



Jawaharlal Nehru Technological University Anantapur
(Established by Govt. of A.P., Act. No. 30 of 2008)
Ananthapuramu-515 002 (A.P) India

**Academic Regulations (R23) for
B. Pharm. (Regular-Full time)**

(Effective for the students admitted into I year from the Academic Year
2023-2024 onwards)

and

**Academic Regulations (R23) for
B. Pharm. (Lateral Entry Scheme)**

(Effective for the students getting admitted into II year through Lateral Entry
Scheme from the Academic Year **2024-2025** onwards)

1. Award of the Degree

a) Award of the B. Pharm. Degree

A student will be declared eligible for the award of the B. Pharm. degree if he/she fulfils the following:

- i) Pursues a course of study for not less than four academic years and not more than eight academic years. However, for the students availing Gap year facility this period shall be extended by two years at the most and these two years would in addition to the maximum period permitted for graduation (Eight years).
- ii) Registers for 208 credits and secures all 208 credits.

b) Award of B. Pharm. degree with Honors / Research

A student will be declared eligible for the award of the B. Pharm. with Honors/Research if he/she fulfils the following:

- i) A Student secures an additional 15 credits fulfilling all the requisites of a B. Pharm. programme i.e., 208 credits.
- ii) A student is permitted to register either for Honors or Research but not for both.
- iii) Registering for Honours/Research is optional.
- iv) Honors/Research is to be completed simultaneously with B. Pharm. programme.

2. Students who fail to fulfil all the academic requirements for the award of the degree within eight academic years from the year of their admission shall forfeit their seat in B. Pharm. course and their admission stands cancelled. This clause shall be read along with clause 1 a) i).

3. Admissions

Admission to the B. Pharm. programme shall be made subject to the eligibility, qualifications and specialization prescribed by the A.P. State Government/University from time to time. Admissions shall be made either based on the merit rank obtained by the student in the common entrance examination conducted by the A.P. Government/University or any other order of merit approved by the A.P. Government/University, subject to reservations as prescribed by the Government/University from time to time.

4. Program related terms:

- i) **Credit:** A unit by which the course work is measured. It determines the number of hours of instruction 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
2 Hrs. Practical (Lab) per week	1 credit

- ii) **Academic Year:** Two consecutive (one odd + one even) semesters constitute one academic year.
- iii) **Choice Based Credit System (CBCS):** The CBCS provides a choice for students to select from the prescribed courses.

5. Course Classification

All subjects/ courses offered for the B.Pharm. programme are broadly classified as follows. The University has followed the guidelines issued by UGC/PCI.

S.No.	Broad Course Classification	Course Category	Description
1.	Foundation Courses	Fundamental courses	Includes sciences, humanities, social sciences and engineering courses
2.	Core Courses	Professional Core Courses (PC)	Includes core subjects related to the programme.
3.	Elective Courses	Professional Elective Courses (PE)	Includes elective subjects related to the programme.
		Open Elective Courses (OE)	Electives which include multidisciplinary subjects in an area outside the programme.
4.	Skill Courses	Skill Enhancement Courses (SEC)	Courses to develop and strengthen the necessary skills to gain, maintain, and advance in a chosen area.
5.	Project & Internships	Project	B. Pharm. Project or Major Project
		Internships	Community based and Industry Internships
6.	Audit Courses	Mandatory noncredit courses	Covering subjects of developing desired attitude among the learners

6. Programme Pattern

- The total duration of the B. Pharm. (Regular) programme is four academic years.
- Each academic year of study is divided into two semesters.
- The minimum number of instruction days in each semester is 90.
- There shall be a mandatory student induction program for freshers, with a three-week duration before the commencement of the first semester. Physical activity, Creative Arts, Universal Human Values, Literary, Proficiency Modules, Lectures by Eminent People, Visits to local Areas, Familiarization to Branch & Innovations etc., are to be included as per the AICTE guidelines.
- Increased flexibility for students through an increase in the elective component of the curriculum.
- A pool of job-oriented/domain skill courses which are relevant to the industry are integrated into the curriculum. There shall be 05 skill-oriented courses offered during III to VII semesters. Among the five skill courses, four courses shall focus on the basic and advanced skills related to the domain and the other shall be a soft skills course.
- Students shall undergo practice school and mandatory internships.
- An undergraduate degree either with Honours or Research is introduced by the University for the students having good academic record.
- Each college shall assign a faculty advisor/mentor after admission to a group of students to provide guidance in courses registration / career growth / placements / opportunities for higher studies / GPAT / other competitive exams etc.
- Preferably 25% of course work for the theory courses in every semester shall be conducted in the blended mode of learning.

7. Evaluation Process

The performance of a student in each semester shall be evaluated subject-wise with a maximum of 100 marks for theory and 100 marks for practical subject. Practice School and Internships shall be evaluated for 50 marks, Project work in the final semester shall be evaluated for 200 marks, mandatory courses with no credits shall be evaluated for 30 mid semester marks.

A student has to secure not less than 35% of marks in the end examination and a minimum of 40% of marks in the sum total of the mid semester and end examination marks taken together for the theory, practical or project etc. In the case of a mandatory course, he/she should secure 40% of the total marks.

- i) For the theory subject, the distribution shall be 30 marks for Internal Evaluation and 70 marks for the End-Examination.
- ii) For practical subjects, the distribution shall be 30 marks for the Internal Evaluation and 70 marks for the End- Examination.
- iii) If any subject has both theory and practical components, they will be evaluated separately as theory subject and practical subject.

A. Theory Courses

Assessment Method	Marks
Continuous Internal Assessment	30
Semester End Examination	70
Total	100

Continuous Internal Evaluation

- i) For theory subjects, during the semester, there shall be two midterm examinations. Each midterm examination shall be evaluated for 30 marks of which 10 marks for objective paper (20 minutes duration), 15 marks for subjective paper (90 minutes duration) and 5 marks for assignment.
- ii) Objective paper shall contain for 05 short answer questions with 2 marks each or maximum of 20 bits for 10 marks. Subjective paper shall contain 3 either or type questions (totally six questions from 1 to 6) of which student has to answer one from each either-or type of questions. Each question carries 10 marks. The marks obtained in the subjective paper are condensed to 15 marks.

Note:

- The objective paper shall be prepared in line with the quality of competitive examinations questions.
 - The subjective paper shall contain 3 either or type questions of equal weightage of 10 marks. Any fraction shall be rounded off to the next higher mark.
 - The objective paper shall be conducted by the respective institution on the day of subjective paper test.
 - Assignments shall be in the form of mini projects, slip tests, quizzes etc., depending on the course content. It should be continuous assessment throughout the semester and the average marks shall be considered.
- iii) If the student is absent for the mid semester examination, no re-exam shall be conducted and mid semester marks for that examination shall be considered as zero.
 - iv) First midterm examination shall be conducted for I, II units of syllabus with one either or type question from each unit and third either or type question from both the units. The second midterm examination shall be conducted for III, IV and V units with one either or type question from each unit.

- v) Final mid semester marks shall be arrived at by considering the marks secured by the student in both the mid examinations with 80% weightage given to the better mid exam and 20% to the other.

For Example:

Marks obtained in first mid: 25

Marks obtained in second mid: 20

Final mid semester Marks: $(25 \times 0.8) + (20 \times 0.2) = 24$

If the student is absent for any one midterm examination, the final mid semester marks shall be arrived at by considering 80% weightage to the marks secured by the student in the appeared examination and zero to the other. For Example:

Marks obtained in first mid: Absent

Marks obtained in second mid: 25

Final mid semester Marks: $(25 \times 0.8) + (0 \times 0.2) = 20$

End Examination Evaluation:

End examination of theory subjects shall have the following pattern:

- i) There shall be 6 questions and all questions are compulsory.
- ii) Question I shall contain 10 compulsory short answer questions for a total of 20marks such that each question carries 2 marks.
- iii) There shall be 2 short answer questions from each unit.
- iv) In each of the questions from 2 to 6, there shall be either/or type questions of 10 marks each. Student shall answer any one of them.
- v) The questions from 2 to 6 shall be set by covering one unit of the syllabus for each question.

B. Practical Courses

Assessment Method	Marks
Continuous Internal Assessment	30
Semester End Examination	70
Total	100

- a) For practical courses, there shall be a continuous evaluation during the semester for 30 sessional marks and the end examination shall be for 70 marks.
 - b) Day-to-day work in the laboratory shall be evaluated for 15 marks by the concerned laboratory teacher based on the record/viva and 15 marks for the internal test.
 - c) The end examination shall be evaluated for 70 marks, conducted by the concerned laboratory teacher and a senior expert in the subject from the same department.
 - Procedure: 20 marks
 - Experimental work & Results: 30 marks
 - Synopsis: 10 marks
 - Viva voce: 10 marks.
- C. There shall be no external examination for mandatory courses with zero credits. 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 40% or more in the internal examinations. In case the student fails, a re-examination shall be conducted for failed candidates for 30 marks satisfying the conditions mentioned in item 1 & 2 of the regulations.

- D. 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.

8. Skill oriented Courses

- i) There shall be five skill-oriented courses offered during III to VII semesters.
- ii) Out of the five skill courses, four shall be domain specific and other soft skills course.
- iii) The course shall carry 100 marks and shall be evaluated through continuous assessments during the semester for 30 sessional marks and end examination shall be for 70 marks. Day-to-day work in the class / laboratory shall be evaluated for 30 marks by the concerned teacher based on the regularity/assignments/viva/mid semester test. The end examination similar to practical examination pattern shall be conducted by the concerned teacher and an expert in the subject nominated by the principal.
- iv) The Head of the Department shall identify a faculty member as coordinator for the course. A committee consisting of the Head of the Department, coordinator and a senior Faculty member nominated by the Head of the Department shall monitor the evaluation process. The marks/grades shall be assigned to the students by the above committee based on their performance.
- v) The student shall be given an option to choose either the skill courses being offered by the college or to choose a certificate course being offered by industries/Professional bodies or any other accredited bodies. If a student chooses to take a Certificate Course offered by external agencies, the credits shall be awarded to the student upon producing the Course Completion Certificate from the agency. A committee shall be formed at the level of the college to evaluate the grades/marks given for a course by external agencies and convert to the equivalent marks/grades.
- vi) The recommended courses offered by external agencies, conversions and appropriate grades/marks are to be approved by the University at the beginning of the semester. The principal of the respective college shall forward such proposals to the University for approval.
- vii) If a student prefers to take a certificate course offered by external agency, the department shall mark attendance of the student for the remaining courses in that semester excluding the skill course in all the calculations of mandatory attendance requirements upon producing a valid certificate as approved by the University.

9. Massive Open Online Courses (MOOCs):

A Student has to pursue and complete one course compulsorily through MOOCs approved by the University. A student can pursue courses other than core through MOOCs and it is mandatory to complete one course successfully through MOOCs for awarding the degree. A student is not permitted to register and pursue core courses through MOOCs.

A student shall register for the course (Minimum of either 8 weeks or 12 weeks) offered through MOOCs with the approval of Head of the Department. The Head of the Department shall appoint one mentor to monitor the student's progression. The student needs to earn a certificate by passing the exam. The student shall be awarded the credits assigned in the curriculum only by submission of the certificate. Examination fee, if any, will be borne by the student.

Students who have qualified in the proctored examinations conducted through MOOCs platform can apply for credit transfer as specified and are exempted from appearing internal as

well as external examination (for the specified equivalent credit course only) conducted by the university.

Necessary amendments in rules and regulations regarding adoption of MOOC courses would be proposed from time to time.

10. Credit Transfer Policy

Adoption of MOOCs is mandatory, to enable Blended model of teaching-learning as also envisaged in the NEP 2020. As per University Grants Commission (Credit Framework for Online Learning Courses through SWAYAM) Regulation, 2016, the University shall allow up to a maximum of 20% of the total courses being offered in a particular programme through MOOCs platform.

- i) 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.
- ii) Student registration for the MOOCs shall be only through the respective department of the institution, it is mandatory for the student to share necessary information with the department.
- iii) Credit transfer policy will be applicable to the Professional & Open Elective courses only.
- iv) The concerned department shall identify the courses permitted for credit transfer.
- v) The University/institution shall notify at the beginning of semester the list of the online learning courses eligible for credit transfer.
- vi) 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.
- vii) The university shall ensure no overlap of MOOC exams with that of the university examination schedule. In case of delay in results, the university will re-issue the marks sheet for such students.
- viii) 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.
- ix) 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 certificate of completion.
 - b) Undertaking form filled by the students for credit transfer.
- x) The universities 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 government.

Note: Students shall be permitted to register for MOOCs offered through online platforms approved by the University from time to time.

11. Academic Bank of Credits (ABC)

The University has implemented Academic Bank of Credits (ABC) to promote flexibility in curriculum as per NEP 2020 to

- i. provide option of mobility for learners across the universities of their choice
- ii. provide option to gain the credits through MOOCs from approved digital platforms.
- iii. facilitate award of certificate/diploma/degree in line with the accumulated credits in ABC
- iv. execute Multiple Entry and Exit system with credit count, credit transfer and credit

acceptance from students' account.

12. Summer Internships & Project Work

Summer Internships: Two summer internships either onsite or virtual each with a minimum of 08 weeks duration, done at the end of second and third years, respectively are mandatory. One of the two summer internships at the end of second year (Community Service Project) shall be society oriented and shall be completed in collaboration with government organizations/NGOs & others. The other internship at the end of third year is Industry Internship and shall be completed in collaboration with Industries. The student shall register for the internship as per course structure after commencement of academic year. The guidelines issued by the APSCHE / University shall be followed for carrying out and evaluation of Community Service Project and Industry Internship.

Evaluation of the summer internships shall be through the departmental committee. A student will be required to submit a summer internship report to the concerned department and appear for an oral presentation before the departmental committee comprising of Head of the Department, supervisor of the internship and a senior faculty member of the department. A certificate of successful completion from industry shall be included in the report. The report and the oral presentation shall carry 50% weightage each. It shall be evaluated for 50 external marks. There shall be no internal marks for Summer Internship. A student shall secure minimum 40% of marks for successful completion. In case, if a student fails, he/she shall reappear as and when semester supplementary examinations are conducted by the University.

Full Semester Internship and Project work: In the final semester, the student should mandatorily register and undergo internship (onsite/virtual) and in parallel he/she should work on a project with well-defined objectives. At the end of the semester the candidate shall submit an internship completion certificate and a project report. A student shall also be permitted to submit project report on the work carried out during the internship.

The project report shall be evaluated with an external examiner. The total marks for project work 200 marks and distribution shall be 60 marks for internal and 140 marks for external evaluation. The supervisor assesses the student for 30 marks (Report: 15 marks, Seminar: 15 marks). At the end of the semester, all projects shall be showcased at the department for the benefit of all students and staff and the same is to be evaluated by the departmental Project Review Committee consisting of supervisor, a senior faculty and HOD for 30 marks. The external evaluation of Project Work is a Viva-Voce Examination conducted in the presence of internal examiner and external examiner appointed by the University and is evaluated for 140 marks.

The college shall facilitate and monitor the student internship programs. Completion of internships is mandatory, if any student fails to complete internship, he/she will not be eligible for the award of degree. In such cases, the student shall repeat and complete the internship.

13. Guidelines for offering B. Pharm. with Honors / Research

The objective is to facilitate the students to choose specialized courses of their choice and build their competence in a specialized area at the UG level. There is an opportunity for students who have a good academic record and interest in higher studies and research.

B. Pharm. with Honors / Research is applicable to all the Regular and Lateral Entry students.

- i) A student shall earn an additional 15 credits for the award of B. Pharm. (Honors / Research) degree. This is in addition to the credits essential for obtaining the B. Pharm. degree (i.e., 208 credits).
- ii) A student is permitted to register for Honors / Research in IV semester after the results of III Semester are declared and students may be allowed to take maximum two subjects per semester pertaining to the Honors / Research from V Semester onwards.
- iii) The Concerned Principal of the college shall arrange separate class work and timetable of the courses offered under Honors / Research program.
- iv) Courses that are used to fulfil the student's primary major may not be double counted towards the Honors / Research.
- v) Courses with content substantially equivalent to courses in the student's primary Major may not be counted towards the Honors / Research.
- vi) Students can complete the courses offered under Honors / Research either in the college or in online platforms like SWAYAM with a minimum duration of 12 weeks for a 3-credit course and 8 weeks duration for a 2-credit course satisfying the criteria for credit mobility. If the courses under Honors / Research are offered in conventional mode, then the teaching and evaluation procedure shall be like the regular B. Pharm. programme.
- vii) The attendance for the registered courses under Honors / Research and regular courses offered for Major degree in a semester are to be considered separately.
- viii) A student shall maintain an attendance of 75% in all registered courses under Honors / Research to be eligible for attending semester end examinations.
- ix) A student registered for Honors / Research shall pass in all subjects that constitute the requirement for the Honors / Research degree program. No class/division (i.e., second class, first class and distinction, etc.) shall be awarded.
- x) If a student drops or is terminated from the Honors / Research program, the additional credits so far earned cannot be converted into open or core electives; they will remain extra. However, such students will receive a separate grade sheet mentioning the additional courses completed by them.
- xi) The Honors / Research will be mentioned in the degree certificate as Bachelor of Pharmacy (Honors / Research).

Enrolment into Honors / Research:

- i) The enrolment of students into Honors / Research is based on the percentage of marks obtained in the major degree program.
- ii) The percentage of marks shall be taken up to III semester in case of regular entry students and only III semester in case of lateral entry students.
- iii) Students having 7 CGPA without any backlog subjects will be permitted to register for Honors / Research.
- iv) If a student is detained due to lack of attendance either in Major or in Honors / Research, registration shall be cancelled.
- v) The minimum strength required for offering Honors / Research offline is considered as 20% of the sanctioned intake. If a minimum enrolments criterion is not met, then the students may be permitted to register for the equivalent MOOC courses as approved by the concerned Head of the department satisfying criteria for credit mobility.
- vi) Transfer of credits from Honors / Research to regular B. Pharm. degree and vice versa shall not be permitted.
- vii) Honors / Research is to be completed simultaneously with a Major degree program.

Registration for Honors / Research:

- i) The institution will announce courses offered under Honors / Research before the start of the semester.
- ii) The eligible and interested students shall apply through the HOD of the department. The whole

process should be completed within one week before the start of every semester. Selected students shall be permitted to register for the courses under Honors / Research.

- iii) The selected students shall submit their willingness to the Principal through the department and the department shall maintain the record of students pursuing the Honors / Research.
- iv) The students enrolled for the Honors/Research courses will be monitored continuously. An advisor/mentor from the department shall be assigned to monitor the progress.
- v) There is no fee for registration of subjects for Honors / Research program offered in offline at the respective institutions.

14. Attendance Requirements:

- i) A student shall be eligible to appear for the University external examinations if he/she acquires a minimum of 40% attendance in each subject and 75% of attendance in aggregate of all the subjects. b) 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.
- ii) Shortage of Attendance below 65% in aggregate shall in NO CASE be condoned.
- iii) A stipulated fee shall be payable towards condonation of shortage of attendance to the University.
- iv) Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examination of that class and their registration shall stand cancelled.
- v) A student will not be promoted to the next semester unless he satisfies the attendance requirements of the present semester. They may seek readmission for that semester from the date of commencement of class work.
- vi) If any candidate fulfils the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.
- vii) 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.
- viii) For induction programme attendance shall be maintained as per AICTE norms.

15. Promotion Rules:

The following academic requirements must be satisfied in addition to the attendance requirements mentioned in section 16.

- i) A student shall be promoted from first year to second year if he/she fulfils the minimum attendance requirement as per university norms.
- ii) A student will be promoted from II to III year if he/she fulfils the academic requirement of securing 40% of the credits (any **decimal** fraction should be **rounded off to lower** digit) up to in the subjects that have been studied up to III semester.
- iii) A student shall be promoted from III year to IV year if he/she fulfils the academic requirements of securing 40% of the credits (any **decimal** fraction should be **rounded off to lower** digit) in the subjects that have been studied up to V semester.
And in case a student is detained for want of credits for a particular academic year by ii) & iii) above, the student may make up the credits through supplementary examinations and only after securing the required credits he/she shall be permitted to join in the V semester or VII semester respectively as the case may be.
- iv) When a student is detained due to lack of credits/shortage of attendance he/she may be re-admitted when the semester is offered after fulfilment of academic regulations. In such case, he/she shall be in the academic regulations into which he/she is readmitted.

16. 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 & above	Superior	10
80 - 89	A (Excellent)	9
70 - 79	B (Very Good)	8
60 - 69	C (Good)	7
50 - 59	D (Average)	6
40 - 49	E (Pass)	5
< 40	F (Fail)	0
Absent	Ab (Absent)	0

- 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.
- For non-credit 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.,

$$SGPA = \frac{\sum (C_i \times G_i)}{\sum C_i}$$

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.

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.,

$$CGPA = \frac{\sum (C_i \times S_i)}{\sum C_i}$$

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

Both SGPA and CGPA shall be rounded off to 2 decimal points and reported in the transcripts. While computing the SGPA the subjects in which the student is awarded Zero grade points will also be included.

Grade Point: It is a numerical weight allotted to each letter grade on a 10-point scale. Letter Grade: It is an index of the performance of students in a said course. Grades are denoted by the letters S, A, B, C, D and F.

Award of Class:

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

Class Awarded	CGPA Secured
First Class with Distinction	≥ 7.5
First Class	$\geq 6.5 < 7.5$
Second Class	$\geq 5.5 < 6.5$
Pass Class	$\geq 5.0 < 5.5$

CGPA to Percentage conversion Formula – $(\text{CGPA} - 0.5) \times 10$

17. With-holding of Results

If the candidate has any dues not paid to the university or if any case of indiscipline or malpractice is pending against him/her, the result of the candidate shall be withheld in such cases.

18. Multiple Entry / Exit Option**(a) Exit Policy:**

The students can choose to exit the four-year programme at the end of first/second/third year.

- i) **UG Certificate in (Field of study/discipline)** - Programme duration: First year (first two semesters) of the undergraduate programme, 52 credits followed by an additional exit 10-credit bridge course(s) lasting two months, including at least 6-credit job-specific internship/ apprenticeship that would help the candidates acquire job-ready competencies required to enter the workforce.
- ii) **UG Diploma (in Field of study/discipline)** - Programme duration: First two years (first four semesters) of the undergraduate programme, 104 credits followed by an additional exit 10-credit bridge course(s) lasting two months, including at least 6-credit job-specific internship/ apprenticeship that would help the candidates acquire job-ready competencies required to enter the workforce.
- iii) **Bachelor of Science (in Field of study/discipline)** - Programme duration: First three years (first six semesters) of the undergraduate programme, 160 credits.

(b) Entry Policy:

Modalities on multiple entry by the student into the B. Pharm. programme will be provided in due course of time.

Note: The Universities shall resolve any issues that may arise in the implementation of Multiple Entry and Exit policies from time to time and shall review the policies in the light of periodic changes brought by UGC, AICTE and State government.

19. Gap Year Concept:

Gap year concept for Student Entrepreneur in Residence is introduced and outstanding students who wish to pursue entrepreneurship / become entrepreneur are allowed to take a break of one year at any time after II year to pursue full-time entrepreneurship programme/to establish startups. This period may be extended to two years at the most and these two years would not be counted for the time for the maximum time for graduation. The principal of the respective college shall forward such proposals submitted by the students to the University. An evaluation committee constituted by the University shall evaluate the proposal submitted by the student and the committee shall decide whether to permit the student(s) to avail the Gap Year or not.

20. 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.

Candidates who are permitted to avail Gap Year shall be eligible for re-joining into the succeeding year of their B. Pharm. from the date of commencement of class work, subject to Section 2 and they will follow the academic regulations into which they are readmitted.

21. Minimum Instruction Days for a Semester:

The minimum instruction days including exams for each semester shall be 90 days.

22. Medium of Instruction:

The medium of instruction of the entire B. Pharm. undergraduate programme (including examinations and project reports) will be in English only.

23. Student Transfers:

Student transfers shall be as per the guidelines issued by the Government of Andhra Pradesh and the Universities from time to time.

24. General Instructions:

- i. The academic regulations should be read as a whole for purpose of any interpretation.
- ii. Malpractices rules-nature and punishments are appended.
- iii. Where the words “he”, “him”, “his”, occur in the regulations, they also include “she”, “her”, “hers”, respectively.
- iv. In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- v. The Universities 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 Universities.
- vi. In the case of any doubt or ambiguity in the interpretation of the guidelines given, the decision of the Vice-Chancellor / Head of the institution is final.

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ACADEMIC REGULATIONS (R23)
FOR B.PHARM. (LATERAL ENTRY SCHEME)

(Effective for the students admitted into II year through Lateral Entry Scheme from the Academic Year 2024-25 onwards)

1. Award of the Degree

a) Award of the B.Pharm. Degree if he/she fulfils the following:

- (i) Pursues a course of study for not less than three academic years and not more than six academic years. However, for the students availing Gap year facility this period shall be extended by two years at the most and these two years would in addition to the maximum period permitted for graduation (Six years).
- (ii) Registers for 156 credits and secures all 156 credits.

b) Award of B.Pharm. degree **with Honors** / Research if he/she fulfils the following:

- (i) A Student secures an additional 15 credits fulfilling all the requisites of a B. Pharm. programme i.e., 208 credits.
- (ii) A student is permitted to register either for Honors or Research but not for both.
- (iii) Registering for Honours/Research is optional.
- (iv) Honors/Research is to be completed simultaneously with B. Pharm. programme.

2. Students who fail to fulfil the requirement for the award of the degree within six consecutive academic years from the year of admission, shall forfeit their seat.

3. Minimum Academic Requirements:

The following academic requirements must be satisfied in addition to the requirements mentioned for the regular B. Pharm. programme:

- i) A student has to secure not less than 35% of marks in the end examination and a minimum of 40% of marks in the sum total of the mid semester and end examination marks taken together for the theory, practical or project etc. In the case of a mandatory course, he/she should secure 40% of the total marks.
- ii) A student shall be promoted from III year to IV year if he/she fulfils the academic requirements of securing 40% of the credits (any decimal fraction should be rounded off to lower digit) in the subjects that have been studied up to V semester.

And in case if student is already detained for want of credits for particular academic year, the student may make up the credits through supplementary exams of the above exams before the commencement of IV year I semester class work of next year.

4. All other regulations applicable for B. Pharm. four-year degree course (Regular) will hold good for B. Pharm. (Lateral Entry Scheme).

RULES FOR

DISCIPLINARY ACTION FOR MALPRACTICES / IMPROPER CONDUCT IN EXAMINATIONS

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

Malpractices identified by squad or special invigilators.

- i) Punishments to the candidates as per the above guidelines.
- ii) Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
- iii) A show cause notice shall be issued to the college.
- iv) Impose a suitable fine on the college.
- v) 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/she has to register for End Examinations in that subject/subjects consequently and has to fulfil all the norms required for the award of Degree.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

(Established by Govt. of A.P., ACT No.30 of 2008)

ANANTHAPURAMU – 515 002 (A.P) INDIA

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B. Pharm. (Regular-Full time)

(Effective for the students admitted into I year from the Academic
Year **2023-24** onwards)



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

INDUCTION PROGRAMME

S.No.	Course Name	Category	L-T-P
1	Physical Activities -- Sports, Yoga and Meditation, Plantation	MC	0-0-6
2	Counselling	MC	2-0-2
3	Career Options	MC	3-0-0
4	Orientation on admitted Branch	EC	2-0-3
5	Proficiency Modules & Productivity Tools	ES	2-1-2
6	Assessment on basic aptitude and skills	MC	2-0-3
7	Remedial Training in Foundation Courses	MC	2-1-2
8	Human Values & Professional Ethics	MC	3-0-0
9	Communication Skills, Listening, Speaking, Reading, Writing skills	BS	2-1-2
10	Programming Skills	ES	2-0-2



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year I Semester

SEMESTER - I						
S.No.	Course Code	Course Name	Hours per Week			Credits
			L	T	P	
1.	23BP101T	Human Anatomy and Physiology - I	3	1	-	4
2.	23BP102T	Pharmaceutical Analysis	3	1	-	4
3.	23BP103T	Pharmaceutics - I	3	-	-	3
4.	23BP104T	Pharmaceutical Inorganic Chemistry	3	-	-	3
5.	23BP105T	Communication Skills	2	-	-	2
6.	23BP106RBT 23BP106RMT	Remedial Biology ^{\$} / Remedial Mathematics	2/3	-	-	2/3
7.	23BP101P	Human Anatomy and Physiology – I Lab	-	-	3	1.5
8.	23BP102P	Pharmaceutical Analysis Lab	-	-	3	1.5
9.	23BP103P	Pharmaceutics – I Lab	-	-	3	1.5
10.	23BP104P	Pharmaceutical Inorganic Chemistry Lab	-	-	3	1.5
11.	23BP105P	Communication Skills Lab	-	-	2	1
12.	23BP106RBP	Remedial Biology Lab ^{\$}	-	-	2	1
		Total	16/17	2	16/14	26

^{\$}Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course.

I Year II Semester

SEMESTER - II						
S.No.	Course Code	Course Name	Hours per week			Credits
			L	T	P	
1.	23BP201T	Human Anatomy and Physiology - II	3	1	-	4
2.	23BP202T	Pharmaceutical Organic Chemistry - I	3	1	-	4
3.	23BP203T	Biochemistry	3	1	-	4
4.	23BP204T	Computer Applications in Pharmacy	3	-	-	3
5.	23BP205T	Environmental Sciences	2	-	-	2
6.	23BP206T	Social and Preventive Pharmacy	3	-	-	3
7.	23BP201P	Human Anatomy and Physiology – II Lab		-	3	1.5
8.	23BP202P	Pharmaceutical Organic Chemistry – I Lab		-	3	1.5
9.	23BP203P	Biochemistry Lab		-	3	1.5
10.	23BP204P	Computer Applications in Pharmacy Lab		-	3	1.5
		Total	17	3	12	26



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP101T) HUMANAN ATOMY AND PHYSIOLOGY-I

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their balances.
- Identify the various issues and organs of different systems of the human body.
- Perform various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system.

UNIT I

Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extra cellular signal molecule, Forms of intracellular signaling a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

Tissue level of organization

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

UNIT II

Integumentary system

Structure and functions of skin

Skeletal system

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

Joints

Structural and functional classification, types of joints movements and its articulation

UNIT III

Body fluids and blood

Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticuloendothelial system.

Lymphatic system

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

UNIT IV

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

Special senses

Structure and functions of eye, ear, nose and tongue and their disorders.

UNIT V

Cardiovascular system

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
4. Textbook of Medical Physiology- Arthur C, Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Textbook of Medical Physiology- Arthur C, Guyton and John E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee, Academic Publishers Kolkata



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP102T) PHARMACEUTICAL ANALYSIS

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

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

- Understand the principles of volumetric and electrochemical analysis.
- Carryout various volumetric and electro chemical titrations
- Develop analytical skills.

UNIT I

(a) Pharmaceutical analysis-Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions-Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

UNIT II

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves.

Non aqueous titration: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT III

Precipitation titrations: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.
Basic Principles, methods and application of diazotization titration.

UNIT IV

Redox titrations

- (a) Concepts of oxidation and reduction
 - (b) Types of redox titrations (Principles and applications)
- Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT V

Electrochemical methods of analysis

Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Potentiometry- Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

Polarography- Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Textbook of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

Reference Books (Latest Editions)

1. Bassett J, Denny R C, Jeffery G H, Mendharn J, Vogel's Textbook of Quantitative Inorganic Analysis, 7th edition, ELBS/Longman, Londo, 1988
2. Ewing. Grant, Statistical Quality control 6. Instrumental methods of Analysis, 6th edition, McGraw Hill, 1988
3. Connors KA, A Textbook of Pharmaceutical Analysis, 3rd edition, Wiley Interscience, New York, 1982



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	0	0	3

(23BP103T) PHARMACEUTICS-I

45 Hours

Scope: This course is designed to impart fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the students should be able to:

- Know the history of profession of pharmacy.
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations.
- Understand the professional way of handling the prescription.
- Preparation of various conventional dosage forms

UNIT I

Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharma copoeia. Latin terms used in prescription.

Dosage forms: Introduction to dosage forms, classification and definitions

Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription.

Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT II

Pharmaceutical calculations: Weights and measures—Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

Powders: Definition, classification, advantages and disadvantages, Simple & compound powders—official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT III

Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

Biphasic liquids:

Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT IV

Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Pharmaceutical incompatibilities: Definition, classification, physical, chemical, and therapeutic incompatibilities with examples.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

UNIV V

Semi solid dosage forms: Definitions, classification, mechanisms and factors in influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Wilkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Textbook of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

Reference Books (Latest Editions)

1. Allen, Loyd V., Jr, Remington-The Science and Practice of Pharmacy (Vol.1 & 2), 22nd edition, Lippincott Williams & Wilkins, 2012
2. J.W. Cooper, Colin Gunn, Tutorial Pharmacy, 4th edition, Sir Isaac Pitman & Sons Ltd., London, 1950
3. Michael E. Aulton, Pharmaceutics: The Science Of Dosage Form Design, Churchill-Livingstone, 1988



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	0	0	3

(23BP104T) PHARMACEUTICAL INORGANIC CHEMISTRY

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course, student shall be able to

- Know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals.
- Understand the medicinal and pharmaceutical importance of inorganic compounds.

UNIT I

Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with asterisk (*), properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II

Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.

Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.

Dental products: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III

Gastrointestinal agents

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV

Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride*. Emetics: Copper sulphate*, Sodium potassium tartarate Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite 333

Astringents: Zinc Sulphate, Potash Alum

UNIT V

Radio pharmaceuticals: Radioactivity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radioisotopes-Sodium iodide 131 , introduction to radio contrast



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agents used in diagnosis, Storage conditions, precautions & pharmaceutical application of radioactive substances.

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Textbook of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

Reference Books (Latest Editions)

1. J.H. Block, E. Roche, T.O. Soine and C. O. Wilson: Inorganic Medicinal and Pharmaceutical chemistry, Lee Febiger, Philadelphia. PA.
2. Roger's Inorganic Pharmaceutical Chemistry.
3. S.N. Pandeya: A Textbook of inorganic medicinal chemistry, S.G.Publishers, Varanasi.
4. M. Ali: Textbook of Pharmaceutical Inorganic chemistry, CBS, New Delhi.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
2	0	0	2

(23BP105T) COMMUNICATION SKILLS

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

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

- Understand the behavioral needs for a pharmacist to function effectively in the areas of pharmaceutical operation.
- Communicate effectively (Verbal and Non-Verbal)
- Effectively manage the team as a team player
- Develop interview skills.
- Develop Leadership qualities and essentials.

UNIT I

Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process–Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective–Past Experiences, Prejudices, Feelings, Environment

UNIT II

Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with example for each–Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT III

Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT IV

Interview Skills: Purpose of an interview, Do's and Don'ts of an interview

Giving Presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

UNIT V

Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen.P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green Hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals –
8. PHI, 2011
9. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
10. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning indiaptvt.ltd, 2011
11. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
12. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
13. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

Reference Books (Latest Editions)

1. Elements of style – Strunk and white
2. Industrial Psychology and sociology for B. Pharmacy students. The author is Prof. B.V. Pathak.
3. Schermerhorn, Hunt, and Osborn, Organizational Behavior, Seventh Edition, Wiley, 2010
4. Stephen.P. Robbins, OrganizationBehavior, Prentive-Hall, India



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	0	0	3

(23BP106RBT) REMEDIAL BIOLOGY

30 Hours

Scope: To learn and understand the components of the living world, structure and functional system of plants and animal kingdom.

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

- Know the classification and salient features of five kingdoms of life.
- Understand the basic components of anatomy & physiology of plants.
- Know the basic components of anatomy & physiology animal with special reference to human

UNIT I

Living world:

Definition and characters of living organisms

Diversity in the living world

Binomial nomenclature

Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.

General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

UNIT II

Body fluids and circulation

Composition of blood, blood groups, coagulation of blood

Composition and functions of lymph

Human circulatory system

Structure of human heart and blood vessels

Cardiac cycle, cardiac output and ECG

Digestion and Absorption

Human alimentary canal and digestive enzymes

Role of digestive enzymes

Digestion, absorption and assimilation of digested food

Breathing and respiration

Human respiratory system

Mechanism of breathing and its regulation

Exchange of gases, transport of gases and regulation of respiration

Respiratory volumes

UNIT III

Excretory products and their elimination

Modes of excretion

Human excretory system- structure and function

Urine formation

Renin-angiotensin system

Neural control and coordination

Definition and classification of nervous system



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Structure of a neuron

Generation and conduction of nerve impulse

Structure of brain and spinal cord

Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

Endocrine glands and their secretions.

Functions of hormones secreted by endocrine glands.

Human reproduction

Parts of female reproductive system

Parts of male reproductive system

Spermatogenesis and Oogenesis

Menstrual cycle

UNIT IV

Plants and mineral nutrition:

Essential mineral, macro and micronutrients

Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

Cell- The unit of life

Structure and functions of cell and cell organelles. Cell division

Tissues

Definition, types of tissues, location and functions.

Textbooks

1. Textbook of Biology by S.B. Gokhale
2. A Textbook of Biology by Dr. Thulajappa and, Dr. Seetaram.

Reference Books

1. A Textbook of Biology by B.V. Sreenivasanaidu
2. A Textbook of Biology by Naidu and Murthy
3. Botany for Degree students By A.C. Dutta.
4. Outlines of Zoology by M. Ekambaranathan and T.N. Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C.K. Kokate



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
3	0	0	3

(23BP106RMT) REMEDIAL MATHEMATICS

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplacetrans form.

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

- Know the theory and their application in Pharmacy.
- Solve the different types of problems by applying theory.
- Appreciate the important application of mathematics in Pharmacy.

UNIT I

Partial fractions

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction.

Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples.

Functions, Limits and Continuity:

Real Valued function, Classification of real valued functions, Introduction to Limit of a function, Definition of limit of a function ($\epsilon - \delta$ definition),

$$\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}, \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1,$$

$$x \rightarrow a \quad x - a \rightarrow 0 \quad \theta \rightarrow 0 \quad \theta$$

UNIT II

Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear equations using matrix method.

UNIT III

Calculus

Differentiation: Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula)–**Without Proof**, Derivative of x^n w.r.t x , where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles (**without Proof**), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point.

UNIT IV

Analytical Geometry



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Introduction: Signs of the Coordinates, Distance formula,

Straight Line: Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope– intercept form of a straight line.

UNIT V

Integration: Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

Differential Equations: Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S. Grewal
5. Intermediate mathematics books from Telugu Academy
6. An introduction to Differential Equation by R.K. Gosh & K.C. Maity

Reference Books

1. Bali NP, Gupta PN, Gandhi CP, A Textbook of Pharmaceutical Mathematics (Remedial Mathematics Vol.I and Vol. II).
2. Jain RK, Iyengar SRK, Advanced Engineering Mathematics, 3rd Edition, Naros, 2007
3. Wartikar PN, Wartikar JN, Elements of Applied Mathematics, 6th Edition, Pune VidyarthiGruha, 1997



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP107P) HUMANAN ATOMY AND PHYSIOLOGY LAB)

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of whitebloodcell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocytesedimentation rate (ESR).
14. Determination of heartrate and pulserate.
15. Recording of blood pressure.

Recommended Textbooks:

1. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
2. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP108P) PHARMACEUTICAL ANALYSIS LAB

I Preparation and standardization of

- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Cericammonium sulphate

II Assay of the follow ingcompounds along with Standardization of Titrant

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

III Determination of Normality by electro-analytical methods

- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Textbook of Quantitative Inorganic analysis



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP109P) PHARMACEUTICS - I LAB

1. Syrups

- Syrup IP'66
- Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs

- Piperazine citrate elixir
- Paracetamol pediatric elixir

3. Linctus

- Terpin Hydrate Linctus IP'66
- Iodine Throat Paint (Mandles Paint)

4. Solutions

- Strong solution of ammonium acetate
- Cresol with soap solution
- Lugol's solution

5. Suspensions

- Calamine lotion
- Magnesium Hydroxide mixture
- Aluminium Hydroxide gel

6. Emulsions

- Turpentine Liniment
- Liquid paraffin emulsion

7. Powders and Granules

- ORS powder (WHO)
- Effervescent granules
- Dusting powder
- Divided powders

8. Suppositories

- Glycero gelatin suppository
- Cocoa butter suppository
- Zinc Oxide suppository

9. Semisolids

- Sulphur ointment
- Non-staining-Iodine Ointment with methyl salicylate
- Carbopal gel

10. Gargles and Mouthwashes

- Iodine gargle
- Chlorhexidine mouthwash



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Recommended Books: (Latest Editions)

1. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
2. Indian pharmacopoeia.
3. British pharmacopoeia.
4. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
5. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP110P) PHARMACEUTICAL INORGANIC CHEMISTRY LAB

1. Limit tests for following ions

- Limit test for Chlorides and Sulphates
- Modified limit test for Chlorides and Sulphates
- Limit test for Iron
- Limit test for Heavy metals Limit test for Lead
- Limit test for Arsenic

2. Identification test

Magnesium hydroxide, Ferrous sulphate, Sodium bicarbonate, Calcium gluconate, Copper sulphate

3. Test for purity

- Swelling power of Bentonite
- Neutralizing capacity of aluminum hydroxide gel
- Determination of potassium iodate and iodine in potassium Iodide
- Preparation of inorganic pharmaceuticals
- Boric acid Potash alum Ferrous sulphate

Recommended Books: (Latest Editions)

- A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4 th edition.
- A.I. Vogel, Textbook of Quantitative Inorganic analysis



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	2	1

(23BP111P) COMMUNICATION SKILLS LAB

The following learning modules are to be conducted using words worth English language lab software:

1. Basic communication covering the following topics.
2. Meeting People Asking Questions Making Friends What did you do? Do's and Dont's
3. Pronunciations covering the following topics Pronunciation (Consonant Sounds) Pronunciation and Nouns
4. Pronunciation (Vowel Sounds)
5. Advanced Learning
6. Listening Comprehension / Direct and Indirect Speech Figures of Speech
7. Effective Communication Writing Skills
8. Effective Writing Interview Handling Skills E-Mail Etiquette Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford,
2. 2 nd Edition, Pearson Education, 2011 2. Communication skills, Sanjay Kumar, Pushpalata, 1 stEdition, Oxford Press, 2011



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. I Semester

L	T	P	C
0	0	2	1

(23BP112RBP) REMEDIAL BIOLOGY LAB

30 Hours

1. Introduction to experiments in biology
 - a. Study of Microscope
 - b. Section cutting techniques.
 - c. Mounting and staining
 - d. Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Textbooks

1. Textbook of Biology by S. B. Gokhale b.
2. A Textbook of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. Practical human anatomy and physiology. by S.R. Kale and R.R. Kale.
2. A Manual of pharmaceutical biology practical by S.B. Gokhale, C.K. Kokate and S.P. Shriwastava.
3. Biology practical manual according to National core curriculum. Biology forum of Karnataka. Prof.M.J.H. Shafi



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
3	1	0	4

(23BP201T) HUMAN ANATOMY AND PHYSIOLOGY – II

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

- Explain the gross morphology, structure, and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of the human body.
- Perform hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
- Appreciate coordinated working pattern of different organs of each system.
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

UNIT I

Nervous system: Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, electro physiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.
Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

UNIT II

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

Energetics

Formation and role of ATP, Creatinine Phosphate and BMR.

UNIT III

Respiratory system

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration, Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

Urinary system

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

UNIT IV

Endocrine system

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

UNIT V

Reproductive system

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

Introduction to genetics

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
4. Textbook of Medical Physiology- Arthur C. Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers' medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers' medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Textbook of Medical Physiology- Arthur C. Guyton and John E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee, Academic Publishers Kolkata



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
3	1	0	4

(23BP202T) PHARMACEUTICAL ORGANIC CHEMISTRY-I

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes mechanisms and orientation of reactions.

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

- Write the structure, name and the type of isomerism of the organic compound.
- Write the reaction, name the reaction and orientation of reactions.
- Account for reactivity/stability of compounds,
- Identify/confirm the identification of organic compounds.

Course Content: General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds (upto 10 Carbons open chain and Cyclic compounds)

Alkanes*, Alkenes*, Alkynes and Conjugated dienes*

SP³ hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP² hybridization in alkenes

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene. Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT II

E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidence. E1 versus E2 reactions, Factors affecting E1 and E2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Alkyl halides*

SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions.

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetra chloromethane and iodoform.

Conjugated system: Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT III

Alcohols*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Carbonyl compounds* (Aldehydes and ketones)

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT IV

Carboxylic acids*

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

Aromatic Acids* –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

Phenols* - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols

Aliphatic amines* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

Aromatic Amines* - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts

UNIT V

10 Hours

Stereo isomerism

Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules, DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules, Racemic modification and resolution of racemic mixture. **Asymmetric synthesis:** partial and absolute

Geometrical isomerism

Nomenclature of geometrical isomers (Cis / Trans, E/Z, Syn /Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar, Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L. Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's textbook of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K. Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwalia/Chatwal.

Reference Books:

1. J. McMurry, Brooks/Cole, Organic Chemistry, 6th Ed. 2004
2. T.W.G. Solomons, C.B. Fryhle, Organic Chemistry, John Wiley and Sons Inc., 10th Ed. 2009
3. L.G. Wade Jr, Organic Chemistry, Pearson Education India, 2008
4. E.L. Eliel, Stereochemistry of Carbon compounds, McGraw-Hill, 1962



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B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
3	1	0	4

(23BP203T) BIOCHEMISTRY

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives:**Upon completion of course student shall able to**

- Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
- Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

UNIT I**Biomolecules**

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

Bioenergetics

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II**Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers level

UNIT III**Lipid metabolism**

β -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Amino acid metabolism

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV

Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

Structure of DNA and RNA and their functions DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitor

UNIT V

Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: Enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murray, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U. Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

Reference Books:

1. Lehninger AL, Nelson DL and Cox MM, Principles of Biochemistry, 5th Edition, MacMillan, 2008
2. Berg, Jeremy M., John L. Tymoczko, Lubert Stryer, and L. Stryer. Biochemistry. 5th edit. 2002.
3. Murray, R. K., D. K. Granner, P. A. Mayes, and V. Rodwell. W. Harper's Illustrated Biochemistry 26th Edition ed. 2003.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP204T) COMPUTER APPLICATIONS IN PHARMACY

45 Hours

Scope: This subject deals with the introduction of Database, Database Management system, computer application in clinical studies and use of databases.

Objectives:

Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy.
- Know the various types of databases.
- Know the various applications of databases in pharmacy.

UNIT I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division.

UNIT II

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT III

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT V

Computers as data analysis in Preclinical development: Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS)

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E. Fassett – Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development – Sean Ekins –
3. Wiley-Interscience, A John Wiley and Sons, INC., Publication, USA
4. Bioinformatics (Concept, Skills and Applications) – S.C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

5. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N. Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

Reference Books:

1. Bryon S. Gottfried: McGraw Hill Book Co. (Schaum's Series) Programming with C.
2. E. Balagumswamy: Tata McGraw Hill Publishing Co., Programming in C.
3. John Sheeley and Roger Hunt: Computer Studies, First Course, Delhi: A.K. Wheeler & Co 1986.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
2	0	0	2

(23BP205T) ENVIRONMENTAL SCIENCECS

30 Hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

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

- Create awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learners to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

UNIT I

Introduction to Environmental Studies and Natural Resources:

The multidisciplinary nature of environmental studies

Role of an individual in the conservation of natural resources

UNIT II

Natural Resources and Associated Problems:

- a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

UNIT III

Ecosystems and Their Types:

- Concept of an ecosystem
- Structure and function of an ecosystem
- Overview of ecosystem types
- Characteristics of different ecosystems

UNIT IV

Detailed Study of Ecosystems:

- Forest ecosystem and its components
- Grassland ecosystem and its features
- Desert ecosystem and challenges faced.
- Aquatic ecosystems: ponds, streams, lakes, rivers, oceans, estuaries

UNIT V

Environmental Pollution: Air pollution; Water pollution; Soil pollution



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T. H. Gorhani, E & Hepworth, M.T.2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP206T) SOCIAL AND PREVENTIVE PHARMACY

45 Hours

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programs. The roles of the pharmacist in these contexts are also discussed.

Objectives: After the successful completion of this course, the student shall be able to

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to healing it and pharmaceutical issues.

UNIT I

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Sociocultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health.

Hygiene and health: personal hygiene and health care; avoidable habits

UNIT II

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

UNIT III

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control program, TB, Integrated disease surveillance program (IDSP), National leprosy control program, National mental health program, National program for prevention and control of deafness, Universal immunization program, National program for control of blindness, Pulse polio program.

UNIT IV

National health intervention program for mother and child, National family welfare program, National tobacco control program, National Malaria Prevention Program, National program for the health care for the elderly, social health program; role of WHO in Indian national program

UNIT V

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

1. Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
0	0	3	1.5

(23BP201P) HUMAN ANATOMY AND PHYSIOLOGY – II LAB

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyzer
16. Permanent slides of vital organs and gonads.

Recommended Books: (Latest Edition)

1. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
2. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
0	0	3	1.5

(23BP202P) PHARMACEUTICAL ORGANIC CHEMISTRY – I LAB

1. Systematic qualitative analysis of unknown organic compounds like
 - a. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
 - b. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
 - c. Solubility test
 - d. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
 - e. Melting point/Boiling point of organic compounds
 - f. Identification of the unknown compound from the literature using melting point/ boiling point.
 - g. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
 - h. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books: (Latest Edition)

1. Practical Organic Chemistry by Mann and Saunders.
2. Vogel's textbook of Practical Organic Chemistry
3. Advanced Practical organic chemistry by N.K. Vishnoi.
4. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
0	0	3	1.5

(23BP203P) BIOCHEMISTRY LAB

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
2. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
3. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
4. Practical Biochemistry by Harold Varley.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B.Pharm. – I YEAR COURSE STRUCTURE & SYLLABUS

I Year B.Pharm. II Semester

L	T	P	C
0	0	3	1.5

(23BP204P) COMPUTER APPLICATIONS IN PHARMACY LAB

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create an HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard, generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access.
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended Books (Latest Editions)

1. Computer Application in Pharmacy – William E. Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B. PHARMACY II YEAR COURSE STRUCTURE AND SYLLABUS

II B. Pharm. I Semester

S.No.	Course Code	CourseName	Hours per week			Credits
			L	T	P	
1.	23BP301T	Pharmaceutical Organic Chemistry II– Theory	3	1	-	4
2.	23BP302T	Physical Pharmaceutics I–Theory	3	1	-	4
3.	23BP303T	Pharmaceutical Microbiology–Theory	3	1	-	4
4.	23BP304T	Pharmaceutical Engineering–Theory	3	-	-	3
5.	23BP305T	Pathophysiology –Theory	3	-	-	3
6.	23BP301P	Pharmaceutical Organic Chemistry II –Practical	-	-	3	1.5
7.	23BP302P	Physical Pharmaceutics I–Practical	-	-	3	1.5
8.	23BP303P	Pharmaceutical Microbiology–Practical	-	-	3	1.5
9.	23BP304P	Pharmaceutical Engineering–Practical	-	-	3	1.5
10.	23BP305	Skill Oriented course - 1 Preparation of cosmetics (any five)	1	-	2	2
11.	23BP306	Non-Credit Mandatory Course Universal Human values and Professional ethics	3	-	-	-
		Total	19	3	14	26

II B. Pharm. II Semester

S.No.	Course Code	Course Name	Hours per week			Credits
			L	T	P	
1.	23BP401T	Medicinal Chemistry I–Theory	3	1	-	4
2.	23BP402T	Physical Pharmaceutics II–Theory	3	1	-	4
3.	23BP403T	Pharmacology I–Theory	3	1	-	4
4.	23BP404T	Pharmacognosy and Phytochemistry I–Theory	3	-	-	3
5.	23BP405T	Pharmaceutical Jurisprudence–Theory	3	-	-	3
6.	23BP401P	Medicinal Chemistry I–Practical	-	-	3	1.5
7.	23BP402P	Physical Pharmaceutics II–Practical	-	-	3	1.5
8.	23BP403P	Pharmacology I–Practical	-	-	3	1.5
9.	23BP404P	Pharmacognosy and Phytochemistry I–Practical	-	-	3	1.5
10.	23BP405	Skill Oriented course-II Synthesis of API drugs (minimum five)	1	-	2	2
		Total	16	3	14	26

Mandatory community service internship for 6 to 8 week duration during summer vacation

* For exit Diploma in pharmacy certificate candidate has to secure additional four credits from the following courses:

1. Pharmacotherapeutics 2 credits
2. Hospital and clinical Pharmacy 2 credits

OR

Any course offered by MOOCs / NPTEL/ Swayam/ college/ Govt. agencies equivalent to the above four credits, approved by JNTUA

3. Hospital Training not less than 500 Hrs mandatory

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B. PHARMACY II YEAR COURSE STRUCTURE AND SYLLABUS

II Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP301T) PHARMACEUTICAL ORGANIC CHEMISTRY – II (Theory)

45Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

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

1. Write the structure, name and the type of isomerism of the organic compound
2. Write the reaction, name the reaction and orientation of reactions
3. Account for reactivity/stability of compounds,
4. Prepare organic compounds

Course Content: General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained, to emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

10 Hours

Benzene and its derivatives

- A. Synthetic and other evidence in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel-Crafts alkylation- reactivity, limitations, Friedel-Crafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

10 Hour

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

Reactions and synthetic importance:

Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement, Claisen-Schmidt condensation

UNIT III

08 Hours

Polynuclear hydrocarbons:

- A. Synthesis, reactions
- B. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT IV

07 Hours

Cyclo alkanes*

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS

UNIT-V

07 Hours

Fats and Oils

- A. Fatty acids – reactions.
- B. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- C. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

Recommended Books (Latest Editions)

- 1. Organic Chemistry by Morrison and Boyd
- 2. Organic Chemistry by I.L. Finar, Volume-I
- 3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
- 4. Organic Chemistry by P.L.Soni
- 5. Practical Organic Chemistry by Mann and Saunders.
- 6. Vogel's text book of Practical Organic Chemistry
- 7. Advanced Practical organic chemistry by N.K.Vishnoi.
- 8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
- 9. Heterocyclic Chemistry by T.L. Gilchrist
- 10. Heterocyclic Chemistry by Raj K. Bansal

Reference Books:

- 1. Louden M., Organic Chemistry, 5 th edition, Roberts and Company Publishers, 2009.
- 2. Carey F., Organic Chemistry, 9 th edition, McGraw-Hill Education, 2013.
- 3. Corey E.J., Logic of Chemical Synthesis, Wiley-Blackwell; Revised ed., 1995.

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS****II Year B.Pharm. I Semester**

L	T	P	C
3	1	0	4

(23BP302T) PHYSICAL PHARMACEUTICS – I (Theory)**45Hours**

Scope: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives:

Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:**UNIT-I****10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II**10Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols
– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid- crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III**08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions, surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilization, detergency, adsorption at solid interface.

UNIT-IV**08Hours**

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V**07 Hours**

P^H, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2,3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

Reference Books:

1. A.T. Florence and D. Attwood W: Physiochemical principles of Pharmacy.
2. Shotton and Ridgeway: Physical Pharmaceutics.
3. Remingtons Pharmaceutical Sciences, Mark Publishing Co.
4. H.S. Beans, A.H. Beckett and J.E. Carless: Advances in Pharmaceutical Sciences, Vol. 1 to 4.
5. S.P.Agarwal, Rajesh Khanna: Physical Pharmacy, CBS Publishers, New Delhi.

JAWAHRALAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS****II Year B.Pharm. I Semester**

L	T	P	C
3	1	0	4

(23BP303T) PHARMACEUTICAL MICROBIOLOGY – (Theory)**45Hours**

Scope: Study of all categories of microorganism's especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.

Objectives:

Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:**Unit I****10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit II**10 Hours**

Identification of bacteria using staining techniques (simple, Gram's & Acid-fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipment's employed in large scale sterilization. Sterility indicators.

Unit III**10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV**08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

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B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

Unit V

07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

Reference Books:

1. McNeil, Brian, and Linda M. Harvey. Practical fermentation technology. Chichester: Wiley, 2008.
2. Pharmacopoeias: IP,BP,USP,EP

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L	T	P	C
3	0	0	3

(23BP304T) PHARMACEUTICAL ENGINEERING – (Theory)**45Hours**

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

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

1. To know various unit operations used in pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in pharmaceutical industries.

Course content:**UNIT-I****10 Hours**

Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.

Size Reduction: Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II**10 Hours**

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III**08 Hours**

Drying: Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silvers on Emulsifier,

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Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seitz filter.

Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V**07 Hours**

Materials of pharmaceutical plant construction, Corrosion and its prevention: Factors affecting during materials selected for pharmaceutical plant construction, Theories of corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic nonmetals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

Reference Books:

1. J.F. Richardson and J.M. Coulron: Chemical Engineering
2. Perry: Handbook of Chemical Engineering
3. Lauer & Heckmann: Chemical Engineering Techniques
4. Peters: Elementary Chemical Engineering

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L	T	P	C
3	0	0	3

(23BP305T) PATHOPHYSIOLOGY – (Theory)**45Hours**

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:**Unit I****10Hours****Basic principles of Cell injury and Adaptation:**

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

Basic mechanism involved in the process of inflammation and repair:

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit II**10Hours****Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

Respiratory system: Asthma, Chronic obstructive airways diseases.

Renal system: Acute and chronic renal failure

Unit III**10Hours**

Hematological Diseases: Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia

Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones

Nervous system: Epilepsy, Parkinson's disease, stroke,

Psychiatric disorders: Depression, Schizophrenia and Alzheimer's disease.

Gastrointestinal system: Peptic Ulcer

Unit IV**8 Hours**

Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout

Principles of cancer: classification, etiology and pathogenesis of cancer

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Unit V

7 Hours

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

Reference Books:

1. Kulkarni, Shrinivas Krishnarao. Hand book of experimental pharmacology. 3rd edition, Vallabh prakashan, 1999.
2. R.K.Goyal, Practicals in Pharmacology, 6th, edition, B.S.ShahPrakashan, Ahmedabad, 2006-2007
3. U.K.Seth, N.K.Dadkar, Usha G.Kamat, Selected Topics in Experimental Pharmacology, 1st edition, Kothari Book Depot Mumbai, 1972
4. Ghosh M.N, Fundamentals of Experimental Pharmacology, 3rd edition, Hilton and Co, Kolkata, 2005

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L	T	P	C
0	0	3	1.5

(23BP301P) PHARMACEUTICAL ORGANIC CHEISTRY – II (Practical)
3 Hours/week

I Experiments involving laboratory techniques

1. Recrystallization
2. Steam distillation

II Determination of following oil values (including standardization of reagents)

1. Acid value
2. Saponification value
3. Iodine value

III Preparation of compounds

1. Benzanilide/ Phenylbenzoate/ Acetanilide from Aniline/Phenol
2. /Aniline by acylation reaction.
3. 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
4. Acetanilide by halogenation (Bromination) reaction.
5. 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
6. Benzoic acid from Benzyl chloride by oxidation reaction.
7. Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
8. 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
9. Benzil from Benzoin by oxidation reaction.
10. Dibenzyl acetone from Benzaldehyde by Claisen Schmidt reaction
11. Cinnamic acid from Benzaldehyde by Perkin reaction
12. P-Iodo benzoic acid from P-amino benzoic acid

Reference books

1. Practical Organic Chemistry by Mann and Saunders.
2. Vogel's text book of Practical Organic Chemistry
3. Advanced Practical organic chemistry by N.K. Vishnoi.

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L	T	P	C
0	0	3	1.5

(23BP302P) PHYSICAL PHARMACEUTICS – I (Practical)**3 Hours/week**

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl₄ and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Reference Books

1. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
2. Experimental Pharmaceutics by Eugene, Parott.

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L	T	P	C
0	0	3	1.5

(23BP303P) PHARMACEUTICAL MICROBIOLOGY – (Practical)**3 Hours/week**

1. Introduction and study of different equipment's and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Gram's staining and acid-fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Reference Books

1. McNeil, Brian, and Linda M. Harvey. Practical fermentation technology. Chichester: Wiley, 2008.
2. Pharmacopoeias: IP, BP, USP, EP

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L	T	P	C
0	0	3	1.5

(23BP304P) PHARMACEUTICAL ENGINEERING – (Practical)**3 Hours/week**

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
12. To study the effect of time on the Rate of Crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

Reference Books

1. Remington practice of pharmacy- Martin, Latest edition.
2. Theory and practice of industrial pharmacy by Lachmann., Latest edition.

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L	T	P	C
1	0	2	2

(23BP305) PREPARATION OF COSMETICS (ANY FIVE)

Scope: This subject is designed to impart fundamental knowledge on the preparation of cosmetics. The subject enhance the skills in preparation of cosmetic formulation. The subject also emphasizes regulatory guidelnes on cosmetics.

Upon successful completion of this course, the student should be able to:

CO 1: Understand and Apply of Cosmetic Science Principles

CO 2: Develop skill in Cosmetic Formulation Techniques

CO 3: Adhere to Safety, Regulatory Compliance, and Ethical Considerations in cosmetics.

PREPARATION OF COSMETICS (ANY FIVE)

1. Preparation of Cold Cream
2. Preparation of Calamine lotion
3. Preparation of Tooth powder
4. Preparation of lipsticks
5. Preparation of shampoo
6. Preparation of Sun screen cream
7. Preparation Prefumed Talcum Powder
8. Preparation of Face wash
9. Preparation of Herbal hair oil
10. Preparation of Anti-aging Cream

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L	T	P	C
3	0	0	0

(23BP306) UNIVERSAL HUMAN VALUES AND PROFESSIONAL ETHICS
(Non-Credit Mandatory Course)

Scope: This subject is designed to impart a Holistic perspective among students towards life and profession as well as towards happiness and prosperity based on a correct understanding of the Human reality and the rest of Existence. Such a holistic perspective forms the basis of Universal Human Values and movement towards value-based living in a natural way.

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

1. To develop understanding of the concepts of Universal Human Values
2. To recognize the relevance of Universal Human Values
3. To develop understanding of value systems that are shared by our culture
4. To critically analyze current issues related to values
5. To develop a sense of personal self in harmony with society and nature through integration of Universal Human Values
6. To explore ways to integrate human values in personal and professional life

Course Content:

This course is intended to provide a much needed orientational input in value education to the young enquiring minds.

UNIT-I: Course Introduction - Need, Basic Guidelines, Content and Process for Value Education (9 Hours)

Understanding the Need, Basic Guidelines, Content and Process for Value Education, Self-Exploration-What is it? - its Content and Process; 'Natural Acceptance' and Experiential Validation-as the Mechanism for Self-Exploration, Continuous Happiness and Prosperity- A Look at Basic Human Aspirations, Right Understanding, Relationship and Physical Facilities- the Basic Requirements for Fulfillment of Aspirations of Every Human being with their Correct Priority, Understanding Happiness and Prosperity Correctly- A Critical Appraisal of the Current Scenario, Method to Fulfill the Above Human Aspirations: Understanding and Living in Harmony at Various Levels.

UNIT-II: Understanding Harmony in the Human Being - Harmony in Myself (9 Hours)

Understanding human being as a co-existence of the sentient 'I' and the material 'Body', Understanding the needs of Self ('I') and 'Body' - Sukh and Suvidha, Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer), Understanding the characteristics and activities of 'I' and harmony in 'I', Understanding the harmony of I with the Body: Sanyam and Swasthya; correct appraisal of Physical needs, meaning of Prosperity in detail, Programs to ensure Sanyam and Swasthya

UNIT-III: Understanding Harmony in the Family and Society- Harmony in Human-Human Relationship (9 Hours)

Understanding Harmony in the Family- the Basic Unit of Human Interaction, Understanding Values in Human-Human Relationship; Meaning of Nyaya and Program for its Fulfillment to Ensure Ubhayatripti; Trust (Vishwas) and Respect (Samman) as the Foundational Values of Relationship, Understanding the Meaning of Vishwas; Difference between Intention and Competence, Understanding the Meaning of Samman, Difference between Respect and Differentiation; the Other

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B. PHARMACY II YEAR COURSE STRUTURE AND SYLLABUS

Salient Values in Relationship, Understanding the Harmony in the Society (Society Being an Extension of Family): Samadhan, Samridhi, Abhay, Sah-Astitva as Comprehensive Human Goals, Visualizing a Universal Harmonious Order in Society- Undivided Society (AkhandSamaj), Universal Order (SarvabhaumVyawastha)- from Family to World Family!

UNIT-IV: Understanding Harmony in the Nature and Existence - Whole Existence as Coexistence (9 Hours)

Understanding the Harmony in the Nature, Interconnectedness and Mutual Fulfilment Among the Four Orders of Nature- Recyclability and Self-Regulation in Nature, Understanding Existence as Coexistence (Sah-Astitva) of Mutually Interacting Units in All-Pervasive Space, Holistic Perception of Harmony at All Levels of Existence.

UNIT-V: Implications of the above Holistic Understanding of Harmony on Professional Ethics (9 Hours)

Natural Acceptance of Human Values, Definitiveness of Ethical Human Conduct, Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order, Competence in Professional Ethics: a) Ability to Utilize the Professional Competence for Augmenting Universal Human Order, b) Ability to Identify the Scope and Characteristics of People-Friendly and Eco-Friendly Production Systems, Technologies and Management Models, Case Studies of Typical Holistic Technologies, Management Models and Production Systems, Strategy for Transition from the Present State to Universal Human Order: a) At the level of Individual: as Socially and Ecologically Responsible Engineers, Technologists and Managers, b) At the Level of Society: as Mutually Enriching Institutions and Organisations.

Recommended Books (Latest Editions)

1. Dr R. R. Gaur, Sh. Rajul Asthana, Sh G.P. Bagaria, A textbook of Human Values and Professional Ethics, Excel books, New Delhi.
2. R.R Gaur, R Sangal, G P Bagaria, A foundation course in Human Values and professional Ethics, Excelbooks, New Delhi, 2010, ISBN 978-8-174-46781-2.
3. R.R Gaur, R Sangal, G P Bagaria, A foundation course in Human Values and professional Ethics – Teachers Manual, Excel books, New Delhi, 2010.
4. B L Bajpai, 2004, Indian Ethos and Modern Management, New Royal Book Co., Lucknow. Reprinted 2008.
5. PL Dhar, RR Gaur, 1990, Science and Humanism, Commonwealth Purblishers.

Reference Books:

1. Sussan George, 1976, How the Other Half Dies, Penguin Press. Reprinted 1986, 1991.
2. Ivan Illich, 1974, Energy & Equity, The Trinity Press, Worcester, and HarperCollins, USA.
3. Donella H. Meadows, Dennis L. Meadows, Jorgen Randers, William W. Behrens III, 1972, limits to Growth, Club of Rome's Report, Universe Books.
4. Subhas Palekar, 2000, How to practice Natural Farming, Pracheen (Vaidik) Krishi Tantra Shodh, Amravati.

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L	T	P	C
3	1	0	4

(23BP401T) MEDICINAL CHEMISTRY – I (Theory)**60 Hours**

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

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

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship (SAR) of different class of drugs
4. Write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I**10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II**10 Hours**

Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

Indirectactingagents: Hydroxy amphetamine,Pseudoephedrine, Propylhexedrine.

Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III**10 Hours**

Cholinergic neurotransmitters.

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

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Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echthiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV**10 Hours****Drugs acting on Central Nervous System****A.Sedatives and Hypnotics:**

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

Miscellaneous:

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B.Antipsychotics

Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluorobutyrophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C.Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbital, Methobarbital.

Hydantoins: Phenytoin*, Mephenytoin,

Ethoin Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine* Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V**10 Hours****Drugs acting on Central Nervous System****General anesthetics**

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbiturates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride*.

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

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Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

Reference Books:

1. R.T. Morrison and R.N. Boyd: Organic Chemistry, Allyn and Bacon Inc., Boston (USA).
2. I.L. Finar: Organic Chemistry, Vol. I & II, ELBS and Longman Group Ltd., London.
3. L.M. Atherden: Bentley and Driver's-Textbookof Pharmaceutical Chemistry, Oxford University Press, Delhi

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L	T	P	C
3	1	0	4

(23BP402T) PHYSICAL PHARMACEUTICS – II (Theory)

60 Hours

Scope: The course deals with the various physical and physicochemical properties, and principals involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I

10 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

UNIT-II

10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers
Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III

10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT-IV

10Hours

Micromeritics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V

10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common

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reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

Reference Books:

1. A.T. Florence and D. Attwood W: Physiochemical principles of Pharmacy.
2. Shotton and Ridgeway: Physical Pharmaceutics.
3. Remingtons Pharmaceutical Sciences, Mark Publishing Co.
4. H.S. Beans, A.H. Beckett and J.E. Carless: Advances in Pharmaceutical Sciences, Vol. 1 to 4.
5. S.P.Agarwal, Rajesh Khanna: Physical Pharmacy, CBS Publishers, New Delhi.

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L	T	P	C
3	1	0	4

(23BP403T) PHARMACOLOGY – I (Theory)**60 Hours**

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:**UNIT-I****08 hours****1.General Pharmacology**

a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non-competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II**12 Hours**

c. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein-coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

d. Adverse drug reactions.

e. Drug interactions (pharmacokinetic and pharmacodynamic)

f. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III**10 Hours****2. Pharmacology of drugs acting on peripheral nervous system**

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Para sympathomimetics, Parasympatholytic, Sympathomimetics, sympatholytic.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

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UNIT-IV

10 Hours

3. Pharmacology of drugs acting on central nervous system

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

UNIT-V

10 Hours

3. Pharmacology of drugs acting on central nervous system

- f. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- g. Drugs used in Parkinsons disease and Alzheimer's disease.
- h. CNS stimulants and nootropics.
- i. Opioid analgesics and antagonists
- j. Drug addiction, drug abuse, tolerance and dependence.

Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
- 2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
- 5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
- 6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
- 9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

Reference Books:

- 1. Lippincott's Illustrated Reviews, Pharmacology 6th edition, Wolters Kluwer, 2015
- 2. R.S. Satoskar, S.D. Bhandarkar, Pharmacology and Pharmacotherapeutics 24th Edition, 2015
- 3. F.S.K. Barar, Essentials of Pharmacotherapeutics 1st edition, S. Chand and Company Ltd, 2004

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L	T	P	C
3	0	0	3

(23BP404T) PHARMACOGNOSY AND PHYTOCHEMISTRY – I (Theory)**45Hours**

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. To know the techniques in the cultivation and production of crude drugs
2. To know the crude drugs, their uses and chemical nature
3. Know the evaluation techniques for the herbal drugs
4. To carry out the microscopic and morphological evaluation of crude drugs

Course Content:**UNIT-I****10 Hours****Introduction to Pharmacognosy:**

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II**10 Hours****Cultivation, Collection, Processing and storage of drugs of natural origin:**

Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants**UNIT-III****07 Hours****Plant tissue culture:**

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV**10 Hours****Pharmacognosy in various systems of medicine:**

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids,

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Tannins, Volatile oil and Resins

UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes: Gelatin, casein, proteolytic enzymes (Papain, bromelain, serrati peptidase, urokinase, streptokinase, pepsin).

Lipids (Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

Recommended Books: (Latest Editions)

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

Reference Books:

1. Dewick, Paul M. Medicinal natural products: a biosynthetic approach. 2nd edition, John Wiley & Sons, 2002
2. Bruneton J, Pharmacognosy & Phytochemistry Medicinal Plants, 2nd edition, Lavoisier Publishing Inc. 1999
3. Harborne J.B. Phytochemical Methods- A Guide to modern techniques of Plant analysis, 3rd edition, Springer, 1998
4. Ikan R., Natural Products- A Laboratory Guide, 2nd edition, Academic Press, 1994

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L	T	P	C
3	0	0	3

(23BP405T) PHARMACEUTICAL JURISPRUDENCE – I (Theory)**45Hours**

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:**UNIT-I****8 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II**10 Hours****Drugs and Cosmetics Act, 1940 and its rules 1945**

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III**10 Hours**

•**Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties

•**Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

•**Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV**09 Hours**

•**Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

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•**Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

•**National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V

08 Hours

•**Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

•**Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

•Medical Termination of Pregnancy Act

•Right to Information Act

•Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government.

Reference Books:

1. N. K. Jain: Pharmaceutical Jurisprudence
2. S. P. Aggarwal and R. Khanna: Pharmaceutical Jurisprudence, Tata Publishers.

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L	T	P	C
0	0	3	1.5

(23BP401P) MEDICINAL CHEISTRY – I (Practical)**3 Hours/week****I. Preparation of drugs/ intermediates**

1. 1,3-pyrazole
2. 1,3-oxazole
3. Benzimidazole
4. Benztriazole
5. 2,3- diphenyl quinoxaline
6. Benzocaine
7. Phenytoin
8. Phenothiazine
9. Barbiturate

II. Assay of drugs

1. Chlorpromazine
2. Phenobarbitone
3. Atropine
4. Ibuprofen
5. Aspirin
6. Furosemide

III. Determination of Partition coefficient for any two drugs**Recommended Books (Latest Editions)**

1. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
2. Indian Pharmacopoeia.
3. Text book of practical organic chemistry- A.I.Vogel

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L	T	P	C
0	0	3	1.5

(23BP402P) PHYSICAL PHARMACEUTICS – II (Practical)**3 Hours/week**

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books (Latest Editions)

1. Experimental pharmaceutics by Eugene, Parott.
2. Physical Pharmacy by Alfred Martin, Sixth edition

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L	T	P	C
0	0	3	1.5

(23BP403P) PHARMACOLOGY – I (Practical)**3 Hours/week**

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog esophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by software's and videos

Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan

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L	T	P	C
0	0	3	1.5

(23BP404P) PHARMACOGNOSY AND PHYTOCHEMISTRY – I (Practical)
3 Hours/week

1. Analysis of crude drugs by chemical tests:
 - i. Tragacanth
 - ii. Acacia
 - iii. Agar
 - iv. Gelatin
 - v. starch
 - vi. Honey
 - vii. Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books (Latest Editions)

1. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
2. Anatomy of Crude Drugs by M.A. Iyengar.

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L	T	P	C
1	0	2	2

(23BP405) SYNTHESIS OF API DRUGS (MINIMUM FIVE)
(Skill Oriented Course – II)

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under different classes. This skill will enhance the ability of student to synthesis new chemical entities.

Course outcomes: Upon successful completion of this course the student should be able to:

1. Understand fundamental principles of synthetic organic chemistry for synthesizing APIs, including reaction mechanisms and stereochemistry
2. Analyse and predict the outcomes of key synthetic reactions commonly used in API synthesis, such as acetylation, alkylation, esterification, and amination.
3. Understand the influence of molecular structure on chemical reactivity in API synthesis

SYNTHESIS OF API DRUGS (MINIMUM FIVE)

1. Synthesis of Non-Steroidal Anti-Inflammatory Drugs
2. Synthesis of Anti-convulsant drugs
3. Synthesis of Sedatives and Hypnotics
4. Synthesis of Antipyrene
5. Synthesis of Chlorobutanol
6. Synthesis of 7 hydroxy 4 methyl coumarin
7. Synthesis of Sulphonamides
8. Synthesis of Amines
9. Synthesis of Anti-bacterial
10. Synthesis of Anti-psychotic

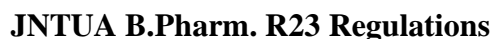


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B. PHARMACY III YEAR COURSE STRUCTURE AND SYLLABUS

Semester V (III-I)

S.No	Course Code	Name of the Course	Hours per week			Credits
			L	T	P	
1	23BP501T	Medicinal Chemistry II–Theory	3	1	-	4
2	23BP502T	Industrial Pharmacy I–Theory	3	-	-	3
3	23BP503T	Pharmacology II–Theory	3	1	-	4
4	23BP504T	Pharmacognosy & Phy to Chemistry II–Theory	3	1	-	4
5	23BP505T	Pharmaceutical Biotechnology -Theory	3	1	-	4
6	23BP506a	Open Elective – I 1. Pharmacovigilance–Theory	3	-	-	3
	23BP506b	2 Generic Product Development				
	23BP506c	3.Dietary Supplements and Nutraceuticals.				
	23BP506d	4.Artificial Intelligence in Pharmaceutical Industry				
7	23BP502P	Industrial Pharmacy I–Practical	-	-	3	1.5
8	23BP503P	Pharmacology II–Practical	-	-	3	1.5
9	23BP504P	Pharmacognosy & Phyto Chemistry II –Practical	-	-	3	1.5
10	23BP507	Skill Oriented Course – III Life skills (JEEVAN KAUSHAL) /Soft skills and employability	1	0	2	2
11	23BP508	Non credit mandatory course Health , wellness and Stress Management by yoga, Dhyana and sports	3	-	-	-
12	23BP509	Evaluation of Community Service Summer Internship	-	-	-	1.5
Total:			22	4	11	30



B. PHARMACY III YEAR COURSE STRUTURE AND SYLLABUS

S.No	Course Code	Name of the Course	Hours Per Week			Credits
			L	T	P	
1	23BP601T	Medicinal Chemistry III–Theory	3	1	-	4
2	23BP602T	Pharmacology III–Theory	3	1	-	4
3	23BP603T	Herbal Drug Technology –Theory	3	-	-	4
4	23BP604T	Biopharmaceutics and Pharmacokinetics–Theory	3	1	-	4
5	23BP605T	<i>Biostatistics and Research Methodology–Theory (Proposed) (R19-IV-II)</i>	3	1	0	4
6	23BP606a	Professional Elective – I	3	0	0	3
	23BP606b	1. Computer Aided Drug Design –Theory				
	23BP606c	2. Pharmacognosy & Metabolic Engineering				
	23BP606d	3. Pharmaceutical Regulatory Science–Theory 4. Drug Delivery: Principles and Engineering				
7	23BP601P	Medicinal chemistry III –Practical	-	-	3	1.5
8	23BP602P	Pharmacology III–Practical	-	-	3	1.5
9	23BP603P	Herbal Drug Technology –Practical	-	-	3	1.5
10	23BP607	Skill Oriented Course – IV Biopharmaceutics and Pharmacokinetics	0	0	3	1.5
11	23BP608	Non credit mandatory course Constitution of India	3	-	-	0
Total			21	4	12	29
Mandatory Industry Internship for a minimum of 6 weeks duration during summer vacation						



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III Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP501T) MEDICINAL CHEMISTRY II–THEORY

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Course objectives: Upon completion of the course, the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Identify the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Report the chemical synthesis of selected drugs

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT-I

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the human body

H₁–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Triptelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidaminetartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorothamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin



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Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT– II

10Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonicanhydraseinhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide.

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol.

Anti-hypertensive Agents:

Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT-III

10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents:

Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT-IV

08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sexhormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethylstilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.



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UNIT– V

07 Hours

Antidiabetic agents:

Insulin and its preparations

Sulfonylureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine,

Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipreron, Dibucaine.*

Recommended Book (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design-Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L.Finlar, Vol.II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol.1 to 5.
9. Indian Pharmacopoeia.
10. Textbook of practical organic chemistry-A.I.Vogel.



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III Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP502T) INDUSTRIAL PHARMACY I (THEORY)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

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

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

UNIT-I

07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization
BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

10 Hours

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia



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UNIT-III

08 Hours

Capsules:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and min/mg factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

10 Hours

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V

10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

Recommended Books :(Latest Editions)

1. Pharmaceutical dosage forms-Tablets, volume 1-3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition



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5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics-The science of dosage form design by M.E. Aulton, Churchill Livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H.C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability-Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.



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III Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP503T) PHARMACOLOGY-II (THEORY)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Course Objective: Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

UNIT-I

10hours

Pharmacology of drugs acting on cardiovascular system

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

UNIT-II

10hours

Pharmacology of drugs acting on cardiovascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

Pharmacology of drugs acting on urinary system



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- a.Diuretics
- b.Anti-diuretics.

UNIT-III

10hours

Autocoids and related drugs

- a. Introduction to autacoids and classification
- b.Histamine,5-HTandtheirantagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Anti rheumatic drugs

UNIT-IV

08hours

Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones-analogues and their inhibitors.
- c. Thyroid hormones-analogues and their inhibitors.
- d. Hormones regulating plasma calcium level-Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V

07hours

Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

Recommended Books (Latest Editions)

1. RangH.P., DaleM.M., RitterJ.M., Flower R.J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B.G., Masters S.B., Trevor A.J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics



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4. Marry Anne K.K., Lloyd YeeY., Brian K.A., Robbin L.C., Joseph G.B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.Band Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H.L., Sharma K.K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by CharlesR. Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Hand book of experimental pharmacology. Vallabh Prakashan.

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L	T	P	C
3	-	0	4

(23BP504T) PHARMACOGNOSY & PHYTO CHEMISTRY II (THEORY)

45 Hours

Scope:

The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Course Objective: Upon completion of the course, the student shall be able

- To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carry out isolation and identification of phytoconstituents

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

14 Hours

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,



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Phenyl propanoids and Flavonoids: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

6Hours

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

UNIT-IV

10Hours

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.

UNIT-V

8Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs

Recommended Books : (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D.Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. SH. Ansari, 2nd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N.Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VETylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.



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11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

III Year B.Pharm. I Semester

L	T	P	C
3	-	0	3

(23BP505T) PHARMACEUTICAL BIOTECHNOLOGY (THEORY)

45 Hours

Scope:

Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting. Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs. Biotechnology has already produced transgenic crops and animals and the future promises lot more. It is basically a research-based subject.

Course Objective: Upon successful completion of this course, the student should be able to:

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Importance of Monoclonal antibodies in Industries
- Appreciate the use of microorganisms in fermentation technology

UNIT-I

10 Hours

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.



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- e) Use of microbes in industry. Production of Enzymes- General consideration Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering

UNIT-II

10 Hours

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
 - i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
- d) Brief introduction to PCR

UNIT-III

10 Hours

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines.
- f) Hybridoma technology- Production, Purification and Applications
- g) Blood products and Plasma Substitutes

UNIT-IV

8 Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes 08Hours
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

UNIT-V

7 Hours

- a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b) Large scale production fermenter design and its various controls.
- c) Study of the production of- penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Recommended Books (Latest edition):

1. R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.



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2. RA Goldshy et. al.: Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitaker A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi.

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L	T	P	C
3	-	0	3

(23BP506a) PHARMACOVIGILANCE – THEORY
(Open Elective - I)

45 Hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Course Objective

- At completion of this paper it is expected that students will be able to (know, do, and appreciate):
- Why is drug safety monitoring important?
- National and international scenario of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance,
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs,
- Adverse drug reaction reporting systems and communication in pharmacovigilance



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- Methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle, Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India, ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning, CIOMS requirements for ADR reporting, Writing case narratives of adverse events and their quality.

Unit-I

10Hours

Introduction to Pharmacovigilance: History and development of Pharmacovigilance, Importance of safety monitoring of Medicine. WHO international drug monitoring program, Pharmacovigilance Program of India (PvPI)

Introduction to adverse drug reactions: Definition and classification of ADRs, Detection and reporting. Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment. Management of adverse drug reactions

Basic terminologies used in pharmacovigilance: Terminologies of adverse medication related events. Regulatory terminologies.

Unit II

10Hours

Drug and disease classification: Anatomical, therapeutic and chemical classification of drugs, International classification of diseases. Daily defined doses International Nonproprietary Names for drugs.

Drug dictionaries and coding in pharmacovigilance: WHO adverse reaction terminology, MedDRA and Standardised MedDRA queries, WHO drug dictionary. Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance: Basic drug information resources, Specialised resources for ADRs

Establishing pharmacovigilance program: Establishing in a hospital Establishment & operation of drug safety department in industry. Contract Research Organisations (CROs), Establishing a national programme

Unit III

10Hours

Vaccine safety surveillance: Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization.

Pharmacovigilance methods: Passive surveillance—Spontaneous reports and case series. Stimulated reporting, Active surveillance—Sentinel sites, drug event monitoring and registries. Comparative observational studies—Cross sectional study, case control study and cohort study. Targeted clinical investigations

Communication in pharmacovigilance: Effective communication in Pharmacovigilance. Communication in Drug Safety Crisis management. Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media.



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Unit- IV

8Hours

Safety data generation: Preclinical phase, Clinical phase, Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH. Expedited reporting, Individual case safety reports. Periodic safety update reports. Post approval expedited reporting Pharmacovigilance planning. Good clinical practice in pharmacovigilance studies

Unit-V

7hours

Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population: Paediatrics. Pregnancy and lactation. Geriatrics. CIOMS. CIOMS Working Group. CIOMS Form

CDSCO (India) and Pharmacovigilance: D&C Act and Schedule Y. Differences in Indian and global pharmacovigilance requirements.

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: SK Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, PierreBiron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice-Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India Text Book of Medicine by Yashpal Munjal



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

B. PHARMACY III YEAR COURSE STRUCTURE AND SYLLABUS

III Year B.Pharm. I Semester

L	T	P	C
3	-	0	3

(23BP506b) GENERIC PRODUCT DEVELOPMENT
(Open Elective - I)

45 Hours

Scope:

To learn the generic drug product development process, dosage form design and development, analytical method development and dossier approval process.

Course Objectives: After completion of this course, the students will able to:

- To explain the concept of generic drug product development, its historical context in the US, and the provisions of the Hatch-Waxman Act.
- To design and optimize generic dosage forms to achieve equivalence with reference listed drugs, covering formulation, process, and packaging.
- To develop and validate analytical methods for the comprehensive assessment of active ingredients, impurities, and finished dosage forms.
- To conduct and interpret stability studies for drug products and active ingredients, and to apply principles of scale-up for manufacturing process optimization.



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- To evaluate bioequivalence study designs, outline the eCTD structure, and compare drug product approval processes in India and the US.

UNIT – I 8 Hours

- Concept of generic drug product development, Hatch-Waxman act and its amendments.
- History of generic product development in US

UNIT – II 9 Hours

Design of dosage form to meet equivalence to reference listed drug, product development steps, formula optimization, process optimization and packaging selection.

UNIT – III 8 Hours

Analytical method development for verification and validation for active ingredient and impurities, inprocess samples and finished dosage forms.

UNIT – IV 10 Hours

- Stability studies on active ingredient and finished dosage forms, accelerated stability studies, stability studies at different conditions, determination of expiration date.
- Scale up studies to optimize manufacturing process and execution of exhibit batches.

UNIT – V 10 Hours

- Bioequivalence studies, various designs of bioequivalence studies, bioequivalence criteria and in-vitro tests to ensure bioequivalence of test product.
- Introduction to electronic Common Technical Document (eCTD), various modules and the important information in each module.
- Drug product approval process in India and US.

REFERENCE BOOKS:

- Generic Drug product Development: Solid oral dosage forms-Leon Shargel.
- ICH guidelines.
- Subba Rao Chaganti, Cracking the Generics code – Your Single-Source Success Manual for Winning in Multi-Source Product Markets, Pharma Med Press



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III Year B.Pharm. I Semester

L	T	P	C
3	-	0	3

(23BP506c) DIETARY SUPPLEMENTS AND NUTRACEUTICALS
(Open Elective - I)

45 Hours

Scope:

This subject covers foundational topics that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Course objective: This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.



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- Appreciate the components in dietary supplements and the application.
- Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I

07 hours

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

15 hours

- Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following
- a) Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, leutin
- b) Sulfides: Diallyl sulfides, Allyl trisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phyto estrogens : Isoflavones, daidzein, Geobustan, lignans
- g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III

07 hours

- a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b) Dietary fibres and complex carbohydrates as functional food ingredients.

UNIT IV

10 hours

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C,



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Vitamin E, α - Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
c) Functional foods for chronic disease prevention

UNIT V

06 hours

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.

III Year B.Pharm. I Semester

L	T	P	C
3	-	0	3

(23BP506d) ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL INDUSTRY
(Open Elective - I)

45 Hours

Scope: Explore the cutting-edge intersection of Artificial Intelligence (AI) and the Pharmaceutical Industry with our comprehensive online course. This program is designed to equip learners with the essential knowledge and skills to navigate the dynamic landscape where AI transforms drug discovery, development, and healthcare in the pharmaceutical sector.

1. Introduction to Artificial Intelligence

1.1 Introduction to Artificial Intelligence



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B. PHARMACY III YEAR COURSE STRUTURE AND SYLLABUS

- 1.2. Compare Between Human and Machine
- 1.3. Steps in AI, How Its Work
- 1.4. Examples and Applications of AI in Pharma
- 1.5. Predictive Analytics for Patient Outcomes
- 1.6. Treatment Plan
- 1.7. Natural Language Processing
- 1.8. Chatbots
- 1.9. Drug Discovery
- 1.10. Remote Patient Monitoring

2. Fundamentals of Pharmaceutical Sciences and Pharmaceutical Data and Database

- 2.1. Drug Discovery
- 2.2. Virtual Screening
- 2.3. Lead Optimization
- 2.4. Predictive Modeling
- 2.5. Clinical Trials
- 2.6. Pharmaceutical Product Development
- 2.7. Example of AIML in Pharmaceutical Research
- 2.8. RD Kit
- 2.9. Python Libraries in Pharma
- 2.10. Example of AIML in Pharmaceutical Research

III Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP502P) INDUSTRIAL PHARMACY-I (PRACTICAL)

Scope: This subject will provide an opportunity for the student to learn manufacturing of dosage forms such as tablets, capsules and parenteral.

Course Objectives: Upon completion of the subject student shall be able to

- a. Manufacture the various types of tablets.
- b. Evaluate the finished pharmaceutical products.

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets



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B. PHARMACY III YEAR COURSE STRUTURE AND SYLLABUS

3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets-film coating of tablets/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/and Eye ointments
10. Preparation of Creams (cold/ vanishing cream)
11. Evaluation of Glass containers (asper IP)

III Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP503P) PHARMACOLOGY-II (PRACTICAL)

Scope: This course uses simulated lab techniques and animal experiments to teach experimental pharmacology. It covers in-vitro and in-vivo drug effects on physiological systems, emphasizing quantitative analysis, drug-receptor interactions, bioassays, and assessing specific pharmacological activities like diuretic, anti-inflammatory, and analgesic effects. The focus is on learning experimental methodologies and data interpretation in a simulated environment.

Course Objectives: Upon completion of the practical student shall be able to



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- Explain in-vitro pharmacology principles and physiological salt solutions.
- Demonstrate drug effects on isolated organs and in-vivo models via simulation.
- Apply methods for Dose-Response Curves (DRC) and determining pharmacological parameters (PA₂, PD₂) using simulated data.
- Conduct and interpret various bioassay techniques for drug potency using simulated data.
- Identify and analyze drug effects across different classes on simulated biological systems.

1. Introduction to in-vitro pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdomen is muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdomen is muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA₂ value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD₂ value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos



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L	T	P	C
0	0	3	1.5

(23BP504P) PHARMACOGNOSY AND PHYTOCHEMISTRY-II (PRACTICAL)

Scope: This practical course covers the identification, characterization, extraction, and analysis of crude drugs and their active principles. It focuses on macroscopic, microscopic, and powder characteristics of medicinal plants, along with isolation, detection, and separation techniques for phytoconstituents. Emphasis is on using chemical tests and chromatography (Paper, TLC) for authentication and quality control of herbal materials.



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Course Objectives:

- To identify and characterize specified crude drugs based on their morphology, histology, and powder characteristics.
- To perform extraction and detection procedures for key active principles (e.g., caffeine, diosgenin, atropine, sennosides) from natural sources.
- To apply chromatographic techniques (Paper, TLC) for the separation and detection of sugars and phytoconstituents from herbal extracts and volatile oils.
- To conduct and interpret chemical tests for the analysis and authentication of specified crude drugs (e.g., Asafoetida, Benzoin, Colophony, Aloes, Myrrh).
- To demonstrate the process of volatile oil distillation from crude drugs.

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
 - a. Caffeine-from tea dust.
 - b. Diosgenin from Dioscorea
 - c. Atropine from Belladonna
 - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests:
 - (i) Asafoetida
 - (ii) Benzoin
 - (iii) Colophony
 - (iv) Aloes
 - (v) Myrrh

III Year B.Pharm. I Semester

L	T	P	C
1	0	2	2

(23BP507) SKILL ORIENTED COURSE – III Life skills (JEEVAN KAUSHAL) /Soft skills and employability

45 hours

Course Objectives: The objectives are to help learners

- To encourage all round development of the students by focusing on soft skills
- To enhance healthy relationship and understanding within and outside an organization



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- To function effectively with heterogeneous teams
- To make the students aware of Goal setting and writing skills
- Acquire career skills and fully pursue to partake in a successful career path
- Prepare a good résumé
- Prepare for interviews and group discussions

UNIT – I

6 hours

Goal Setting and Self-Management

Definition, importance, types of Goal Setting – SMART Goal Setting –Advantages- Motivation – Intrinsic and Extrinsic Motivation – Self-Management - Knowing about self – SWOC Analysis

UNIT – II

10 hours

Problem Solving & Decision Making

Meaning & features of Problem Solving – Managing Conflict – Conflict resolution – Team building - Effective decision making in teams – Methods & Styles

Activities:

Placing a problem which involves conflict of interests, choice and views – formulating the problem – exploring solutions by proper reasoning – Discussion on important professional, career and organizational decisions and initiate debate on the appropriateness of the decision. Case Study & Group Discussion

UNIT – III

10 hours

Emotional Intelligence & Stress Management

Managing Emotions – Thinking before Reacting – Empathy for Others – Self-awareness – Self-Regulation – Stress factors – Controlling Stress – Tips

Activities:

Providing situations for the participants to express emotions such as happiness, enthusiasm, gratitude, sympathy, and confidence, compassion in the form of written or oral presentations. Providing opportunities for the participants to narrate certain crisis and stress –ridden situations caused by failure, anger, jealousy, resentment and frustration in the form of written and oral presentation, Organizing Debates

UNIT – IV

10 hours

Corporate Etiquette

Etiquette- Introduction, concept, significance - Corporate etiquette - meaning, modern etiquette, benefits - Global and local culture sensitivity - Gender Sensitivity - Etiquette in interaction- Cell phone etiquette - Dining etiquette - Netiquette - Job interview etiquette - Corporate grooming tips -Overcoming challenges

Activities



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Providing situations to take part in the Role Plays where the students will learn about bad and good manners and etiquette - Group Activities to showcase gender sensitivity, dining etiquette etc. - Conducting mock job interviews - Case Study - Business Etiquette Games

NOTE:-

- 1.The facilitator can guide the participants before the activity citing examples from the lives of the great, anecdotes, epics, scriptures, autobiographies and literary sources which bear true relevance to the prescribed skill.
2. Case studies may be given wherever feasible for example for Decision Making- The decision of King Lear.

UNIT –V

9 hours

Professional Skills

Exploring Career Opportunities,

Team Skills: Cognitive and Non-Cognitive Skills, Trust and Collaboration, Brainstorming, Social and Cultural Etiquette

Leadership and Management Skills: Leadership Skills, Managerial Skills, Innovative Leadership and Design Thinking, Ethics and Integrity, Managing Personal Finance

III Year B.Pharm. I Semester

L	T	P	C
3	-	0	0

(23BP508) HEALTH AND WELLNESS, YOGA AND SPORTS

(Non-credit mandatory course)

45 hours

Scope:



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The main objective of introducing this course is to make the students maintain their mental and physical wellness by balancing emotions in their life. It mainly enhances the essential traits required for the development of the personality.

Course Objectives :

Upon completion of this course, students will be able to:

- Explain core concepts of health, fitness, nutrition, and immunity, analyzing the impact of diet and globalization on health, and calculating BMI for various age groups.
- Understand the historical and philosophical foundations of yoga, including Ashtanga Yoga, and proficiently practice and describe the anatomical and physiological effects of various yoga asanas, including Surya Namaskar.
- Master the practice of Pranayama, Shatkriyas, Bandhas, and Mudras, while comprehending their physiological benefits and roles in holistic well-being.
- Engage in meditation practices, such as Heartfulness Odyssey for Personal Excellence (HOPE), and articulate the benefits of meditation for personal integration and well-being.
- Comprehend the importance of sports and fitness, identify key fitness components, understand the history of major sporting events, and actively participate in and practice foundational exercises for general and cardiorespiratory fitness.

UNIT I

6 Hours

Concept of health and fitness, Nutrition and Balanced diet, basic concept of immunity
Relationship between diet and fitness, Globalization and its impact on health, Body Mass Index (BMI) of all age groups.

Activities:

- i) Organizing health awareness programmes in community
- ii) Preparation of health profile
- iii) Preparation of chart for balance diet for all age groups

UNIT II

10

Hours

Concept of yoga, Ashtanga yoga (The eight fold path), need for and importance of yoga, origin and history of yoga, origin of asana names, yoga in Indian context.
Classification of yoga, Anatomical and Physiological effects of Asanas. Preliminary asana, surya namaskar, yoga asana-standing postures, sitting postures, supine lying postures, prone lying postures, balancing asana, relaxation postures.

Activities: Yoga practices – Asana, Surya Namaskar

UNIT-III

9 Hours

Antomical and Physiological effects of Pranayama, art of breathing, types of pranayama.

Sudhrashan kriya,
shatkriyas and types,



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Bandha(neuromuscular co-ordination),

Mudras and types

Activities: Yoga practices – Pranayama, kriyas, Mudra and Bandha

UNIT-IV

8 Hours

Meditation for human integration:

Heartfulness odyssey for personal excellence (HOPE), Benefit of meditation.

Activities:

Yoga practices – Meditation and cleaning

UNIT V

12 Hours

Concept of Sports and fitness, importance, fitness components, history of sports, Ancient and Modern Olympics, Asian games and Commonwealth games.

Activities:

i) Participation in one major game and one individual sport viz., Athletics, Volleyball, Basketball, Handball, Football, Badminton, Kabaddi, Kho-kho, Table tennis, Cricket etc.

Practicing general and specific warm up, aerobics

ii) Practicing cardio respiratory fitness, treadmill, run test, skipping and running.

Reference Books:

1. Gordon Edlin, Eric Golanty. Health and Wellness, 14th Edn. Jones & Bartlett Learning, 2022
2. T.K.V.Desikachar. The Heart of Yoga: Developing a Personal Practice
3. Archie J.Bahm. Yoga Sutras of Patanjali, Jain Publishing Company, 1993
4. Wiseman, John Lofty, SAS Survival Handbook: The Ultimate Guide to Surviving Anywhere Third Edition, William Morrow Paperbacks, 2014
5. The Sports Rules Book/ Human Kinetics with Thomas Hanlon. -- 3rd ed. Human Kinetics, Inc.2014

III Year B.Pharm. II Semester

L	T	P	C
3	1	0	4

(23BP601T) MEDICINAL CHEMISTRY III–THEORY

45 hours

Scope:



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This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Course Objective:

Upon successful completion of this course, the student should be able to:

- Understand the importance of drug design and different techniques of drug design.
- Illustrate the chemistry of drugs with respect to their biological activity.
- Know the importance of SAR, metabolism, adverse effects and therapeutic value of drugs.

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT– I

10 Hours

Antibiotics:

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. β -

Lactam antibiotics: Penicillin, Cephalosporins,

β - Lactamase inhibitors, Monobactams

Aminoglycosides:

Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Minocycline, Doxycycline

UNIT– II

9 Hours

Antibiotics Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.



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UNIT– III

10 Hours

Anti-tubercular Agents:

Synthetic anti tubercular agents:

Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics:

Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents.

Quinolones:

SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Moxifloxacin, Gatifloxacin

Miscellaneous:

Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT– IV

10 Hours

Antifungal agents:

Antifungal antibiotics:

Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents:

Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents:

Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics:

Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones:

Historical development, chemistry, classification and SAR of Sulfonamides:

Sulphamethizole, Sulfisoxazole, Sulphapyridine, Sulphamethizine, Sulfacetamide*, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT– V

8 Hours

Introduction to Drug Design

Various approaches used in drug design.



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Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis.

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia
7. Organic Chemistry by I.L. Finar, Vol. II.
8. 8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5. 9. Indian Pharmacopoeia. 10. Text book of practical organic chemistry- A.I.Vogel.

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L	T	P	C
3	1	0	4



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(23BP602T) PHARMACOLOGY-III –THEORY

45 hours

Scope:

This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Course Objectives:

Upon successful completion of this course, the student should be able to:

- Illustrates the general principles of chemotherapy
- Apply the knowledge of chemotherapeutic agents for the management of infectious diseases
- Describe the principles of animal toxicology and human toxicology
- Explain the principles of chrono pharmacology in optimization of drug therapy

UNIT-I

10 hours

Pharmacology of drugs acting on Respiratory system

- a. Anti-asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II

10 hours

Chemotherapy 10hours

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III

10 hours

Chemotherapy

- a. Antitubercular agents



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- b. Antileprotic agents 10hours
- c. Antifungal agents
- d. Antiviral drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

UNIT-IV

08 hours

Chemotherapy

Urinary tract infections and sexually transmitted diseases.

Chemo therapy of malignancy.

Immuno pharmacology

- a. Immuno stimulants
- b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

07hours

Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organo phosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.



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7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
Modern Pharmacologywith clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company,
Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan N.Udupa
and P.D. Gupta, Concepts in Chronopharmacology



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L	T	P	C
3	1	0	4

(23BP603T) HERBAL DRUG TECHNOLOGY –THEORY

45 hours

Scope:

This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Course Objectives: Upon completion of this course the student should be able to:

- Understand raw material as source of herbal drugs from cultivation to herbal drug product
- Know the WHO and ICH guidelines for evaluation of herbal drugs
- Know the herbal cosmetics, natural sweeteners, Nutraceuticals
- Appreciate patenting of herbal drugs, GMP.

UNIT-I

11 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material.

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

- a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-II

7 Hours

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food:

Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina.

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.



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UNIT-III

10 Hours

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients– Significance of substances of natural origin as excipients– colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

UNIT- IV

10 Hours

Evaluation of Drugs

WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma &Neem.

Regulatory Issues-

Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs- Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V

07 Hours

General Introduction to Herbal Industry

Herbal drugs industry:

Present scope and future prospects.

A brief account of plant-based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T– Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule– T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipment's, standard operating procedures, health and hygiene, documentation and records.

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.



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2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.



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L	T	P	C
3	1	0	4

(23BP604T) BIOPHARMACEUTICS AND PHARMACOKINETICS–THEORY

45 hours

Scope:

This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arising there in.

Course Objectives: At the end of the theory course, the student will be able to

- Understand the concepts of Absorption, Distribution, Metabolism and Elimination of Drugs
- Estimate various pharmacokinetic parameters of drugs following various
- Compartment models with different routes of administration.
- Understand the concepts of Design of Dosage Regimen
- Demonstrate the understanding of Bioavailability and Bioequivalence

UNIT-I

10 Hours

Introduction Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes

Distribution: Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

UNIT- II

Hours 10

Elimination:

Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs.

Bioavailability and Bioequivalence:

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III

10 Hours



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Pharmacokinetics:

Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters- KE , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CLR - definitions methods of eliminations, understanding of their significance and application.

UNIT- IV

08 Hours

Multicompartment models:

Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settings.

UNIT- V

07 Hours

Nonlinear Pharmacokinetics:

- Introduction,
- Factors causing Non-linearity.
- Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Internationaledition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
11. Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvania



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III Year B.Pharm. II Semester

L	T	P	C
3	1	0	4

(23BP605T) BIOSTATISTICS AND RESEARCH METHODOLOGY –THEORY

45 hours

Scope:

To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Course Objective: Upon successful completion of this course, the student should be able to:

- Define Basics concepts of Statistics
- Recognize types of clinical studies, types of data distribution, data graphics and statistical applications in Pharmacy.
- Formulate parametric tests and non-parametric tests.
- Able to the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)

Course Content:

UNIT-I

13 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode-Pharmaceutical examples Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples.

UNIT-II

13 Hours

Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression – Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) -Pharmaceutical examples

Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.



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UNIT-III

13 Hours

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney Utest, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot

graph Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

UNIT-IV

11 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:

Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

UNIT-V

10 Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha.
3. Design and Analysis of Experiments – PHI Learning Private Limited, R.Pannerselvam.
4. Design and Analysis of Experiments –Wiley Students Edition, Douglas and C. Montgomery.
5. Text book of Statistical Methods and Computer applications by Dr. Ramakrishna Prasad.
6. Fundamentals of Biostatistics by Khan and Khanum.



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III Year B.Pharm. II Semester

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3	0	0	3

(23BP606a) COMPUTER AIDED DRUG DESIGN –THEORY
Professional Elective-I

45 hours

Scope:

This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Course Objectives: Upon completion of the course, the student shall be able to

- Design and discovery of lead molecules
- Estimate the role of drug design in drug discovery process
- Apply the concept of QSAR, docking, molecular modelling software and various
- Strategies to design & develop new drug like molecules.

UNIT-I

10 Hours

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design:

Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II

10 Hours

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III

10 Hours

Molecular Modeling and virtual screening techniques



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

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.

UNIT-IV

8 Hours

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V:

7 Hours

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Koro I kovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience. .
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. The organic Chemistry of Drug Design and Drug Action" Academic Press New York.



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III Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP606b) PHARMACOGNOSY & METABOLIC ENGINEERING
Professional Elective-I

45 hours

Scope: This subject explores the fascinating world of plant specialized metabolism, from its evolutionary origins to complex biochemical pathways. It focuses on modern biotechnological approaches like metabolic engineering and genetic transformation to enhance the production of valuable compounds such as medicinal alkaloids, terpenoids, and phenylpropanoids. The ultimate goal is to harness plants as sustainable biofactories for pharmaceuticals, industrial chemicals, and improved agricultural products, supporting both human health and a greener bioeconomy.

Course Objectives: Upon completion of the course, the student shall be able to

- Understand and manipulate the diverse specialized metabolic pathways in plants through advanced biotechnological approaches.
- Engineer the biosynthesis of key plant compounds like alkaloids, terpenoids, and phenylpropanoids for improved production and novel applications.
- Apply principles of metabolic engineering to produce high-value medicinal compounds, industrial bioproducts, and enhanced plant traits.
- Explore the potential of plants as biofactories for pharmaceuticals through molecular pharming.

UNIT-I

Medicinal and aromatic plants. Origin and Evolution of plant specialized metabolism. Eliciting specialized metabolism in plant cell and organ culture. Different strategies of metabolic engineering. Genetic transformation for manipulation of plant specialized metabolism.

UNIT-II

Introduction to alkaloids. Engineering tropane alkaloid pathways in plants. Engineering morphine and purine alkaloid pathways. Biosynthesis and genetic manipulation of indole alkaloid pathways. Metabolic reprogramming for non-natural indole alkaloids in plants. Discovery of new alkaloid pathways in plants (strychnine and colchicine).



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UNIT-III

Terpenoid metabolism and pathway manipulation. Genetic manipulation of carotenoid pathway. Emission biology of terpenoid floral volatiles. Biotechnological intervention for production of complex terpenes viz. hyperforin and taxol.

UNIT-IV

Biochemistry of phenylpropanoid/benzenoid metabolism. Pathway manipulation for reduction of lignin content and composition.

Biochemistry and cell biology of anthocyanin formation in flowers. Manipulation of anthocyanin pathways and creation of blue rose. : Biochemistry of tea polyphenols.

UNIT-V

Biosynthesis of phenolic alcohols and esters. Pathway manipulation for production of phenolic esters. Metabolic engineering for vanillin biosynthesis.

Genetic engineering of shikonin pathway. Molecular pharming for human somatotropin production in transplastomic plants.

Recommended Books: (Latest Editions)

1. Biren Shah , AK Seth, Textbook of Pharmacognosy and Phytochemistry, CBS Publishers & Distributors, 2nd Edn 2019.
2. Prof. (Dr.) Raj Kumari, Dr. Seema Gupta, Dr. Vasundhara Saxena, Dr. Abhishek Banke, Mr. Vitthal R. Muley, Text Book of Pharmacognosy and Phytochemistry- II, Shashwat publishers, 2025
3. https://onlinecourses.nptel.ac.in/noc24_bt08/preview



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III Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP606c) PHARMACEUTICAL REGULATORY SCIENCE (THEORY)
Professional Elective-I

45 hours

Scope:

This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Objectives: Upon successful completion of this course, the student should be able to:

- Know about the process of drug discovery and development
- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

Unit I

10Hours

New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II

Regulatory Approval Process

10Hours

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)



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Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials:

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee- formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance- safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190. \
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and RodneyK. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition ByRick Ng



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III Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP606d) DRUG DELIVERY: PRINCIPLES AND ENGINEERING
Professional Elective-I

45 hours

Scope:

This course introduces concepts of drug delivery to meet medical challenges. The course is designed to be modular, with each module focusing on the various aspects of drug delivery.

Course Objectives: Upon successful completion of this course, the student should be able to:

- Provide a comprehensive understanding of the principles of drug delivery.
- Equip learners with the knowledge to design and evaluate novel drug delivery systems.
- Explore different strategies for controlled and targeted drug delivery.
- Cover various delivery routes and systems.
- Introduce advanced concepts like nanocarriers, biocompatibility, and drug targeting.
- Address practical aspects like translation into clinical applications and potential issues like nanotoxicology.

UNIT-1

10 Hours

Pharmacokinetics: Bioavailability, Elimination, Therapeutic index, Prodrugs, Controlled release.

Polymers: Synthesis, properties, characterization, crystallinity and amorphousness

Biopolymers: Natural and Synthetic, biocompatibility, Biodegradation, commonly used biopolymers. Polymer-Drug conjugates, PEGylation

UNIT-II

9 Hours

Diffusion controlled systems, Ficks laws, Reservoir systems, Non-erodible matrix systems, Bio-erodible Systems

Hydrogels: Physical or chemical, pore-size calculation, in-situ cross linking

UNIT-III

7 Hours



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Nano and Micro-particles: Dendrimers, Liposomes, Micelles. Metal and polymeric particles, effect of particle shape, charge and elasticity

UNIT-IV

10 Hours

Protein Adsorption and tissue engineering, Drug delivery in tissue engineering
Implant associated infections, Route specific delivery: Oral, Subcutaneous, Intramuscular, transdermal, inhalation, intravenous

UNIT-V

9 Hours

Vaccines, Cancer vaccines, Cell and gene delivery, Smart responsive drug delivery, Targeted drug delivery, Nanotoxicology and market translation

Books and references

1. Drug Delivery: Engineering Principles for Drug Therapy, W. Mark Saltzman, Oxford University Press, 2001
2. Drug Delivery: Fundamentals and Applications, Anya M. Hillery and Kinam Park, 2nd Edition, CRC Press, 2016.
3. https://onlinecourses.nptel.ac.in/noc19_bt23/preview



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III Year B.Pharm. II Semester

L	T	P	C
3	0	0	1.5

(23BP601P) MEDICINAL CHEMISTRY-III (PRACTICAL)

Scope: This subject will provide an opportunity for the student on synthesis of various compounds.

Course Objectives: Upon completion of the subject student shall be able to

- Synthesis various chemical compounds.
- Provide knowledge on monograph analysis of some chemical compounds.

I. Preparation of drugs and intermediates

Sulphanilamide
7-Hydroxy, 4-methyl coumarin
Chlorobutanol
Triphenyl imidazole
Tolbutamide
Hexamine

II. Assay of drugs

Isonicotinic acid hydrazide
Chloroquine
Metronidazole
Dapsone Chlorpheniramine maleate
Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV. Drawing structures and reactions using chem draw®



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V. Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

III Year B.Pharm. II Semester

L	T	P	C
3	0	0	1.5

(23BP602P) PHARMACOLOGY-III (PRACTICAL)

Scope:

To find out the agents suitable for clinical use.

Study the toxicity and mechanism of Action and Site of action

Study the actions of drugs in Preclinical

Course Objectives:

To know and understand pharmacological investigation techniques applied in the research

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility.
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data.
11. Determination of acute skin irritation /corrosion of a test substance
12. Determination of acute eye irritation /corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology (student's t test, ANOVA)



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15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

*Experiments are demonstrated by simulated experiments/videos

III Year B.Pharm. II Semester

L	T	P	C
3	0	0	1.5

(23BP603P) HERBAL DRUG TECHNOLOGY (PRACTICAL)

Scope

The course covers **phytochemical screening, quantitative analysis of key constituents** (alcohol, aldehydes, phenols, alkaloids), and the **incorporation and evaluation of standardized herbal extracts** in both cosmetic and pharmaceutical products, all while adhering to pharmacopoeial standards.

Course Objectives:

Upon completion students will learn to:

- **Perform preliminary phytochemical analysis** of crude drugs.
- **Quantify specific compounds** like alcohol, aldehydes, phenols, and total alkaloids.
- **Evaluate natural excipients** and **formulate/evaluate herbal extracts** in cosmetic and pharmaceutical preparations.
- **Analyze herbal drug monographs** from pharmacopoeias.
 1. To perform preliminary phytochemical screening of crude drugs.
 2. Determination of the alcohol content of Asava and Arista
 3. Evaluation of excipients of natural origin
 4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
 5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
 6. Monograph analysis of herbal drugs from recent Pharmacopoeias
 7. Determination of Aldehyde content



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8. Determination of Phenol content
9. Determination of total alkaloids

III Year B.Pharm. II Semester

L	T	P	C
3	0	0	1.5

(23BP607) BIOPHARMACEUTICS AND PHARMACOKINETICS
(Skill Oriented Course-IV)

Scope: This subject will provide an opportunity for the student to learn about the Biopharmaceutics and pharmacokinetic.

Course Objective:

- The course is designed to analysis of biological samples for drug content.
- The course helps to estimation of the pharmacokinetic parameters.

I. EXPERIMENTS

1. Analysis of biological samples for drug content and estimation of the pharmacokinetic parameters.
2. In vitro evaluation of tablet/capsule for drug release
3. Drug-protein binding studies.
4. Statistical treatment of pharmaceutical data.
5. Problems related to pharmacokinetics – determination of PK Parameters
6. Problems related to bioavailability and bioequivalence.

II. DEMO/ WORKSHOP

1. Absorption studies – in vitro.
2. Experiments designed for the estimation of various pharmacokinetic parameters.

III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

Chronopharmacokinetics



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Text Books:

1. L. Shargel and ABC Yu, textbook of applied biopharmaceutics & Pharmacokinetics, 4th edn, Appleton – century – crofts, Connecticut, 2004.
2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma BookSyndicate.Hyderabad.
3. DM Brahmanekar and SB Jaiswal, biopharmaceutics and pharmacokinetics- a treatise, Vallabhprakasham, Delhi.

Reference Books:

1. Ronald & Trueter. Clinical pharmacokinetics concepts & applications. 3rd ed, Wolterskluwer Pvt Ltd., 2007.
2. Robert E Notari, Biopharmaceutics and pharmacokinetics – an introduction, Marcel Dekker Inc., NY
3. Basic pharmacokinetics by Hedaya, CRC Press.

III Year B.Pharm. II Semester

L	T	P	C
3	0	0	0

**(23BP608) CONSTITUTION OF INDIA
(MANDATORY COURSE)**

45 Hours

Course Objectives:

The objective of this course is:

- To Enable the student to understand the importance of constitution
- To understand the structure of executive, legislature and judiciary
- To understand philosophy of fundamental rights and duties
- To understand the autonomous nature of constitutional bodies like Supreme Court and High Court Controller and Auditor General of India and Election Commission of India.
- To understand the central-state relation in financial and administrative control

UNIT-I

7 Hours

Introduction to Indian Constitution – Constitution -Meaning of the term - Indian Constitution- Sources and constitutional history - Features– Citizenship – Preamble - Fundamental Rights and Duties - Directive Principles of State Policy.

UNIT-II

10 Hours

Union Government and its Administration Structure of the Indian Union - Federalism - Centre State relationship – President's Role, power and position - PM and Council of



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ministers - Cabinet and Central Secretariat –Lok Sabha - Rajya Sabha - The Supreme Court and High Court - Powers and Functions

UNIT-III

7 Hours

State Government and its Administration - Governor - Role and Position -CM and Council of ministers - State Secretariat-Organization Structure and Functions

UNIT-IV

12 Hours

Local Administration - District's Administration Head - Role and Importance - Municipalities - Mayor and role of Elected Representatives -CEO of Municipal Corporation Pachayati Raj - Functions– PRI –Zilla Parishath - Elected officials and their roles – CEO,ZillaParishath - Block level Organizational Hierarchy - (Different departments) - Village level - Role of Elected and Appointed officials - Importance of grass root democracy

UNIT-V

9 Hours

Election Commission - Election Commission- Role of Chief Election Commissioner and Election Commissionerate - State Election Commission -Functions of Commissions for the welfare of SC/ST/OBC and Women

TEXT BOOKS

1. Durga Das Basu, “ Introduction to the Constitution of India”, Prentice – Hall of India Pvt. Ltd.. New Delhi
2. Subash Kashyap, “Indian Constitution”, National Book Trust
- REFERENCES: 1. J.A. Siwach, “Dynamics of Indian Government & Politics”.
2. H.M.Sreevai, “Constitutional Law of India”, 4th edition in 3 volumes (Universal Law Publication)
3. J.C. Johari, “Indian Government andPolitics”, Hans India
4. M.V. Pylee, “Indian Constitution Durga Das Basu, Human Rights in Constitutional Law, Prentice”, Hall of India Pvt. Ltd.. New Delhi

E-RESOURCES:

1. nptel.ac.in/courses/109104074/8
2. nptel.ac.in/courses/109104045/
3. nptel.ac.in/courses/101104065/
4. www.hss.iitb.ac.in/en/lecture-details
5. www.iitb.ac.in/en/event/2nd-lecture-institute-lecture-series-indian-constitution



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B. PHARMACY IV YEAR COURSE STRUTURE AND SYLLABUS

Semester VII (IV-I)

S.No	Course Code	Name of the Course	Hours per week			Credits
			L	T	P	
1	23BP701T	Instrumental Methods of Analysis–Theory	3	1	0	4
2	23BP702T	Industrial Pharmacy II–Theory	3	1	0	4
3	23BP703T	Novel Drug Delivery System–Theory	3	1	0	4
4	23BP704T	Pharmaceutical Quality Assurance –Theory	3	0	0	3
5	23BP705T	Pharmacy practice	3	0	1	4
6	23BP701P	Instrumental Methods of Analysis – Practical	0	0	3	1.5
7	23BP706	Skill-V clinical Research/Medical coding/Biomedical equipment Training Program/ Infection course in Medical Toxicology	0	0	3	1.5
8	23BP707	Practice School	0	0	4	2
9	23BP708	Industry Internship during summer vacation & Evaluation of Industry Internship	0	0	0	3
10	23BP709	Non credit mandatory course Essence of Indian Traditional Knowledge	3	-	-	0
Total			18	3	11	27



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Semester VIII (IV-II)

S.No	Course Code	Name of the Course	L	T	P	Credits
1	23BP801a	Professional Elective – II 1. Pharma Marketing Management	3	0	0	3
	23BP801b	2. Cell and Molecular Biology				
	23BP801c	3. Bioanalytical Techniques and Bioinformatics				
	23BP801d	4. Pharmaceutical Dosage forms				
2	23BP802a	Professional Elective – III 1. Experimental Pharmacology –Theory	3	0	0	3
	23BP802b	2. Quality Control and Standardization of Herbals				
	23BP802c	3. AI and ML in Pharmaceutical Sciences				
	23BP802b	4. Regulatory requirements for medical devices				
3	23BP803	Project Work	0	0	24	12
Total			6	0	24	18



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IV Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP701T) INSTRUMENTAL METHODS OF ANALYSIS (THEORY)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT –I

10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation- Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications- Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and Applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications



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Nuclear Magnetic Resonance spectroscopy: Introduction, principle, instrumentation, Applications

Mass Spectroscopy: Introduction, principle, instrumentation, Applications

UNIT –III

10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Column Chromatography-Introduction, Principle, Methodology and applications

UNIT –IV

08 Hours

Electrophoresis-Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

UNIT –V

07 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

Introduction to Hyphenated –LC-MS/MS, GC-MS/MS,HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein



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L	T	P	C
3	1	0	4

(23BP702T) INDUSTRIAL PHARMACY II (THEORY)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Course Objectives: Upon completion of the course, the student shall be able to:

- Know the process of pilot plant and scale up of pharmaceutical dosage forms
- Understand the process of technology transfer from lab scale to commercial batch
- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products
-

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB)



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and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV

08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.

UNIT-V

07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.



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IV Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP703T) NOVEL DRUG DELIVERY SYSTEMS (THEORY)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Course Objectives: Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems.

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump.

Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastro retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications



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Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV

08 Hours

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

Unit-V

07

Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

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

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)



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IV Year B.Pharm. I Semester

L	T	P	C
3	1	0	3

(23BP704T) PHARMACEUTICAL QUALITY ASSURANCE (THEORY)

45 Hours

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

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

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures.

UNIT - II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III

10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.



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Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

UNIT – IV

08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V

07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines



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IV Year B.Pharm. I Semester

L	T	P	C
3	1	0	4

(23BP705T) PHARMACY PRACTICE (THEORY)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Course Objectives: Upon completion of the course, the student shall be able to

1. Know various drug distribution methods in a hospital
2. Appreciate the pharmacy stores management and inventory control
3. Monitor drug therapy of patient through medication chart review and clinical review
4. Obtain medication history interview and counsel the patients
5. Identify drug related problems
6. Detect and assess adverse drug reactions
7. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. Know pharmaceutical care services

Unit I

10Hours

a) Hospital and its organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug reaction reporting and management.



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d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit-II

10Hoursa)

Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit-III

10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counselling

Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.



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Unit IV

8 Hours

a) preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over thecounter medications.

Unit V

7Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, haematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr.J.S.Quadry. A textbook of hospital pharmacy, 4th ed.Ahmadabad: B.S. Shah Prakashan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of ClinicalPharmacy Practice- essential concepts and skills, 1st ed. Chennai: OrientLongman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea &Febiger;1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society ofHealth System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326



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IV Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

(23BP701P) INSTRUMENTAL METHODS OF ANALYSIS (PRACTICAL)

45 Hours

Scope:

This subject will provide an opportunity for the student on handling of modern analytical instruments or equipment.

Course Objective:

- The course is designed to explore the knowledge in handling of modern analytical instruments or equipment.
 - The course helps to understand the instrumental or equipment operational procedures
1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
 2. Estimation of dextrose by colorimetry
 3. Estimation of sulfanilamide by colorimetry
 4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
 5. Assay of paracetamol by UV- Spectrophotometry
 6. Estimation of quinine sulfate by fluorimetry
 7. Study of quenching of fluorescence
 8. Determination of sodium by flame photometry
 9. Determination of potassium by flame photometry
 10. Determination of chlorides and sulphates by nepheloturbidometry
 11. Separation of amino acids by paper chromatography
 12. Separation of sugars by thin layer chromatography
 13. Separation of plant pigments by column chromatography
 14. Demonstration experiment on HPLC
 15. Demonstration experiment on Gas Chromatography



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B. PHARMACY IV YEAR COURSE STRUCTURE AND SYLLABUS

IV Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

SKILL-V

Clinical Research/ Medical coding/Biomedical equipment Training Program/ Infection course in Medical Toxicology

(23BP706) CLINICAL RESEARCH (SKILL DZIRE)

45 Hours

Scope: This subject will provide an opportunity for the student to learn about the Introduction to clinical trials.

Course Objective:

- To learn Phase I, II and III levels of clinical trials.
- To gain knowledge on statistical approaches for various endpoints.

UNIT-I

8 Hours

Introduction to Clinical Research

Overview of Clinical Research

Guidelines for Clinical Trials

Pre-clinical Studies

UNIT-II

10 Hours

Bioequivalence (BE) Studies

Introduction to BE Studies

BE Clinical Phase

Analytical Phase in BE Studies

BE Clinical Study Report (CSR)

Bioequivalence & Bioavailability

Bioequivalence Case Study: Metformin IR

Bioequivalence Study of Olmesartan

Topical Product Bioequivalence

UNIT-III

7 Hours

Clinical Trial Phases

Phase I Clinical Trials

Phase II, III, & IV Clinical Trials

Phase III IR



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Phase 3 Rosuvastatin + Ezetimibe

UNIT-IV

10 Hours

Special Topics in Clinical Research

Clinical Pharmacology

Hypertension and its Clinical Trials

Letrozole: A Case Study

Olmesartan IR: Clinical Study Overview

UNIT-V

10 Hours

Real-Time Tasks

MetaforminIR_04

Olmesartan IR_11

Letrozole IR_18

Phase 1 - Topical Product

Phase III (Efficacy & Safety) Study of Rosuvastatin/Ezetimibe Tablets (FDC) in

Hypercholesterolemia Volunteers



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IV Year B.Pharm. I Semester

L	T	P	C
0	0	3	1.5

SKILL-V

Clinical Research/ Medical coding/Biomedical equipment Training Program/ Infection course in Medical Toxicology

(23BP706) CLINICAL RESEARCH 75 HRS/WEEK (KLE)

Scope:

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Course Objectives: Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

1. Historical Perspectives:

06 Hrs

- Nuremberg Code Study,
 - The Belmont Report
- The declaration of Helsinki
- Origin and Principles of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines

2. Informed Consent Process:

06 Hrs

- Ethical principles governing informed consent process
- Structure and content of a Patient Information Sheet
 - Structure and content of an Informed Consent Form
- The process of taking informed consent and documentation

3. Types and Designs used in Clinical Research:

08 Hrs

Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Time Sequences (Prospective and



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Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)

4. Clinical Trial Study team: 06 Hrs

Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization, Site management Organizations.

5. Clinical trial Documents: 08 Hrs

Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Dairy Cards

6. Clinical Trial Start up activities: 06 Hrs

Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission, Site initiation visit,

7. Investigational Product: Procurement and Storage of investigation product 02 Hrs

8. Preparation and conduct of monitoring visit: 10 Hrs

Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

9. Quality Assurance and Quality Control in Clinical Trials: 05 Hrs

Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

10. Clinical Data Management 06 Hrs

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

11. Clinical Trial Data Management: 12 Hrs

Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Central lab, IVRS, source data. Data cleaning, managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing



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RECOMMENDED BOOKS: Theory

1. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.
2. Principles of Clinical Research edited by Giovanna di Ignazio, DiGiovanna and Haynes

Reference books:

1. Recent Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2013,2017.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000, 2014, 2017. 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

Practicals:

Suggested List of Practical: Total: 50 Hrs 3Hrs/week

1. To prepare and submit Informed Consent Process (ICF) for the following population 15 Hrs
 - Geriatric Patients
 - Paediatric patients
 - Psychiatric patients
 - Unconscious patients
2. To prepare and submit dummy patient information sheet (PIS) for the below mentioned population 15 Hrs
 - Geriatric Patients
 - Paediatric patients
 - Psychiatric patients
 - Unconscious patients
3. To prepare and submit the standard operating procedures(SOP) for procurement and storage filing of Investigational product(IP) 10Hrs
4. To prepare and submit e-CRF(Electronic Case Report Form) for dummy clinical data 10 Hrs



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IV Year B.Pharm. I Semester

L	T	P	C
3	0	0	0

(23BP709) ESSENCE OF INDIAN TRADITIONAL KNOWLEDGE

(Non credit mandatory course)

45 hours

Scope: To facilitate the students with the concepts of Indian traditional knowledge and to make them understand the Importance of roots of knowledge system.

UNIT-I

10 hours

Introduction to traditional knowledge:

Define traditional knowledge, nature and characteristics, scope and importance, kinds of traditional knowledge, the physical and social contexts in which traditional knowledge develop, the historical impact of social change on traditional knowledge systems. Indigenous Knowledge (IK), characteristics, traditional knowledge vis-à-vis indigenous knowledge, traditional knowledge Vs western knowledge traditional knowledge vis-à-vis formal knowledge

Unit-II

7 hours

Protection of traditional knowledge :

The need for protecting traditional knowledge Significance of TK Protection, the value of TK in the global economy, Role of Government to harness TK.

Unit-III

10 hours

Legal framework and Traditional Knowledge:

A: The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006, Plant Varieties Protection and Farmers Rights Act, 2001 (PPVFR Act);
B: The Biological Diversity Act 2002 and Rules 2004, the protection of traditional knowledge bill, 2016. Geographical indications act 2003.

Unit-IV

9 hours

Traditional knowledge and intellectual property

Systems of traditional knowledge protection, Legal concepts for the protection of traditional knowledge, Certain non IPR mechanisms of traditional knowledge protection, Patents and traditional knowledge, Strategies to increase protection of traditional knowledge, global legal FORA for increasing protection of Indian Traditional Knowledge.



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Unit-V

9 hours

Traditional knowledge in different sectors

Traditional knowledge and engineering, Traditional medicine system, TK and biotechnology, TK in agriculture, Traditional societies depend on it for their food and healthcare needs, Importance of conservation and sustainable development of environment, Management of biodiversity, Food security of the country and protection of TK.

Text Books:

1. Traditional Knowledge System in India, by Amit Jha, 2009.
2. Traditional Knowledge System and Technology in India by Basanta Kumar Mohanta and Vipin Kumar Singh, Pratibha Prakashan 2012. .

References:

1. Traditional Knowledge System in India by Amit Jha Atlantic publishers, 2002
2. "Knowledge Traditions and Practices of India" Kapil Kapoor, Michel Danino

E-resources:

1. <https://www.youtube.com/watch?v=LZP1StpYEPM>.
2. <http://nptel.ac.in/courses/121106003/>



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP801a) PHARMA MARKETING MANAGEMENT
(Professional Elective – II)

45 hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective:

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit-I

10 Hours

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit-II

7 Hours

Product decision:

Classification, product line and product mix decisions, product lifecycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit-III

8 Hours

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.



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Unit-IV

10 Hours

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit-V

10 Hours

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi.
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective,
7. Indian Context, Macmilan India, New Delhi.
8. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
9. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP801b) CELL AND MOLECULAR BIOLOGY
(Professional Elective – II)

45 hours

Scope:

Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Course Objectives:

- This course is to provide a comprehensive understanding of cell and molecular biology, covering key topics such as cellular structure, molecular processes, genetic mechanisms, and protein synthesis.
- Students will gain insights into the historical developments, functions, and applications of cellular biology, including the flow of molecular information, cell cycle regulation, and signaling pathway

Unit-I

10Hours

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: History and Summation.
- c) Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations – an Introduction and Reactions (Types)

Unit-II

10 Hours

- a) DNA and the Flow of Molecular Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

Unit-III

10 Hours

- a) Proteins: Defined **and** Amino Acids



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- b) Protein Structure
- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

Unit-IV

08 Hours

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

Unit V

07 Hours

- a) Cell Signals: Introduction
- b) Receptors for Cell Signals
- c) Signaling Pathways: Overview
- d) Misregulation of Signaling Pathways
- e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Pepler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshyet.al.,: Kuby Immunology.



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP801c) BIOANALYTICAL TECHNIQUES AND BIOINFORMATICS
(Professional Elective – II)

45 hours

Scope: Course offers a comprehensive overview of bioinformatics, focusing on sequence and structural analysis of DNA and proteins. It also covers protein modeling, molecular interactions, and computational drug design using advanced tools, algorithms, and machine learning techniques

Course Objective:

- Introduction, Modern approaches in Bioanalysis and Bioassays.
- Spectroscopic techniques: UV-Visible spectroscopy, Fluorescence spectroscopy, IR spectroscopy, CD spectroscopy, and Mass spectroscopy.
- To equip students with core knowledge and computational skills in bioinformatics for analyzing biological sequences and protein structures.
- The course also aims to develop proficiency in tools and techniques for drug design, data mining, and algorithm development in life sciences

Unit-I

12 Hours

Introduction, Modern approaches in Bioanalysis and Bioassays, Microscopic Techniques: Light Microscopy; Fluorescence microscopy, Atomic force microscope, Electron microscope, Scanning electron microscopy, Transmission Electron microscope. Application of microscope in analyzing biological samples
Electrophoretic Techniques Electrophoresis; Principle, Design of horizontal and vertical gel electrophoresis apparatus, performing electrophoresis techniques, application of electrophoresis in analyzing macromolecules.

Unit-II

10 Hours

Introduction, DNA sequence analysis, DNA Databases, Protein structure and function, protein sequence databases, sequence alignment PAM matrix, Global and local alignment, BLAST: features and scores, Multiple sequence alignment, Conservation score, phylogenetic trees, Protein sequence analysis, hydrophobicity profiles, non-redundant datasets

Unit-III

7 Hours

protein secondary structures, Ramachandran plot, propensity, secondary structure prediction, Protein tertiary structure, Protein Data Bank, visualization tools, structural classification, contact maps



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Unit-IV

8 Hours

Protein structural analysis, protein structure prediction, Protein stability, energetic contributions, database, stabilizing residues, stability upon mutations, Protein folding rates, proteins interactions, binding site residues

Unit-V

8 Hours

Computer aided drug design, docking, screening, QSAR, Development of algorithms, awk programming, machine learning techniques, applications using WEKA
Bioinformatics Tools: Computational approaches in analyzing protein and nucleic acid sequences; Analysis of protein structures.

Books and references

- M. Michael Gromiha, Protein Bioinformatics: From Sequence to Function, Academic Press, 2010
- D.E. Krane and M.L. Raymer, Fundamental concepts of bioinformatics, Pearson Education Inc. 2006



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP801d) PHARMACEUTICAL DOSAGE FORMS
(Professional Elective – II)

45 hours

Scope: Course provides comprehensive knowledge of pharmaceutical processes, dosage form development, and advanced drug delivery systems, including formulation, evaluation, and quality control. It also covers regulatory affairs, packaging, and manufacturing practices essential for ensuring drug safety, efficacy, and compliance with industry standards.

Course Objective:

- To provide foundational and advanced knowledge in pharmaceutical formulation, processing, and quality control.
- The course aims to prepare students for industry roles by integrating principles of drug development, regulatory affairs, and manufacturing practices.

Unit-I

10

Hours

Introduction to Course and Course Plan, Fundamentals of pharmaceutical processes- Unit operations- milling, Fundamentals of pharmaceutical processes- Unit operations- mixing, Fundamentals of pharmaceutical processes- Unit operations –clarification, Fundamentals of pharmaceutical processes- Unit operations –Drying.
Fundamentals of pharmaceutical processes- Unit operations –Compaction, Pharmaceutical Rheology, Dosage form development: Pre-formulation studies-Bulk Characterization-I, Dosage form development: Pre-formulation studies-Bulk Characterization-II, Pre-formulation studies-Solubility and stability Analysis –I

Unit-II

10

Hours

Pre-formulation studies-Solubility and stability Analysis–II, Biopharmaceutics and Pharmacokinetics Principles and PK models, Biopharmaceutics and Pharmacokinetics: Factors affecting drug kinetics , Biopharmaceutics and Pharmacokinetics: Dosage form design and evaluation, Tablets: Types of tablets
Tablet design and Excipients , Tablets: Granulation and compression , Evaluation of tablets and defects, Tablet coating: Types of coating and process of coating , Tablet coating: Evaluation and defects



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Capsules: Hard Gelatin capsules and formulation components ,Soft gelatin capsules: formulation and evaluation , Capsules: Evaluation and quality control, Microencapsulation, Sustained release dosage forms-I

Unit-III

10 Hours

Sustained release dosage forms-II, Sustained release dosage forms-III, Monophasic Liquid Dosage forms- Classification and Components, Monophasic Liquid Dosage forms- Formulation and Evaluation , Pharmaceutical suspensions-Types and formulation excipients
Pharmaceutical suspensions- properties and evaluation , Pharmaceutical Emulsion-types, theories of emulsification , Pharmaceutical Emulsion- formulation excipients and evaluation, Stability of Biphasic liquids , Semi Solid Dosage forms- Types and excipient selection
Semi Solid Dosage forms- properties, evaluation and stability, Sterile products –I, Sterile Products-II, Suppositories-types, bases and properties, Suppositories-evaluation and stability.

Unit-IV

7 Hours

Pharmaceutical aerosols- properties and excipients, Pharmaceutical aerosols- evaluation and stability, Novel drug delivery systems –II , Targeted drug delivery systems-I, Targeted drug delivery systems-II, Targeted drug delivery systems-III, Dissolution , Pilot plant scale up and Manufacturing design-I, Sampling

Unit-V

8 Hours

Pharmaceutical Packaging: Types and Process-I , Pharmaceutical Packaging: Types and Process-II, Pharmaceutical Packaging: Types and Process-II, Stability testing and kinetic principles: I, Stability testing and kinetic principles: II
Concept of Statistical Quality Control , Manufacturing Working Formula Procedures, Quality Management , Drug Regulatory Affairs-I ,Drug Regulatory Affairs-II

Books and references

1. Leon Lachmen, H.A.Lieberman and J.L.Kanig, “The Theory and Practice of Industrial Pharmacy”
2. Cooper and Gunns’ “Tutorial Pharmacy” ed. S.J.Carter
3. Modern Pharmaceutics:,G.S.Banker and C.T.Rhodes, Marcel Dekker Inc., NY.



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP802a) EXPERIMENTAL PHARMACOLOGY – THEORY
(Professional Elective – III)

45 hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Course Objectives: Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Unit –I

08 Hours

Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Unit –II

10 Hours

Preclinical screening models

- Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.
- Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, anti-asthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

Unit –III

5 HOURS

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics

Unit –IV

7 HOURS

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic,



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antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

Unit –V

5 HOURS

Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP802b) QUALITY CONTROL AND STANDARDIZATION OF HERBALS
(Professional Elective – III)

45 hours

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Course Objectives: Upon completion of the subject student shall be able to;

- know WHO guidelines for quality control of herbal drugs
- know Quality assurance in herbal drug industry
- know the regulatory approval process and their registration in Indian and international markets
- appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms. WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

Unit II **10hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines. WHO Guidelines on GACP for Medicinal Plants.

Unit III **7hours**

EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **10hours**

Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal



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Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol.Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.



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IV Year B.Pharm. II Semester

L	T	P	C
3	0	0	3

(23BP802c) AI AND ML IN PHARMACEUTICAL SCIENCES

(Professional Elective – III)

45 hours

Scope:

This subject explores the fundamentals and applications of Artificial Intelligence (AI) and Machine Learning (ML) in the pharmaceutical industry, focusing on their roles in drug discovery, clinical development, manufacturing, and healthcare delivery. It provides insights into modern digital trends, tools, and regulatory frameworks, while addressing the challenges and ethical considerations of implementing AI/ML technologies. Students will gain practical knowledge to assess and apply AI/ML solutions across the pharmaceutical value chain, preparing them for innovation-driven roles in the evolving healthcare landscape.

Course Objectives:

- Key elements of Artificial Intelligence (AI) and Machine learning (ML) in the pharmaceutical sector.
- Modernization in Pharmaceutical Research and Discovery.
- Basics of newly developed pharmaceutical products and services with Artificial Intelligence (AI) and Machine learning (ML) technology.
- Challenges and opportunities of AI/ML Adoption in the pharmaceutical Industries.

Unit - I

10 hours

Basics of AI and ML: Introduction of Artificial Intelligence (AI) and Machine learning (ML), Brief History of Artificial Intelligence and Machine learning, Major component of Artificial Intelligence (AI) and Machine learning (ML), Supervised, Unsupervised and Reinforcement Learning, Deep Learning, Neural Networks, Artificial Neural Network, Data types and resources, Data management.

Unit – II

10 hours

AI and ML concepts in Pharmaceutical :Pharmaceutical Industry 4.0, Digital Technology trends in the pharmaceutical industry, Current implementation and application of Artificial Intelligence and Machine Learning in Pharmaceuticals, Artificial Intelligence and Machine Learning derived drug discovery Good machine learning practice (GMLP); Tools in AI and ML-driven drug discovery (de novo and repurposing approach)



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B. PHARMACY IV YEAR COURSE STRUTURE AND SYLLABUS

Unit – III

10 hours

Modern Pharmaceutical Sector Clinical Development (Trial design, trial start-up, trial conduct, trial closeout), CONSORT-AI (Consolidated Standards of Reporting Trials Artificial Intelligence), Clinical evaluation of software, Manufacturing with quality of experience (QoE) and quality of service (QoS), supply chain management, Launch, commercialization, Post Market surveillance, Role of Artificial Intelligence and Machine learning in Diagnosing, Retail and Distribution, AI/ML based software as a medical device.

Unit – IV

10 hours

Challenges and Opportunities Benefits and Opportunities of AI/ML in the Pharmaceutical Industry, Real-world performance (RWP) monitoring for AI/ML software, Digital Unfamiliar technology, Future with Covid-19 digital Opportunities and challenges, Technical and Logistical challenges, Modern Regulatory challenges in drug discovery, clinical trial, Product registration, Ethical consideration and Cyber security.

Suggested Readings:

1. Ashenden, S. K. (2021). ERA of Artificial Intelligence, Machine Learning, and data science in the pharmaceutical industry. Academic Press.
2. Philip, A., Shahiwala, A., Rashid, M., & Faiyazuddin, M. (2023). A Handbook of Artificial Intelligence in Drug Delivery. Academic Press, an imprint of Elsevier.
3. Artificial Intelligence in Pharma: From Drug Discovery to Patient Care by Yseop
4. Artificial Intelligence: Emerging Applications in Biotechnology and Pharma David Sahner, David C Spellmeyer. Biotechnology Entrepreneurship, 399-417, 2020
5. Daniel D. Lee AI Pharma: Artificial Intelligence in Drug Discovery and Development (Code and Compassion
6. Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again by Eric Topol



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B. PHARMACY IV YEAR COURSE STRUCTURE AND SYLLABUS

IV Year B.Pharm. II Semester

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**(23BP802d) REGULATORY REQUIREMENTS FOR MEDICAL DEVICES
INCLUDING IN VITRO DIAGNOSTICS IN INDIA
(Professional Elective – III)**

45 hours

Scope: Demonstration of safety, efficacy, and performance of the medical device and in vitro diagnostic (IVD) kit for use in humans is essential before the product can be approved for import or manufacture and marketing in the country. Medical devices are currently regulated under the definition of ‘drug’. Recent amendments made in the Rule by incorporating specific rules i.e., “Medical Devices Rules 2017” [G.S.R. 78 (E) dated the 31st January 2017] are published and are mandatory with effect from 1st January 2018.

These rules provides requirements for import, manufacture, clinical investigation, medical device and in vitro diagnostics. All these had been effectively addressed in this course.

Course Objective:

- The objective of this course is to provide students with comprehensive knowledge of medical devices and in vitro diagnostics (IVDs), including their classification, regulation, manufacturing, quality assurance, and global standards.
- The course aims to equip students with the skills to navigate regulatory frameworks, understand clinical and biocompatibility requirements, and apply quality and risk management principles in the medical device industry.

Unit I

10 hours

Introduction to Medical Devices and IVDs

- Overview of medical devices and in vitro diagnostics (IVDs)
- Types of medical devices, including combination devices
- Distinction: Drug vs. Device vs. IVD
- Introduction to Medical Device Rules, 2017
- Implications of rules on device regulation
- Classification and labeling of medical devices

Unit II

7 hours

Regulatory Framework and Classification

- Detailed review of Medical Device Rules, 2017
- Classification criteria and regulatory pathways
- Labeling requirements and regulatory compliance
- Introduction to national regulatory authorities and their roles



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B. PHARMACY IV YEAR COURSE STRUTURE AND SYLLABUS

- Registration process overview

Unit III

10 hours

Standards, Quality Assurance, and Clinical Evaluation

- Standards of medical devices (national and international)
- Quality assurance and testing procedures
- Biocompatibility studies and preclinical evaluations
- Clinical investigation requirements and protocols

Unit IV

8 hours

Manufacturing, Licensing, and Risk Management

- Overview of medical device and IVD manufacturing processes
- Quality Management Systems (QMS) in device manufacturing
- Licensing procedures for medical device manufacturing
- Risk Management Systems for medical devices (ISO 14971)

Unit V

10 hours

Inspection, Trade, and Global Regulatory Practices

- Inspection of medical device and IVD establishments
- Import and export regulations for medical devices and IVDs
- Overview of international regulatory practices (e.g., FDA, EU MDR, WHO)
- Harmonization and global acceptance of medical devices