab	-	-	6	3
6.	21S03104	Modern Pharmaceutics -I lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S03105	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course codes	Course Name	Hours per			Credits
				T	P	
1.	21S03201	Modern Pharmaceutics-II	4	-	-	4
2.	21S03202	Advanced Drug Delivery system	4	-	-	4
3.	21S03203	Industrial Pharmacy	4	-	-	4
4.	21S03204	Nano Drug Delivery system	4	-	-	4
5.	21S03205	Modern Pharmaceutics-II Lab	-	-	6	3
6.	21S03206	Advanced Drug Delivery System Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management for Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S03207	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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SEMSTER - III

S.No.	Course codes	Course Name	Hours per			Credits
				T	P	
1.	21DRM101	Research Methodology and Intellectual Property Right	4	-	-	4
2.	21SOE301d 21SOE301a 21SOE301c	**Open Elective** Biological Screening methods Pharmaceutical Validation Entrepreneurship Management	3	-	-	3
3.	21S03301	Teaching Practice/Assignment	-	-	4	2
4.	21S03302	Comprehensive viva voce	-	-	-	2
5.	21S03303	Research Work - I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course codes	Course Name	Hours per week			Credits
			L	T	P	
1.	21S03401	Co-Curricular Activities	2			2
2.	21S03402	Research Work - II	3		30	18
		Total	5		30	20

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
21S01101		4	0	0	4
	Semester	I			

Course Objectives:

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.

Course Outcomes (CO): Student will be able to

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

UNIT - I

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

UNIT - II

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

UNIT - III

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.

UNIT - IV

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.

UNIT - V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography
g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Reference Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

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4. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
5. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
6. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
10. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
11. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

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Course Code	ADVANCED PHYSICAL PHARMACEUTICS	L	T	P	C
21S03101		4	0	0	4
	Semester	**I**			

Course Objectives:

The students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes (CO): Student will be able to

The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

UNIT - I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT - II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT - III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT - IV

Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

Characterization of API and excipients: Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications and interpretations

X Ray Diffraction methods: Origin of x-rays, principle, advantages, disadvantages, instrumentation, applications and interpretations.

UNIT - V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatization and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment

Textbooks:

1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan

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Delhi – 2013
Reference Books:
1. Dispersive systems I, II, and III 2. Robinson. Controlled Drug Delivery Systems

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Course Code	MODERN PHARMACEUTICS – I	L	T	P	C
21S03102		4	0	0	4
	Semester	**I**			

Course Objectives:

Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcomes (CO): Student will be able to

Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT - I

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug - excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH**)**

UNIT - II

Formulation development of solid dosage forms – I: New materials, excipients science - diluents, disintegrants, super disintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

UNIT - III

Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.
Microencapsulation- types, methodology, problems encountered.

UNIT - IV

Formulation development of soft and hard gelatin capsules: Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT - V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Textbooks:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton

Reference Books:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.

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2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013

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Course Code	ADVANCED BIOPHARMACEUTICS &	L	T	P	C
21S03103	PHARMACOKINETICS	4	0	0	4
	Semester	**I**			

Course Objectives:

The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, nonlinear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Course Outcomes (CO): Student will be able to

Students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for nonlinear kinetics.

UNIT - I

a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.
c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT - II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches.
Application of these models to determine the various pharmacokinetic parameters pertaining to:
a. Distribution: Apparent volume of distribution and its determination, factors affecting.
b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
c. Elimination: Over all apparent elimination rate constant, and half life.
All the above under the following conditions:
1. Intravenous infusion
2. Multiple dose injections
d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT - III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order, Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

UNIT - IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, nonlinear binding, and non-linearity of pharmacological responses.
Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics.

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M.PHARM. IN PHARMACEUTICS

COURSE STRUCTURE & SYLLABI

Kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.		
UNIT - V		
Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency. **Drug Interactions:** Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Numerical problems associated with all units, if any.		
Textbooks:		
1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi. 2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics 3.Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010. 4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean. 5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz		
Reference Books:		
1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu. 2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari. 3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari. 4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G		

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M.PHARM. IN PHARMACEUTICS
COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

List of Experiments

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

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICS – I LAB	L	T	P	C
21S03104		0	0	6	3
	Semester	I			

List of Experiments

1. To carry out the preformulation studies of solid dosage forms**.**
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of tablets
5. To study the effect of binders on dissolution of tablets
6. To study pharmacokinetic models, to determine similarity factors
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products

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M.PHARM. IN PHARMACEUTICS
COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICS - II	L	T	P	C
21S03201		4	0	0	4
	Semester	II			

Course Objectives:

The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and nutraceuticals.

Course Outcomes (CO): Student will be able to

Students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals

UNIT - I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. Pilot plant: Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

b. Scale up: Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT - II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT - III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT - IV

a. Cosmetics: Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.

b. Nutraceuticals:

1. Introduction, source, manufacture and analysis of glucosamine & cartinine.
2. Monographs: General and specific properties of glucosamine & cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT - V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

Textbooks:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr.
5. Nicholas G. Popovich, Howard C. Ansel.
6. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
7. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

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COURSE STRUCTURE & SYLLABI

Reference Books:
1. Bentley`s Text Book of Pharmaceutics by EA Rawlins. 2. Generic Drug Product Development by Leon Shargel. 3. Dispensing for Pharmaceutical Students by SJ Carter. 4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes. 5. Nutraceuticals, 2nd edition by Brian lock wood. 6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi – 2013

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED DRUG DELIVERY SYSTEMS	L	T	P	C
21S03202		4	0	0	4
	Semester	**II**			

Course Objectives:

The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, Transdermal, implants, bio adhesives and targeted drug delivery systems.

Course Outcomes (CO): Student will be able to

Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

UNIT - I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT - II

Design, fabrication, evaluation and applications of the following

a. Implantable Therapeutic systems
b. Transdermal delivery systems
c. Ocular and Intrauterine delivery systems
d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT - III

Biochemical and molecular biology approaches to controlled drug delivery of

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT – IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT – V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

Textbooks:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y. Madhusudan Rao, A.V. Jithan

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COURSE STRUCTURE & SYLLABI

7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

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M.PHARM. IN PHARMACEUTICS
COURSE STRUCTURE & SYLLABI

Course Code	INDUSTRIAL PHARMACY	L	T	P	C
21S03203		4	0	0	4
	Semester	II			

Course Objectives:

The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

Course Outcomes (CO): Student will be able to

The students will explain the machinery involved in milling, mixing, filtration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient feature1s of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

UNIT - I

Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, and drying.

UNIT - II

a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
b. Qualification of equipment (IQ, OQ, PQ)

UNIT - III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT - IV

Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

UNIT - V

Validation: Regulatory basis, validation of analytical methods, and process, in solid dosage forms, sterile products, and liquid dosage forms.

Textbooks:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.

Reference Books:

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COURSE STRUCTURE & SYLLABI

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
   CGMP, H.P.P. Sharma

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COURSE STRUCTURE & SYLLABI

Course Code	NANO DRUG DELIVERY SYSTEMS	L	T	P	C
21S03204		4	0	0	4
	Semester	**II**			

Course Objectives:

To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceuticals, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes (CO): Student will be able to

The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I

Introduction to Nanotechnology

a. Definition of nanotechnology
b. History of nanotechnology
c. Unique properties and classification of nanomaterials
d. Role of size and size distribution of nanoparticles properties.
e. Marketed formulations based on nanotechnology and science behind them

UNIT - II

Synthesis of Nanomaterials

Physical, chemical and biological Methods
Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles, aquasomes and nanoemulsions

UNIT - III

Biomedical applications of Nanotechnology

a. Nanotechnology products used for in vitro diagnostics
b. Improvements to medical or molecular imaging using nanotechnology
c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Reference Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Humanbody, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery,Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U.Kulkarni, Springer (2007)

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COURSE STRUCTURE & SYLLABI

5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V.Braun, Wiley - VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016

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COURSE STRUCTURE & SYLLABI

Course Code	MODERN PHARMACEUTICS – II LAB	L	T	P	C
21S03205		0	0	6	3
	Semester	II			

List of Experiments:

1. Preparation of mouth washes
2. Preparation and evaluation of cold creams and vanishing creams
3. Preparation and evaluation of calamine lotion
4. Preparation and evaluation of foundation creams and cleansing creams
5. Preparation of antiseptic cream (turmeric)
6. Preparation and evaluation Film coated tablets
7. Preparation and evaluation Floating tablets
8. Preparation and evaluation Fast dissolving tablets
9. Preparation and evaluation Chewable tablets
10. Effect of surfactant in *in-vitro* drug release
11. Preparation of oral rehydration solution (ORS)
12. Preparation and evaluation of calcium carbonate tablets

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COURSE STRUCTURE & SYLLABI

Course Code	ADVANCED DRUG DELIVERY SYSTEMS LAB		L	T	P	C
21S03206			0	0	6	3
Pre-requisite		Semester	II			

List of Experiments:

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and evaluation of sustained release oral matrix tablet (2 experiments)
3. Formulation and evaluation of sustained release oral reservoir system (2 experiments)
4. Formulation and evaluation of microspheres / microen capsules (2 experiments)
5. Study of in-vitro dissolution of various SR products in market (2 experiments)
6. Formulation and evaluation of transdermal films (2 experiments)
7. Formulation and evaluation mucoadhesive system (2 experiments)
8. Preparation and evaluation enteric coated pellets / tablets (2 experiments)

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COURSE STRUCTURE & SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	**III**			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT - V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

Reference Books:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

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AUDIT COURSE-I

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COURSE STRUCTURE & SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I	Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II	Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III	Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV	Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V	Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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COURSE STRUCTURE & SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes,Volcanisms,Cyclones,Tsunamis,Floods,DroughtsandFamines,Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering ADisasteror Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

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COURSE STRUCTURE & SYLLABI

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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COURSE STRUCTURE & SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science &technology can be understood
- Being a logical language will help to develop logic in students

UNIT - I		
Alphabets in Sanskrit,		
UNIT - II		
Past/Present/Future Tense, Simple Sentences		
UNIT - III		
Order, Introduction of roots		
UNIT - IV		
Technical information about Sanskrit Literature		
UNIT - V		
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics		

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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AUDIT COURSE-II

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Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof

3. Curriculum Studies, 36 (3): 361-379.
4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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Course Code	STRESSMANAGEMENT BY YOGA	L	T	P	C
21DAC201b		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To achieve overall health of body and mind
- To overcome stres

Course Outcomes (CO): Student will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT - I		
Definitions of Eight parts of yog.(Ashtanga)		
UNIT - II		
Yam and Niyam.		
UNIT - III		
Do`sand Don't'sin life. i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan		
UNIT - IV		
Asan and Pranayam		
UNIT - V		
i)Variousyogposesand theirbenefitsformind &body ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam		

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam- Holistic development of personality
Verses-19,20,21,22(wisdom)
Verses-29,31,32(pride &heroism)
Verses-26,28,63,65(virtue)

UNIT - II

Neetisatakam- Holistic development of personality
Verses-52,53,59(dont's)
Verses-71,73,75,78(do's)

UNIT - III

Approach to day to day work and duties.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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OPEN ELECTIVE

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M.PHARM. IN PHARMACEUTICS
COURSE STRUCTURE & SYLLABI

Course Code	BIOLOGICAL SCREENING METHODS	L	T	P	C
21SOE301d	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcomes (CO): Student will be able to

The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT - I

Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery, Regulations. Alternatives to animal screening procedures, cell-line, patch –clamp technique, In-vitro models, molecular biology techniques

UNIT - II

Bioassays: Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization.

UNIT - III

Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH recommendations).
Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity

UNIT - IV

Screening of different classes of drugs using micro-organisms. Vitamin and antibiotic assays. Screening methods involved in toxins and pathogens.

UNIT - V

Enzymatic screening methods: α-glucosidase, α- amylase, DNA polymerase, nucleases, Lasparginase, lipases and peptidases.

Reference Books:

1. Basic and clinical pharmacology by Bertram G. Katzung (International edition) lange medical book / Mc Graw Hill, USA 2001 8th edition
2. Pharmacology by Rang H.P, Dale MM and Ritter JM., Churchill Livingston, London, 4/e
3. Goodman and Gilman's The pharmacological basis of therapeutics (International edition) Mc Graw Hill, USA 2001 10th edition.
4. General and applid toxicology by B.Ballantyne, T.Marrs, P.Turner (Eds) The Mc Millan press Ltd, London.
5. Drug Discovery by Vogel's
6. Drug Discovery and evaluation – Pharmacological assays by H.Gerhard.Vogel, 2nd edition, Springer verlag, Berlin, Heidelberg.
7. Tutorial Pharmacy (Vol I and II) by Cooper and Gunns.

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COURSE STRUCTURE & SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

Course Outcome: 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

UNIT - I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT - II

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

UNIT - III

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.

UNIT - IV

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

UNIT - V

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

Reference Books:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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COURSE STRUCTURE & SYLLABI

Course Code	ENTREPRENEURSHIP MANAGEMENT	L	T	P	C
21SOE301c	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

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

UNIT - I

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

UNIT - II

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

UNIT - III

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

UNIT - IV

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

UNIT - V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

Reference Books:

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 New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

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SEMESTER – I

S. No.	Course code	Course Name	Hours per week			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S01102	Advanced Pharmacology-I	4	-	-	4
3.	21S01103	Clinical Pharmacology and Pharmacotherapeutics	4	-	-	4
4.	21S01104	Cellular and Molecular Pharmacology	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S01106	Advanced Pharmacology – I Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S01107	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21S01201	Advanced Pharmacology- II	4	-	-	4
2.	21S01202	Pharmacological Screening Methods & Toxicology	4	-	-	4
3.	21S01203	Principles of Drug Discovery	4	-	-	4
4.	21S01204	Clinical research and Pharmacovigilance	4	-	-	4
5.	21S01205	Advanced Pharmacology -II Lab	-	-	6	3
6.	21S01206	Pharmacological Screening Methods & Toxicology Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management from Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S01207	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

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SEMSTER - III

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Rights	4	-	-	4
2.	21SOE301a 21SOE301b 21SOE301c	**Open Elective** Pharmaceutical Validation Biostatistics Entrepreneurship Management	3	-	-	3
3.	21S01302	Teaching Practice/Assignment	-	-	4	2
4.	21S01303	Comprehensive viva voce	-	-	-	2
	21S01304	Research Work – I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21S01401	Co-Curricular Activities	2			2
2.	21S01402	Research Work – II	3		30	18
		Total	5		30	20

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Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
21S01101		4	0	0	4
	Semester	I			

Course Objectives:

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.

Course Outcomes (CO): Student will be able to

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

UNIT - I

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

UNIT - II

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

UNIT - III

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 ^{13}C NMR. Applications of NMR spectroscopy

UNIT - IV

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, 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.

UNIT - V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography
g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Reference Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
4. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

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5. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
6. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
10. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
11. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

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Course Code	ADVANCED PHARMACOLOGY- I	L	T	P	C
21S01102		4	0	0	4
	Semester	I			

Course Objectives:

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

Course Outcomes (CO): Student will 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

UNIT – I

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors quantification of drug receptors interaction and elicited effects.

UNIT – II

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

UNIT - III

Central nervous system Pharmacology
General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.

UNIT - IV

Cardiovascular Pharmacology
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

UNIT - V

Autacoid Pharmacology
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. Pharmacology of antihistamines, 5HT antagonists

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott

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Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B. G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery's Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists

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COURSE STRUCTURE& SYLLABI

Course Code	CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS	L	T	P	C
21S01103		4	0	0	4
	Semester	**I**			

Course Objectives:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

Course Outcomes (CO): Student will be able to

- The pathophysiology of selected disease states and the rationale for drug therapy; the controversies in drug therapy;
- The importance of preparation of individualized therapeutic plans based on diagnosis;
- Needs to identify the patient-specific parameters relevant in initiating drug therapy, and
- Monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
- Summarize the therapeutic approach to management of these diseases including reference
- To the latest available evidence;
- Therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice

UNIT - I

Principles of Pharmacokinetics
1. Revision of basic concepts.
2. Clinical Pharmacokinetics.
a. Dose – response in man
b. Influence of renal and hepatic disease on Pharmacokinetics
c. Therapeutics drug monitoring & individualization of drug therapy
d. Population Pharmacokinetics.

UNIT - II

Adverse Drug Reactions, Drug Interactions, ADR monitoring & Pharmacovigilance

UNIT - III

Pathophysiology and drug therapy of the following disorders. Schizophrenia, anxiety, depression, epilepsy, Parkinson's, alzheimer's diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction.

UNIT - IV

Pathophysiology and drug therapy of the following disorders. TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, G.I. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT - V

Drug therapy in
a) Geriatrics
b) Paediatrics
c) Pregnancy & Lactation.
d) Renal & hepatic insufficiency

Reference Books:

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pathologic basis of disease - Robins SL, W.B. Saunders publication.
4. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
5. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
7. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
8. Relevant review articles from recent medical and pharmaceutical literature.
9. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
10. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
11. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	CELLULAR AND MOLECULAR PHARMACOLOGY	L	T	P	C
21S01104		4	0	0	4
	Semester	I			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT – I

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

UNIT – II

Cell signaling
Intercellular and intracellular signaling pathways.
Classification of receptor family and molecular structure ligand gated 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

UNIT – III

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

UNIT – IV

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,

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COURSE STRUCTURE SYLLABI

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

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

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

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COURSE STRUCTURE SYLLABI

Course Code	ADVANDED PHARMACOLOGY – I LAB	L	T	P	C
21S01106		4	0	0	4
	Semester	I			

List of experiments

Handling of laboratory animals.

1. Various routes of drug administration.
2. Study of techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
4. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
5. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method.
7. Estimation of pA2 value on isolated tissues
8. Bioassay of 5-HT using rat fundus strip
9. Bioassay of oxytocin using rat uterus

Reference Books:

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M. N. Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	ADVANCED PHARMACOLOGY – II	L	T	P	C
21S01201		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will 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

UNIT – I

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.

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

Reference Books:

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David 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 Drug Metabolism for Industrial Scientists

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COURSE STRUCTURE SYLLABI

9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (RobbinsPathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S. K Srivastava published by A P C Avichal Publishing Company.
11 K D. Tripathi. Essentials of Medical Pharmacology Principles of Pharmacology.
12.The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr., EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	PHARMACOLOGICAL SCREENING METHODS & TOXICOLOGY	L	T	P	C
21S01202		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): Student will 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

UNIT – I

Laboratory Animals: Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods

UNIT – II

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.

UNIT – III

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives.

UNIT – IV

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT – V

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

Reference Books:

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COURSE STRUCTURE SYLLABI

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, S K. Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, S K. 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 Bikash Medhi (Author), Ajay Prakash (Author)

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COURSE STRUCTURE& SYLLABI

Course Code	PRINCIPLES OF DRUG DISCOVERY	L	T	P	C
21S01203		4	0	0	4
	Semester	1I			

Course Objectives:

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

Course Outcomes (CO):

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

UNIT – I

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, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT – II

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.

UNIT – III

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

UNIT – IV

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. Denovo 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.

UNIT – V

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.

Reference Books:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation 2006 by Taylor and Francis Group, LLC.

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COURSE STRUCTURE SYLLABI

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 inMedicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design.
6. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
7. Abby L .Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	CLINICAL RESEARCH AND PHARMACOVIGILANCE	L	T	P	C
21S01204		4	0	0	4
	Semester	**I1**			

Course Objectives:

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.

Course Outcomes (CO): Student will 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

UNIT - I		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.

UNIT - II		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.

UNIT - III		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.

UNIT - IV		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.

UNIT - V		12Hrs

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COURSE STRUCTURE SYLLABI

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.
Reference Books:
1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001. 2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230 3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi. 4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons. 5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications. 6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone. 7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 8. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press. 9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

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COURSE STRUCTURE& SYLLABI

Course Code	ADVANDED PHARMACOLOGY – II LAB	L	T	P	C
21S01205		0	0	6	3
	Semester	1I			

1. Effect of drugs on chick/rat mean arterial blood pressure (MABP) by using Condon's mercury manometer.
2. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
3. Isolation of RNA from yeast
4. Gene amplification by PCR.
5. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
6. Cell viability assays (MTT/Trypan blue/SRB).
7. DNA fragmentation assay by agarose gel electrophoresis.
8. DNA damage study by Comet assay.
9. Apoptosis determination by fluorescent imaging studies.
10. Enzyme inhibition and induction activity

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	PHARMACOLOGICAL SCREENING METHODS AND TOXICOLOGY LAB		L	T	P	C
21S01206			0	0	6	3
Pre-requisite		Semester	I1			

1. Analgesic property of drug using analgesiometer.
2. Anti-inflammatory effect of drugs using rat-paw edema method.
3. Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
4. Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
5. Locomotor activity evaluation of drugs using actophotometer and rotarod.
6. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
7. Antidiabetic activity using rats / mice
8. Hepatoprotective activity
9. Anti ulcer activity
10. Antioxidant activity
11. Toxicity studies as per OECD guidelines.
12. Functional observation battery tests (modified Irwin test)

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	III			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT - V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs

Textbooks:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

Reference Books:

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COURSE STRUCTURE SYLLABI

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

AUDIT COURSE-I

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COURSE STRUCTURE SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II		Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III		Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV		Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V		Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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COURSE STRUCTURE& SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes,Volcanisms,Cyclones,Tsunamis,Floods,DroughtsandFamines,Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering ADisasteror Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book

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COURSE STRUCTURE SYLLABI

Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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COURSE STRUCTURE& SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science &technology can be understood
- Being a logical language will help to develop logic in students

UNIT - I

Alphabets in Sanskrit,

UNIT - II

Past/Present/Future Tense, Simple Sentences

UNIT - III

Order, Introduction of roots

UNIT - IV

Technical information about Sanskrit Literature

UNIT - V

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

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COURSE STRUCTURE SYLLABI

AUDIT COURSE-II

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COURSE STRUCTURE& SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	II			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof
3. Curriculum Studies, 36 (3): 361-379.

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COURSE STRUCTURE SYLLABI

4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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COURSE STRUCTURE& SYLLABI

Course Code	STRESSMANAGEMENT BY YOGA	L	T	P	C
21DAC201b		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To achieve overall health of body and mind
- To overcome stres

Course Outcomes (CO): Student will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT - I

Definitions of Eight parts of yog.(Ashtanga)

UNIT - II

Yam and Niyam.

UNIT - III

Do`sand Don't'sin life.
i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii)
Shaucha,santosh,tapa,swadhyay,ishwarpranidhan

UNIT - IV

Asan and Pranayam

UNIT - V

i)Variousyogposesand theirbenefitsformind &body
ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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COURSE STRUCTURE SYLLABI

Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam- Holistic development of personality
Verses-19,20,21,22(wisdom)
Verses-29,31,32(pride &heroism)
Verses-26,28,63,65(virtue)

UNIT - II

Neetisatakam- Holistic development of personality
Verses-52,53,59(dont's)
Verses-71,73,75,78(do's)

UNIT - III

Approach to day to day work and duties.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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COURSE STRUCTURE& SYLLABI

OPEN ELECTIVE

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COURSE STRUCTURE SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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

Course Outcomes (CO): Student will 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

UNIT - I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments

UNIT - II

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

UNIT - III

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.

UNIT - IV

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

UNIT - V

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

Textbooks:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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COURSE STRUCTURE& SYLLABI

Course Code	BIOSTATISTICS	L	T	P	C
21SOE301b	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data

Course Outcomes (CO): Student will be able to

The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

UNIT - I

An introduction to statistics and biostatistics-collection and organization of data, graphical, pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, Coefficient of variation, mean error, relative error, precision and accuracy

UNIT - II

Tests of significance: Testing hypotheses – Principles and applications of Z, t, F–ratio and chi-square tests in pharmaceutical and medical research. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

UNIT - III

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD – their applications and analysis of data;

UNIT - IV

Factorial Experiments – Principles and applications; Probit analysis: Dose – effect relationships, calculation of LD50, ED50

UNIT - V

Statistical quality control: Meaning and uses, Construction of X, R, P, ηp and charts.

Textbooks:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

Reference Books:

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

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COURSE STRUCTURE SYLLABI

Course Code	ENTREPRENEURSHIP MANAGEMENT	L	T	P	C
21SOE301c	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

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

Course Outcomes (CO): Student will be able to

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

UNIT - I

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

UNIT - II

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

UNIT - III

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

UNIT - IV

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

UNIT - V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation

Reference Books:

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 New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson