



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Act No. 30 of 2008)

Kukatpally, Hyderabad, Telangana (India).

ACADEMIC REGULATIONS OF B.PHARM. (REGULAR/FULL TIME) STUDENTS **WITH EFFECT FROM THE ACADEMIC YEAR 2022-23 (R-22)**

1.0 Under-Graduate Degree Programme in Pharmacy

- 1.1** JNTUH offers a 4-year (8 semesters) **Bachelor of Pharmacy (B.Pharm.)** degree programme, under Choice Based Credit System (CBCS) at its affiliated colleges with effect from the academic year 2022-23.

2.0 Eligibility for admission

- 2.1** Admission to the under graduate programme shall be made either on the basis of the merit rank obtained by the qualified candidate in entrance test conducted by the Telangana State Government (EAMCET) or the University or on the basis of any other order of merit approved by the University, subject to reservations as prescribed by the government from time to time.

- 2.2** The medium of instructions for the entire under graduate programme in Pharmacy will be **English** only.

3.0 B.Pharm. Programme structure

- 3.1** A student after securing admission shall pursue the under graduate programme in B.Pharm. in a minimum period of **four** academic years (8 semesters), and a maximum period of **eight** academic years (16 semesters) starting from the date of commencement of first year first semester, failing which student shall forfeit seat in B.Pharm course.

A student shall register for all subjects for covering **209** credits and each student shall secure **209** credits (with CGPA ≥ 6) required for the completion of the under graduate programme and award of the B.Pharm. degree.

- 3.2** **UGC/ PCI** specified definitions/ descriptions are adopted appropriately for various terms and abbreviations used in these academic regulations/ norms, which are listed below.

3.2.1 Semester scheme

Each under graduate programme is of 4 academic years (8 semesters) with the academic year being divided into two semesters of **23** weeks (≥ 100 instructional days) each, each semester shall have - 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester System (CBSS) as indicated by UGC and curriculum/ course structure as suggested by PCI are followed.

3.2.2 Credit courses

All subjects/ courses are to be registered by the student in a semester to earn credits which shall be assigned to each subject/ course in an L: T: P: C (lecture periods: tutorial periods: practical periods: credits) structure based on the following general pattern.

- One credit for one hour/ week/ semester for theory/ lecture (L) courses.

- One credit for two hours/ week/ semester for laboratory/ practical (P) courses or tutorials (T).

Courses like Environmental Sciences, Human Values and Professional Ethics, Gender Sensitization Laboratory and student activities like NCC/NSO and NSS are identified as mandatory courses. These courses will not carry any credits.

3.2.3 Subject Course Classification

All subjects/ courses offered for the under graduate programme in Pharmacy (B.Pharm. degree programmes) are broadly classified as follows. The university has followed almost all the guidelines issued by PCI/UGC.

S. No.	Broad Course Classification	Course Group/ Category	Course Description
1	Foundation Courses (FnC)	BS – Basic Sciences	Includes mathematics, physics and chemistry subjects.
2		PS - Pharmaceutical Sciences	Includes fundamental Pharmacy Subjects.
3		HS – Humanities and Social sciences	Includes subjects related to humanities, social sciences and management.
4	Core Courses (CoC)	PC – Professional Core	Includes core subjects related to the parent discipline.
5	Elective Courses (EiC)	OE – Open Electives	Includes elective subjects related to inter-disciplinary areas of Pharmacy or other than Pharmacy
6	Core Courses	Project Work	B.Pharm. project or UG project or UG major project
7		Seminar	Seminar/ Colloquium based on core contents related to parent discipline.
10	Minor courses	-	1 or 2 Credit courses (subset of HS)
11	Mandatory Courses (MC)	-	Mandatory courses (non-credit)

4.0 Course registration

- 4.1 A 'faculty advisor or counselor' shall be assigned to a group of 15 students, who will advise student about the under graduate programme, its course structure and curriculum, choice/option for subjects/ courses, based on their competence, progress, pre-requisites and interest.
- 4.2 The academic section of the college invites 'registration forms' from students before the beginning of the semester through 'on-line registration', ensuring 'date and time stamping'. The on-line registration requests for any 'current semester' shall be **completed before the commencement of semester end examinations of the 'preceding semester'**.
- 4.3 A student can apply for **on-line** registration, **only after** obtaining the '**written approval**' from faculty advisor/counselor, which should be submitted to the college academic section through the Head of the Department. A copy of it shall be retained with Head of the Department, faculty advisor/ counselor and the student.
- 4.5 If the student submits ambiguous choices or multiple options or erroneous entries during **on-line** registration for the subject(s) / course(s) under a given/ specified course group/ category as listed in

the course structure, only the first mentioned subject/ course in that category will be taken into consideration.

- 4.6 Subject/ course options exercised through **on-line** registration are final and **cannot** be changed or inter-changed; further, alternate choices also will not be considered. However, if the subject/ course that has already been listed for registration by the Head of the Department in a semester could not be offered due to any unforeseen or unexpected reasons, then the student shall be allowed to have alternate choice either for a new subject (subject to offering of such a subject), or for another existing subject (subject to availability of seats). Such alternate arrangements will be made by the Head of the Department, with due notification and time-framed schedule, within the **first week** after the commencement of class-work for that semester.

- 4.7 **Open Electives:** Students have to choose one open elective (OE-I) in III year I semester, one (OE-II) in III year II semester, one (OE-III) in IV year I semester and one (OE-IV) in IV year II semester from the list of Open Electives.

5.0 Subjects/ courses to be offered

- 5.1 A typical section (or class) strength for each semester shall be 60.
- 5.2 A subject/ course may be offered to the students, **only if** a minimum of 20 students (1/3 of the section strength) opt for it. The maximum strength of a section is limited to 80 (60 + 1/3 of the section strength).
- 5.3 If more entries for registration of a subject come into picture, then the Head of Department shall decide, whether or not to offer such a subject/ course for **two (or multiple) sections**.

6.0 Attendance requirements:

- 6.1 Attendance in all Courses (Lectures/Laboratories/Seminar/Project Work) is compulsory. The minimum required attendance in aggregate of all the subjects/ courses including the attendance of mid-term examination/ Laboratory etc. is **80%**. Two periods of attendance for each theory subject shall be considered, if the student appears for the mid-term examination of that subject. A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than **80%** (excluding attendance in mandatory courses like Environmental Sciences, Human Values and Professional Ethics, Gender Sensitization Laboratory, NCC/NSO, NSS and Industrial Training) for that semester.
- 6.2 Condoning of shortage of attendance (between 70% and 80%) up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each semester shall be granted by the College Academic Committee on genuine and valid grounds, based on the student's representation with supporting evidence.
- 6.3 A stipulated fee shall be payable towards condoning of shortage of attendance.
- 6.4 Shortage of attendance below 70% in aggregate shall in **no case be condoned**.
- 6.5 **Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examinations of that semester. They get detained and their registration for that semester shall stand cancelled. They will not be promoted to the next semester.** They may seek re-registration for all those subjects registered in that semester in which student was detained, by seeking re-admission into that semester as and when offered; in case if there are any open electives, the same may also be re-registered if offered. However, if those electives are not offered in later semesters, then alternate electives may be chosen from the **same** set of elective subjects offered under that category.

- 6.6** A student fulfilling the attendance requirement in the present semester shall not be eligible for readmission into the same class.

7.0 Academic requirements

The following academic requirements have to be satisfied, in addition to the attendance requirements mentioned in item no. 6.

- 7.1** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each subject/ course, if student secures not less than 40% marks (30 out of 75 marks) in the semester end examination, and a minimum of 50% of marks in the sum total of the CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together; in terms of letter grades, this implies securing 'D' grade or above in that subject/ course. For practicals/laboratory courses, a student should secure not less than 50% of marks in the sum total of the CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together; in terms of letter grades, this implies securing 'D' grade or above.
- 7.2** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to Practice School (or) Industrial Training if the student secures not less than 50% marks (i.e. 50 out of 100 allotted marks) in each of them. The student is deemed to have failed, if he (i) does not submit a report on Practice School (or) Industrial Training, (ii) does not make a presentation of the same before the evaluation committee as per schedule, or (iii) secures less than 50% marks in Practice School (or) Industrial Training evaluations.
A student may reappear once for each of the above evaluations, when they are scheduled again; if the student fails in such 'one reappearance' evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

7.3 Promotion Rules

S. No.	Promotion	Conditions to be fulfilled
1	First year to second year	Regular course of study of first year.
2	Second year to third year	(i) Regular course of study of second year. (ii) Must have passed all the subjects/ courses up to I Year II Semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
3	Third year to fourth year	(i) Regular course of study of third year. (ii) Must have passed all the subjects/ courses up to II Year II Semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.

- 7.3** A student shall register for all subjects covering **209 credits** as specified and listed in the course structure, fulfills all the attendance and academic requirements for 209 credits, 'earn all 209 credits' by securing SGPA ≥ 6.0 (in each semester) and CGPA (at the end of each successive semester) ≥ 6.0 to successfully complete the under graduate programme.
- 7.4** After securing the necessary 209 credits as specified for the successful completion of the entire under graduate programme, the student shall be eligible to get his CGPA and shall be indicated in the grade card of IV year II semester. However, the performance of student in the earlier individual semesters, with the corresponding SGPA and CGPA for which grade cards have already been given will not be altered.

- 7.5** If a student registers for some more '**extra subjects**' other than those listed subjects totaling to **209 credits** as specified in the course structure, the performances in those '**extra subjects**' (although evaluated and graded using the same procedure as that of the required **209 credits**) will not be considered while calculating the SGPA and CGPA. For such '**extra subjects**' registered, % of marks and letter grade alone will be indicated in the grade card as a performance measure, subject to completion of the attendance and academic requirements as stated in regulations 6 and 7.1 – 7.4 above.
- 7.6** A student eligible to appear in the end semester examination for any subject/ course, but absent from it or failed (thereby failing to secure '**D**' grade or above) may reappear for that subject/ course in the supplementary examination as and when conducted. In such cases, CIE assessed earlier for that subject/ course will be carried over, and added to the marks to be obtained in the SEE supplementary examination for evaluating performance in that subject.
- 7.7** A student **detained in a semester due to shortage of attendance, may be re-admitted when the same semester is offered in the next academic year for fulfillment of academic requirements.** The academic regulations under which student has been readmitted shall be applicable. However, no grade allotments or SGPA/ CGPA calculations will be done for the entire semester in which student has been detained.
- 7.8** A student detained **due to unfulfillment of promotion rules, shall be promoted to the next academic year only after fulfilling the promotion rules.** The academic regulations under which student has been readmitted shall be applicable to him.
- Note:** (1) The SGPA will be computed and printed on the marks memo only if the candidate passes in all the subjects offered and gets minimum '**D**' grade in all the subjects.
 (2) CGPA is calculated only when the candidate passes in all the subjects offered in all the semesters.

8.0 Evaluation - Distribution and Weightage of marks

- 8.1** The performance of a student in every theory subject/course will be evaluated for 100 marks, with 25 marks allotted for CIE (Continuous Internal Evaluation) and 75 marks for SEE (Semester End-Examination).
- 8.2** In CIE, for theory subjects, during a semester, there shall be two mid-term examinations. Each Mid-Term examination consists of two parts i) **Part – A** for 10 marks, ii) **Part – B** for 10 marks with a total duration of 2 hours as follows:
1. Mid Term Examination for 20 marks:
 - a. Part - A: 10 Multiple Choice/ Objective Questions paper for 10 marks.
 - b. Part - B: Descriptive paper for 10 marks. Long Answer Questions for 5 marks (answer 1 out of 2). Short Answer Questions for 5 marks (answer 2 out of 3, each carries 2.5 marks).

While the first mid-term examination shall be conducted on 50% of the syllabus, the second mid-term examination shall be conducted on the remaining 50% of the syllabus.

Five (**5**) marks are allocated for assignments (as specified by the subject teacher concerned). The first assignment should be submitted before the conduct of the first mid-term examination, and the second assignment should be submitted before the conduct of the second mid-term examination. The average of the two assignments shall be taken as the final marks for assignment (for 5 marks).

The average of marks secured in the Two Mid-term examinations, along with the average marks secured in the two assignments will be considered as the final marks secured by a student in the CIE.

8.3 The details of the end semester question paper pattern are as follows,

- The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.
- Part-A is compulsory question which consists of fifteen sub-questions. The first ten sub-questions are of Objective type/ Multiple Choice Questions, 2 from each unit and carry 1 mark each. The next five sub-questions are Short Answer Questions one from each unit and carry 3 marks each.
- Part-B consists of five Long Answer Questions (numbered from 2 to 6) carrying 10 marks each. Each of these questions is from one unit and may contain sub-questions. For each question there will be an “either” “or” choice, which means that there will be two questions from each unit and the student should answer either of the two questions.

8.3 For practical subjects there shall be a Continuous Internal Evaluation (CIE) during the semester for 15 marks and 35 marks for semester end examination. Out of the 15 marks for internal evaluation:

1. A write-up on day-to-day experiment in the laboratory (in terms of aim, components/procedure, expected outcome) which shall be evaluated for 5 marks
2. 5 marks for viva-voce in the course concerned.
3. Internal practical examination conducted by the laboratory teacher concerned shall be evaluated for 5 marks.

The Semester End Examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University.

In the Semester End Examination held for 3 hours, total 35 marks are divided and allocated as shown below:

1. 05 marks for Synopsis
2. 25 for experiment
3. 05 marks for viva-voce on concerned laboratory course

A student has to secure 25 marks (i.e. 50% out of the 50 marks) allotted for CIE and SEE taken together.

8.4 There shall be an Industrial Training in IV year I semester. For the Industrial Training, the student shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the IV year I semester and before the commencement of IV year II semester, the student shall submit satisfactory report of the work and certificate duly signed by the authority of training organization to the head of the institute.

8.5 Practice School: In the IV year I semester, every candidate shall undergo a practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the departmental committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). The report shall be submitted to the departmental committee consisting of Head of the Institution, Head of the Department and a senior faculty member. The practice school report shall be evaluated for 100 marks and grade point shall be awarded.

- 8.6** All the students shall undertake a UG major project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book (Internal Evaluation):

Objective(s) of the work done	- 15 Marks
Methodology adopted	- 20 Marks
Results and Discussions	- 20 Marks
Conclusions and Outcomes	- 20 Marks
Total	- 75 Marks

Evaluation of Presentation (External Evaluation):

Presentation of work	- 25 Marks
Communication skills	- 20 Marks
Viva-Voce	- 30 Marks
Total	- 75 Marks

The **75 marks** assigned to the **dissertation book** shall be **same for all the students** in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria. A student has to secure 75 marks (i.e. 50% of the allotted 150 marks) to be declared successful in the project.

- 8.7** For mandatory courses Environmental Science, Human Values and Professional Ethics, Gender Sensitization Lab and Industrial Training a student has to secure 50 marks out of 100 marks (i.e. 50% of the marks allotted) in the continuous internal evaluation for passing the subject/course.
- 8.8** For mandatory courses NCC/ NSO and NSS, a 'satisfactory participation certificate' shall be issued to the student from the authorities concerned, only after securing $\geq 80\%$ attendance in such a course.
- 8.9** No marks or letter grade shall be allotted for all mandatory/non-credit courses.
- 9.0 Grading procedure**
- 9.1** Marks will be awarded to indicate the performance of student in each theory subject, laboratory / practicals and UG major project. Based on the percentage of marks obtained (Continuous Internal Evaluation plus Semester End Examination, both taken together) as specified in item 8 above, a corresponding letter grade shall be given.
- 9.2** As a measure of the performance of student, a 10-point absolute grading system using the following letter grades (as per UGC/ PCI guidelines) and corresponding percentage of marks shall be followed:

% of Marks Secured in a Subject/Course (Class Intervals)	Letter Grade (UGC Guidelines)	Grade Points
Greater than or equal to 90%	O (Outstanding)	10
80 and less than 90%	A (Excellent)	9
70 and less than 80%	B (Good)	8
60 and less than 70%	C (Fair)	7

50 and less than 60%	D (Average)	6
Below 50%	F (FAIL)	0
Absent	Ab	0

- 9.3** A student obtaining 'F' grade in any subject shall be deemed to have 'failed' and is required to reappear as a 'supplementary student' in the semester end examination, as and when offered. In such cases, internal marks in those subjects will remain the same as those obtained earlier.
- 9.4** A student who has not appeared for examination in any subject, 'Ab' grade will be allocated in that subject, and student shall be considered 'failed'. Student will be required to reappear as a 'supplementary student' in the semester end examination, as and when offered.
- 9.5** A letter grade does not indicate any specific percentage of marks secured by the student, but it indicates only the range of percentage of marks.
- 9.6** A student earns grade point (GP) in each subject/ course, on the basis of the letter grade secured in that subject/ course. The corresponding 'credit points' (CP) are computed by multiplying the grade point with credits for that particular subject/ course.

Credit points (CP) = grade point (GP) x credits For a course

- 9.7** The student passes the subject/ course only when **GP ≥ 6 ('D' grade or above)**
- 9.8** The semester grade point average (SGPA) is calculated by dividing the sum of credit points (ΣCP) secured from all subjects/ courses registered in a semester, by the total number of credits registered during that semester. SGPA is rounded off to **two** decimal places. SGPA is thus computed as

$$\text{SGPA} = \{ \sum_{i=1}^N C_i G_i \} / \{ \sum_{i=1}^N C_i \} \dots \text{For each semester,}$$

where 'i' is the subject indicator index (takes into account all subjects in a semester), 'N' is the no. of subjects 'registered' for the semester (as specifically required and listed under the course structure of the parent department), C_i is the no. of credits allotted to the i^{th} subject, and G_i represents the grade points (GP) corresponding to the letter grade awarded for that i^{th} subject.

- 9.9** The cumulative grade point average (CGPA) is a measure of the overall cumulative performance of a student in all semesters considered for registration. The CGPA is the ratio of the total credit points secured by a student in **all** registered courses in **all** semesters, and the total number of credits registered in **all** the semesters. CGPA is rounded off to **two** decimal places. CGPA is thus computed from the I year II semester onwards at the end of each semester as per the formula

$$\text{CGPA} = \{ \sum_{j=1}^M C_j G_j \} / \{ \sum_{j=1}^M C_j \} \dots \text{for all S semesters registered}$$

(i.e., up to and inclusive of S semesters, $S \geq 2$),

where 'M' is the **total** no. of subjects the student has 'registered' i.e., from the 1st semester onwards up to and inclusive of the 8th semester, 'j' is the subject indicator index (takes into account all subjects from 1 to 8 semesters), C_j is the no. of credits allotted to the j^{th} subject, and G_j represents the grade points (GP) corresponding to the letter grade awarded for that j^{th} subject. After registration and completion of first year first semester, the SGPA of that semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	9	$4 \times 9 = 36$
Course 2	4	O	10	$4 \times 10 = 40$

Course 3	4	C	7	$4 \times 7 = 28$
Course 4	3	B	8	$3 \times 8 = 24$
Course 5	3	A	10	$3 \times 10 = 30$
Course 6	3	C	7	$3 \times 7 = 21$
	Total Credits = 21			Total Credit Points = 179

$$\text{SGPA} = 179/21 = 8.52$$

Illustration of calculation of CGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	9	$4 \times 9 = 36$
Course 2	4	A	9	$4 \times 9 = 36$
Course 3	4	B	8	$4 \times 8 = 32$
Course 4	3	O	10	$3 \times 10 = 30$
Course 5	3	B	8	$3 \times 8 = 24$
Course 6	3	D	6	$3 \times 6 = 18$
I Year II Semester				
Course 7	4	B	8	$4 \times 8 = 32$
Course 8	4	O	10	$4 \times 10 = 40$
Course 9	4	A	9	$4 \times 9 = 36$
Course 10	3	D	6	$3 \times 6 = 18$
Course 11	3	C	7	$3 \times 7 = 21$
Course 12	3	A	9	$3 \times 9 = 27$
	Total Credits = 42			Total Credit Points = 350

$$\text{CGPA} = 350/42 = 8.33$$

9.10 For merit ranking or comparison purposes or any other listing, **only** the '**rounded off**' values of the CGPAs will be used.

9.11 For calculations listed in regulations 9.6 to 9.9, performance in failed subjects/ courses (securing '**F**' grade) will also be taken into account, and the credits of such subjects/ courses will also be included in the multiplications and summations. After passing the failed subject(s) newly secured letter grades will be taken into account for calculation of SGPA and CGPA. However, mandatory courses will not be taken into consideration.

10.0 Passing standards

10.1 A student shall be declared successful or 'passed' in a semester, if student secures a $\text{GP} \geq 6$ ('D' grade or above) in every subject/course in that semester (i.e. when student gets an $\text{SGPA} \geq 6.00$ at the end of that particular semester); and a student shall be declared successful or 'passed' in the entire under graduate programme, only when gets a $\text{CGPA} \geq 6.00$ for the award of the degree as required.

10.2 After the completion of each semester, a grade card or grade sheet (or transcript) shall be issued to all the registered students of that semester, indicating the letter grades and credits earned. It will

show the details of the courses registered (course code, title, no. of credits, and grade earned etc.), credits earned, SGPA, and CGPA.

11.0 Declaration of results

11.1 Computation of SGPA and CGPA are done using the procedure listed in 9.6 to 9.9.

11.2 For final percentage of marks equivalent to the computed final CGPA, the following formula may be used.

$$\% \text{ of Marks} = (\text{final CGPA} - 0.5) \times 10$$

12.0 Award of degree

12.1 A student who registers for all the specified subjects/ courses as listed in the course structure and secures the required number of 209 credits (with CGPA ≥ 6.0), within 8 academic years from the date of commencement of the first academic year, shall be declared to have '**qualified**' for the award of the B.Pharm. degree.

12.2 A student who qualifies for the award of the degree as listed in item 12.1 shall be placed in the following classes.

12.3 Students with final CGPA (at the end of the under graduate programme) ≥ 7.50 , and fulfilling the following conditions -

- (i) Should have passed all the subjects/courses in '**first appearance**' within the first 4 academic years (or 8 sequential semesters) from the date of commencement of first year first semester.
- (ii) Should not have been detained or prevented from writing the end semester examinations in any semester due to shortage of attendance or any other reason, shall be placed in '**first class with distinction**'.

12.4 Students with final CGPA (at the end of the under graduate programme) ≥ 6.00 but < 7.50 , shall be placed in '**first class**'.

12.5 Students with final CGPA (at the end of the under graduate programme) ≥ 5.00 but < 6.00 , shall be placed in '**second class**'.

12.6 A student with final CGPA (at the end of the under graduate programme) < 5.00 will not be eligible for the award of the degree.

12.7 Students fulfilling the conditions listed under item 12.3 alone will be eligible for award of '**university rank**' and '**gold medal**'.

13.0 Withholding of results

13.1 If the student has not paid the fees to the university/ college at any stage, or has dues pending due to any reason whatsoever, or if any case of indiscipline is pending, the result of the student may be withheld, and student will not be allowed to go into the next higher semester. The award or issue of the degree may also be withheld in such cases.

14.0 Transitory regulations

A. For students detained due to shortage of attendance:

1. A Student who has been detained in I year of R15/R16/R17 Regulations due to lack of attendance, shall be permitted to join I year I Semester of R22 Regulations and he is required to complete the

study of B. Pharmacy programme within the stipulated period of eight academic years from the date of first admission in I Year.

2. A student who has been detained in any semester of II, III and IV years of R15/R16/R17 regulations for want of attendance, shall be permitted to join the corresponding semester of R22 regulations and is required to complete the study of B. Pharmacy within the stipulated period of eight academic years from the date of first admission in I Year. The R22 Academic Regulations under which a student has been readmitted shall be applicable to that student from that semester.

See rule (C) for further Transitory Regulations.

B. For students detained due to shortage of credits:

3. A student of R15/R16/R17 Regulations who has been detained due to lack of credits, shall be promoted to the next semester of R22 Regulations only after acquiring the required credits as per the corresponding regulations of his/her first admission. The student is required to complete the study of B. Pharmacy within the stipulated period of eight academic years from the year of first admission. The R22 Academic Regulations are applicable to a student from the year of readmission onwards.

See rule (C) for further Transitory Regulations.

C. For readmitted students in R22 Regulations:

4. A student who has failed in any subject under any regulation has to pass those subjects in the same regulations.
5. The maximum credits that a student acquires for the award of degree, shall be the sum of the total number of credits secured in all the regulations of his/her study including R22 Regulations.
6. If a student readmitted to R22 Regulations, has any subject with 80% of syllabus common with his/her previous regulations, that particular subject in R22 Regulations will be substituted by another subject to be suggested by the University.

Note: If a student readmitted to R22 Regulations, has not studied any subjects/topics in his/her earlier regulations of study which is prerequisite for further subjects in R22 Regulations, the College Principals concerned shall conduct remedial classes to cover those subjects/ topics for the benefit of the students.

15.0 Student transfers

15.1 There shall be no transfers from one college to another within the constituent colleges and units of Jawaharlal Nehru Technological University Hyderabad.

15.3 The students seeking transfer to colleges affiliated to JNTUH from various other Universities/institutions have to pass the failed subjects which are equivalent to the subjects of JNTUH, and also pass the subjects of JNTUH which the students have not studied at the earlier institution. Further, though the students have passed some of the subjects at the earlier institutions, if the same subjects are prescribed in different semesters of JNTUH, the students have to study those subjects in JNTUH in spite of the fact that those subjects are repeated.

15.4 The transferred students from other Universities/institutions to JNTUH affiliated colleges who are on rolls to be provide one chance to write the CBT (internal marks) in the **failed subjects and/or subjects not studied** as per the clearance letter issued by the university.

15.5 The autonomous affiliated colleges have to provide one chance to write the internal examinations in the **failed subjects and/or subjects not studied**, to the students transferred from other universities/institutions to JNTUH autonomous affiliated colleges who are on rolls, as per the clearance (equivalence) letter issued by the University.

16.0 Scope

- 16.1** The academic regulations should be read as a whole, for the purpose of any interpretation.
- 16.2** In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- 16.3** The university may change or amend the academic regulations, course structure or syllabi at any time, and the changes or amendments made shall be applicable to all students with effect from the date notified by the university authorities.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
(Established by Act No. 30 of 2008)
Kukatpally, Hyderabad, Telangana (India).

Academic Regulations for B.Pharm. (Lateral Entry Scheme) w.e.f the AY 2023-24

1. Eligibility for award of B. Pharm. Degree (LES)

The LES students after securing admission shall pursue a course of study for not less than three academic years and not more than six academic years.

2. The student shall register for 153 credits and secure 153 credits with CGPA $\geq$ 6.00 from II year to IV year B.Pharm. programme (LES) for the award of B.Pharm. degree.
3. The students, who fail to fulfil the requirement for the award of the degree in six academic years from the year of admission, shall forfeit their seat in B.Pharm.
4. The attendance requirements of B. Pharm. (Regular) shall be applicable to B.Pharm. (LES).

5. Promotion rule

S. No	Promotion	Conditions to be fulfilled
1	Second year to third year	Regular course of study of second year.
2	Third Year to fourth year	(i) Regular course of study of third year. (ii) Must have passed all the subjects/ courses up to II Year II Semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.

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

MALPRACTICES RULES

DISCIPLINARY ACTION FOR / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractice/Improper conduct	Punishment
	If the student:	
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 student is appearing but has not made use of (material shall include any marks on the body of the student 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 student orally or by any other body language methods or communicates through cell phones with any student 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 students 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 student is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the student has already appeared including practical examinations and UG major project and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The hall ticket of the student is to be cancelled and sent to the university.
3.	Impersonates any other student in connection with the examination.	The student who has impersonated shall be expelled from examination hall. The student is also debarred and forfeits the seat. The performance of the original student who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and UG major project) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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.
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	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 student(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The students also are debarred and forfeit their seats. In case of outsiders, they will be

	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.	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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred and forfeits the seat.
9.	If student of the college, who is not a student 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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student 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 student has already appeared including practical examinations and UG major project 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 and all other subjects the student has appeared including practical examinations and UG major project of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall	

	be reported to the university for further action to award suitable punishment.	
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Malpractices identified by squad or special invigilators

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

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Act No. 30 of 2008)

Kukatpally, Hyderabad, Telangana (India).

ACADEMIC REGULATIONS OF B.PHARM. (REGULAR/FULL TIME) STUDENTS

WITH EFFECT FROM THE ACADEMIC YEAR 2017-18 (R-17)

1.0 Under-Graduate Degree Programme in Pharmacy

- 1.1 JNTUH offers a 4-year (8 semesters) **Bachelor of Pharmacy** (B.Pharm.) degree programme, under Choice Based Credit System (CBCS) at its affiliated colleges with effect from the academic year 2017-18.

2.0 Eligibility for admission

- 2.1 Admission to the under graduate programme shall be made either on the basis of the merit rank obtained by the qualified candidate in entrance test conducted by the Telangana State Government (EAMCET) or the University or on the basis of any other order of merit approved by the University, subject to reservations as prescribed by the government from time to time.
- 2.2 The medium of instructions for the entire under graduate programme in Pharmacy will be **English** only.

3.0 B.Pharm. Programme structure

- 3.1 A student after securing admission shall pursue the under graduate programme in B.Pharm. in a minimum period of **four** academic years (8 semesters), and a maximum period of **eight** academic years (16 semesters) starting from the date of commencement of first year first semester, failing which student shall forfeit seat in B.Pharm course.

A student shall register for all subjects for covering 196 credits and each student shall secure 196 credits (with CGPA ≥ 5) required for the completion of the under graduate programme and award of the B.Pharm. degree.

- 3.2 UGC/ AICTE specified definitions/ descriptions are adopted appropriately for various terms and abbreviations used in these academic regulations/ norms, which are listed below.

3.2.1 Semester scheme

Each under graduate programme is of 4 academic years (8 semesters) with the academic year being divided into two semesters of 22 weeks (≥ 90 instructional days) each, each semester shall have - 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester

System (CBSS) as indicated by UGC and curriculum / course structure as suggested by AICTE are followed.

3.2.2 Credit courses

All subjects/ courses are to be registered by the student in a semester to earn credits which shall be assigned to each subject/ course in an L: T: P: C (lecture periods: tutorial periods: practical periods: credits) structure based on the following general pattern.

- One credit for one hour/ week/ semester for theory/ lecture (L) courses.
- One credit for two hours/ week/ semester for laboratory/ practical (P) courses or tutorials (T).

Courses like environmental science, human values and professional ethics, gender sensitization lab and other student activities like NCC/NSO and NSS are identified as mandatory courses. These courses will not carry any credits.

3.2.3 Subject Course Classification

All subjects/ courses offered for the under graduate programme in Pharmacy (B.Pharm. degree programmes) are broadly classified as follows. The university has followed almost all the guidelines issued by AICTE/UGC.

S. No.	Broad Course Classification	Course Group/ Category	Course Description
1	Foundation Courses (FnC)	BS – Basic Sciences	Includes mathematics, physics and chemistry subjects.
2		PS - Pharmaceutical Sciences	Includes fundamental Pharmacy Subjects.
3		HS – Humanities and Social sciences	Includes subjects related to humanities, social sciences and management.
4	Core Courses (CoC)	PC – Professional Core	Includes core subjects related to the parent discipline.
5	Elective Courses (ElC)	OE – Open Electives	Includes elective subjects related to inter-disciplinary areas of Pharmacy or other than Pharmacy
6	Core Courses	Project Work	B.Pharm. project or UG project or UG major project
7		Seminar	Seminar/ Colloquium based on core contents related to parent discipline.
10	Minor courses	-	1 or 2 Credit courses (subset of HS)
11	Mandatory Courses (MC)	-	Mandatory courses (non-credit)

4.0 Course registration

- 4.1 A 'faculty advisor or counselor' shall be assigned to a group of 15 students, who will advise student about the under graduate programme, its course structure and curriculum, choice/option for subjects/ courses, based on their competence, progress, pre-requisites and interest.
- 4.2 The academic section of the college invites 'registration forms' from students before the beginning of the semester through 'on-line registration', ensuring 'date and time stamping'. The on-line registration requests for any 'current semester' shall be **completed before the commencement of semester end examinations of the 'preceding semester'**.
- 4.3 A student can apply for **on-line** registration, **only after** obtaining the '**written approval**' from faculty advisor/counselor, which should be submitted to the college academic section through the Head of the Department. A copy of it shall be retained with Head of the Department, faculty advisor/ counselor and the student.
- 4.4 If the student submits ambiguous choices or multiple options or erroneous entries during **on-line** registration for the subject(s) / course(s) under a given/ specified course group/ category as listed in the course structure, only the first mentioned subject/ course in that category will be taken into consideration.
- 4.5 Subject/ course options exercised through **on-line** registration are final and **cannot** be changed or inter-changed; further, alternate choices also will not be considered. However, if the subject/ course that has already been listed for registration by the Head of the Department in a semester could not be offered due to any unforeseen or unexpected reasons, then the student shall be allowed to have alternate choice either for a new subject (subject to offering of such a subject), or for another existing subject (subject to availability of seats). Such alternate arrangements will be made by the Head of the Department, with due notification and time-framed schedule, within the **first week** after the commencement of class-work for that semester.
- 4.6 **Open Electives:** Students have to choose one open elective (OE-I) in II year II semester, one (OE-II) in III year I semester, and one (OE-III) in III year II semester and one (OE-IV) in IV year II semester from the list of Open Electives.

5.0 Subjects/ courses to be offered

- 5.1 A typical section (or class) strength for each semester shall be 60.
- 5.2 A subject/ course may be offered to the students, **only if** a minimum of 20 students (1/3 of the section strength) opt for it. The maximum strength of a section is limited to 80 (60 + 1/3 of the section strength).
- 5.3 If more entries for registration of a subject come into picture, then the Head of Department concerned shall decide, whether or not to offer such a subject/ course for **two (or multiple) sections**.

6.0 Attendance requirements:

- 6.1** Attendance in all classes (Lectures/Laboratories/Project Work) is compulsory. The minimum required attendance in aggregate of all the subjects/ courses including the attendance of mid-term examination / Laboratory etc. is 75%. Two periods of attendance for each theory subject shall be considered, if the student appears for the mid-term examination of that subject. A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than 75% (excluding attendance in mandatory courses environmental science, human values and professional ethics, gender sensitization Lab, NCC/NSO, NSS and Industrial Training) for that semester.
- 6.2** Condoning of shortage of attendance (between 65% and 75%) up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each semester shall be granted by the College Academic Committee on genuine and valid grounds, based on the student's representation with supporting evidence.
- 6.3** A stipulated fee shall be payable towards condoning of shortage of attendance.
- 6.4** Shortage of attendance below 65% in aggregate shall in **no case be condoned**.
- 6.5** Students whose shortage of attendance is not condoned in any semester are not eligible to take their end examinations of that semester. They get detained and their registration for that semester shall stand cancelled. They will not be promoted to the next semester. They may seek re-registration for all those subjects registered in that semester in which student was detained, by seeking re-admission into that semester as and when offered; in case if there are any open electives, the same may also be re-registered if offered. However, if those electives are not offered in later semesters, then alternate electives may be chosen from the **same** set of elective subjects offered under that category.
- 6.6** A student fulfilling the attendance requirement in the present semester shall not be eligible for readmission into the same class.

7.0 Academic requirements

The following academic requirements have to be satisfied, in addition to the attendance requirements mentioned in item no.6.

- 7.1** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each subject/ course, if student secures not less than 35% marks (26 out of 75 marks) in the semester end examination, and a minimum of 40% of marks in the sum total of the CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together; in terms of letter grades, this implies securing 'C' grade or above in that subject/ course.

7.2 Promotion Rules

S. No.	Promotion	Conditions to be fulfilled
1	First year first semester to first year second semester	Regular course of study of first year first semester.

2	First year second semester to second year first semester	(i) Regular course of study of first year second semester. (ii) Must have secured at least 24 credits out of 48 credits i.e., 50% of credits up to first year second semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
3.	Second year first semester to second year second semester	Regular course of study of second year first semester.
4	Second year second semester to third year first semester	(i) Regular course of study of second year second semester. (ii) Must have secured at least 58 credits out of 96 credits i.e., 60% of credits up to second year second semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
5	Third year first semester to third year second semester	Regular course of study of third year first semester.
6	Third year second semester to fourth year first semester	(i) Regular course of study of third year second semester. (ii) Must have secured at least 86 credits out of 144 credits i.e., 60% of credits up to third year second semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
7	Fourth year first semester to fourth year second semester	Regular course of study of fourth year first semester.

- 7.3** A student shall register for all subjects covering 196 credits as specified and listed in the course structure, fulfills all the attendance and academic requirements for 196 credits, 'earn all 196 credits' by securing SGPA ≥ 5.0 (in each semester) and CGPA (at the end of each successive semester) ≥ 5.0 to successfully complete the under graduate programme.
- 7.4** After securing the necessary 196 credits as specified for the successful completion of the entire under graduate programme, the student can avail exemption of two subjects up to 6 credits, that is, two open elective subjects for optional drop out from these 196 credits earned; resulting in 190 credits for under graduate programme performance evaluation, i.e., the performance of the student in these 190 credits shall alone be taken into account for the calculation of 'the final CGPA (at the end of under graduate programme, which takes the SGPA of the IV year II semester into account), and shall be indicated in the

grade card of IV year II semester. However, the performance of student in the earlier individual semesters, with the corresponding SGPA and CGPA for which grade cards have already been given will not be altered.

- 7.5** If a student registers for some more '**extra subjects**' other than those listed subjects totaling to 196 credits as specified in the course structure, the performances in those '**extra subjects**' (although evaluated and graded using the same procedure as that of the required 196 credits) will not be taken into account while calculating the SGPA and CGPA. For such '**extra subjects**' registered, % of marks and letter grade alone will be indicated in the grade card as a performance measure, subject to completion of the attendance and academic requirements as stated in regulations 6 and 7.1 – 7.4 above.
- 7.6** A student eligible to appear in the end semester examination for any subject/ course, but absent from it or failed (thereby failing to secure '**C**' grade or above) may reappear for that subject/ course in the supplementary examination as and when conducted. In such cases, CIE assessed earlier for that subject/ course will be carried over, and added to the marks to be obtained in the SEE supplementary examination for evaluating performance in that subject.
- 7.7** A student **detained in a semester due to shortage of attendance, may be re-admitted when the same semester is offered in the next academic year for fulfillment of academic requirements.** The academic regulations under which student has been readmitted shall be applicable. However, no grade allotments or SGPA/ CGPA calculations will be done for the entire semester in which student has been detained.
- 7.8** A student detained **due to lack of credits, shall be promoted to the next academic year only after acquiring the required academic credits.** The academic regulations under which student has been readmitted shall be applicable to him.

Note: (1) The SGPA will be computed and printed on the marks memo only if the candidate passes in all the subjects offered and gets minimum B grade in all the subjects.

(2) CGPA is calculated only when the candidate passes in all the subjects offered in all the semesters.

8.0 Evaluation - Distribution and Weightage of marks

- 8.1** The performance of a student in every subject/course (including practicals and UG major project) will be evaluated for 100 marks each, with 25 marks allotted for CIE (Continuous Internal Evaluation) and 75 marks for SEE (Semester End-Examination).
- 8.2** For theory subjects, during a semester, there shall be two mid-term examinations. Each mid-term examination consists of one objective paper, one descriptive paper and one assignment. The objective paper and the essay paper shall be for 10 marks each with a total duration of 1 hour 20 minutes (20 minutes for objective and 60 minutes for essay paper). The objective paper is set with 20 bits of multiple choice, fill-in the blanks and matching type of questions for a total of 10 marks. The essay paper shall contain 4 full

questions out of which, the student has to answer 2 questions, each carrying 5 marks. While the first mid-term examination shall be conducted on 50% of the syllabus, the second mid-term examination shall be conducted on the remaining 50% of the syllabus. Five marks are allocated for assignments (as specified by the subject teacher concerned). The first assignment should be submitted before the conduct of the first mid-examination, and the second assignment should be submitted before the conduct of the second mid-examination. The total marks secured by the student in each mid-term examination are evaluated for 25 marks, and the average of the two mid-term examinations shall be taken as the final marks secured by each student in internals/sessionals. If any student is absent from any subject of a mid-term examination, an on-line test will be conducted for him by the university. The details of the question paper pattern are as follows,

- The end semester examinations will be conducted for 75 marks consisting of two parts viz. i) **Part- A** for 25 marks, ii) **Part - B** for 50 marks.
- Part-A is compulsory question which consists of ten sub-questions. The first five sub-questions are from each unit and carry 2 marks each. The next five sub-questions are one from each unit and carry 3 marks each.
- Part-B consists of five questions (numbered from 2 to 6) carrying 10 marks each. Each of these questions is from one unit and may contain sub-questions. For each question there will be an “either” “or” choice, which means that there will be two questions from each unit and the student should answer either of the two questions.

8.3 For practical subjects there shall be a continuous internal evaluation during the semester for 25 sessional marks and 75 semester end examination marks. Out of the 25 marks for internal evaluation, day-to-day work in the laboratory shall be evaluated for 15 marks and internal practical examination shall be evaluated for 10 marks conducted by the laboratory teacher concerned. The semester end examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the clusters of colleges which are decided by the examination branch of the university.

8.4 There shall be an Industrial Training in IV year I semester. For the Industrial Training, the student shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the IV year I semester and before the commencement of IV year II semester, the student shall submit satisfactory report of the work and certificate duly signed by the authority of training organization to the head of the institute.

8.5 Practice School: In the IV year I semester, every candidate shall undergo a practice school for a period of 150 hours evenly distributed throughout the semester. The student

shall opt any one of the domains for practice school declared by the departmental committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). The report shall be submitted to the departmental committee consisting of Head of the Institution, Head of the Department and a senior faculty member. The practice school report shall be evaluated for 100 marks and grade point shall be awarded.

- 8.6** Out of a total of 100 marks for the UG major project, 25 marks shall be allotted for internal evaluation and 75 marks for the end semester examination (viva voce). The end semester examination of the project work shall be conducted by a committee consisting of external examiner, Head of the Department, supervisor of the project and a senior faculty member. The evaluation of UG major project shall be made at the end of IV year II semester. The internal evaluation shall be on the basis of two seminars given by each student on the topic of UG major project.
- 8.7** The laboratory marks and the sessional marks awarded by the college are subject to scrutiny and scaling by the university wherever necessary. In such cases, the sessional and laboratory marks awarded by the college will be referred to a committee. The committee will arrive at a scaling factor and the marks will be scaled accordingly. The recommendations of the committee are final and binding. The laboratory records and internal test papers shall be preserved in the respective institutions as per the university rules and produced before the committees of the university as and when asked for.
- 8.8** For mandatory courses environmental science, human values and professional ethics, gender sensitization lab and Industrial Training a student has to secure 40 marks out of 100 marks (i.e. 40% of the marks allotted) in the continuous internal evaluation for passing the subject/course.
- 8.9** For mandatory courses NCC/ NSO and NSS, a 'satisfactory participation certificate' shall be issued to the student from the authorities concerned, only after securing $\geq 65\%$ attendance in such a course.
- 8.10** No marks or letter grade shall be allotted for all mandatory/non-credit courses.

9.0 Grading procedure

- 9.1** Marks will be awarded to indicate the performance of student in each theory subject, laboratory / practicals and UG major project. Based on the percentage of marks obtained (Continuous Internal Evaluation plus Semester End Examination, both taken together) as specified in item 8 above, a corresponding letter grade shall be given.
- 9.2** As a measure of the performance of student, a 10-point absolute grading system using the following letter grades (as per UGC/AICTE guidelines) and corresponding percentage of marks shall be followed:

% of Marks Secured in a Subject/Course (Class Intervals)	Letter Grade (UGC Guidelines)	Grade Points
Greater than or equal to 90%	O (Outstanding)	10

80 and less than 90%	A ⁺ (Excellent)	9
70 and less than 80%	A (Very Good)	8
60 and less than 70%	B ⁺ (Good)	7
50 and less than 60%	B (Average)	6
40 and less than 50%	C (Pass)	5
Below 40%	F (FAIL)	0
Absent	Ab	0

- 9.3 A student obtaining ‘F’ grade in any subject shall be deemed to have ‘failed’ and is required to reappear as a ‘supplementary student’ in the semester end examination, as and when offered. In such cases, internal marks in those subjects will remain the same as those obtained earlier.
- 9.4 A student who has not appeared for examination in any subject, ‘Ab’ grade will be allocated in that subject, and student shall be considered ‘failed’. Student will be required to reappear as a ‘supplementary student’ in the semester end examination, as and when offered.
- 9.5 A letter grade does not indicate any specific percentage of marks secured by the student, but it indicates only the range of percentage of marks.
- 9.6 A student earns grade point (GP) in each subject/ course, on the basis of the letter grade secured in that subject/ course. The corresponding ‘credit points’ (CP) are computed by multiplying the grade point with credits for that particular subject/ course.

Credit points (CP) = grade point (GP) x credits For a course

- 9.7 The student passes the subject/ course only when **GP ≥ 5** (‘C’ grade or above)
- 9.8 The semester grade point average (SGPA) is calculated by dividing the sum of credit points (ΣCP) secured from all subjects/ courses registered in a semester, by the total number of credits registered during that semester. SGPA is rounded off to **two** decimal places. SGPA is thus computed as

$$SGPA = \{ \sum_{i=1}^N C_i G_i \} / \{ \sum_{i=1}^N C_i \} \dots \text{For each semester,}$$

where ‘i’ is the subject indicator index (takes into account all subjects in a semester), ‘N’ is the no. of subjects ‘**registered**’ for the semester (as specifically required and listed under the course structure of the parent department), C_i is the no. of credits allotted to the i^{th} subject, and G_i represents the grade points (GP) corresponding to the letter grade awarded for that i^{th} subject.

- 9.9 The cumulative grade point average (CGPA) is a measure of the overall cumulative performance of a student in all semesters considered for registration. The CGPA is the ratio of the total credit points secured by a student in **all** registered courses in **all** semesters, and the total number of credits registered in **all** the semesters. CGPA is rounded off to **two** decimal places. CGPA is thus computed from the I year II semester onwards at the end of each semester as per the formula

$$CGPA = \{ \sum_{j=1}^M C_j G_j \} / \{ \sum_{j=1}^M C_j \} \dots \text{for all S semesters registered}$$

(i.e., up to and inclusive of S semesters, $S \geq 2$),

where ‘M’ is the **total** no. of subjects the student has ‘**registered**’ i.e., from the 1st semester onwards up to and inclusive of the 8th semester, ‘j’ is the subject indicator index (takes into account all subjects from 1 to 8 semesters), C_j is the no. of credits allotted to the jth subject, and G_j represents the grade points (GP) corresponding to the letter grade awarded for that jth subject. After registration and completion of first year first semester, the SGPA of that semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	8	$4 \times 8 = 32$
Course 2	4	O	10	$4 \times 10 = 40$
Course 3	4	C	5	$4 \times 5 = 20$
Course 4	3	B	6	$3 \times 6 = 18$
Course 5	3	A+	9	$3 \times 9 = 27$
Course 6	3	C	5	$3 \times 5 = 15$
	Total Credits = 21			Total Credit Points = 152

$$\text{SGPA} = 152/21 = 7.24$$

Illustration of calculation of CGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	8	$4 \times 8 = 32$
Course 2	4	A+	9	$4 \times 9 = 36$
Course 3	4	B	6	$4 \times 6 = 24$
Course 4	3	O	10	$3 \times 10 = 30$
Course 5	3	B+	7	$3 \times 7 = 21$
Course 6	3	A	8	$3 \times 8 = 24$
I Year II Semester				
Course 7	4	B+	7	$4 \times 7 = 28$
Course 8	4	O	10	$4 \times 10 = 40$
Course 9	4	A	8	$4 \times 8 = 32$
Course 10	3	B	6	$3 \times 6 = 18$
Course 11	3	C	5	$3 \times 5 = 15$
Course 12	3	A+	9	$3 \times 9 = 27$
	Total Credits = 42			Total Credit Points = 327

$$\text{CGPA} = 327/42 = 7.79$$

9.10 For merit ranking or comparison purposes or any other listing, **only** the ‘**rounded off**’ values of the CGPAs will be used.

9.11 For calculations listed in regulations 9.6 to 9.9, performance in failed subjects/ courses (securing **F** grade) will also be taken into account, and the credits of such subjects/ courses will also be included in the multiplications and summations. After passing the failed subject(s) newly secured letter grades will be taken into account for calculation of SGPA and CGPA. However, mandatory courses will not be taken into consideration.

10.0 Passing standards

10.1 A student shall be declared successful or ‘passed’ in a semester, if student secures a $GP \geq 5$ (‘C’ grade or above) in every subject/course in that semester (i.e. when student gets an $SGPA \geq 5.00$ at the end of that particular semester); and a student shall be declared successful or ‘passed’ in the entire under graduate programme, only when gets a $CGPA \geq 5.00$ for the award of the degree as required.

10.2 After the completion of each semester, a grade card or grade sheet (or transcript) shall be issued to all the registered students of that semester, indicating the letter grades and credits earned. It will show the details of the courses registered (course code, title, no. of credits, and grade earned etc.), credits earned, SGPA, and CGPA.

11.0 Declaration of results

11.1 Computation of SGPA and CGPA are done using the procedure listed in 9.6 to 9.9.

11.2 For final percentage of marks equivalent to the computed final CGPA, the following formula may be used.

$$\% \text{ of Marks} = (\text{final CGPA} - 0.5) \times 10$$

12.0 Award of degree

12.1 A student who registers for all the specified subjects/ courses as listed in the course structure and secures the required number of 196 credits (with $CGPA \geq 5.0$), within 8 academic years from the date of commencement of the first academic year, shall be declared to have ‘**qualified**’ for the award of the B.Pharm. degree.

12.2 A student who qualifies for the award of the degree as listed in item 12.1 shall be placed in the following classes.

12.3 Students with final CGPA (at the end of the under graduate programme) ≥ 8.00 , and fulfilling the following conditions -

- (i) Should have passed all the subjects/courses in ‘**first appearance**’ within the first 4 academic years (or 8 sequential semesters) from the date of commencement of first year first semester.
- (ii) Should have secured a $CGPA \geq 8.00$, at the end of each of the 8 sequential semesters, starting from first year first semester onwards.

- (iii) Should not have been detained or prevented from writing the end semester examinations in any semester due to shortage of attendance or any other reason, shall be placed in **‘first class with distinction’**.
- 12.4** Students with final CGPA (at the end of the under graduate programme) ≥ 6.50 but < 8.00 , shall be placed in **‘first class’**.
- 12.5** Students with final CGPA (at the end of the under graduate programme) ≥ 5.50 but < 6.50 , shall be placed in **‘second class’**.
- 12.6** All other students who qualify for the award of the degree (as per item 12.1), with final CGPA (at the end of the under graduate programme) ≥ 5.00 but < 5.50 , shall be placed in **‘pass class’**.
- 12.7** A student with final CGPA (at the end of the under graduate programme) < 5.00 will not be eligible for the award of the degree.
- 12.8** Students fulfilling the conditions listed under item 12.3 alone will be eligible for award of **‘university rank’** and **‘gold medal’**.
- 13.0 Withholding of results**
- 13.1** If the student has not paid the fees to the university/ college at any stage, or has dues pending due to any reason whatsoever, or if any case of indiscipline is pending, the result of the student may be withheld, and student will not be allowed to go into the next higher semester. The award or issue of the degree may also be withheld in such cases.
- 14.0 Transitory regulations**
- A. For students detained due to shortage of attendance:**
1. A Student who has been detained in I year of R09/R13/R15/R16 Regulations due to lack of attendance, shall be permitted to join I year I Semester of R17 Regulations and he is required to complete the study of B. Pharmacy programme within the stipulated period of eight academic years from the date of first admission in I Year.
 2. A student who has been detained in any semester of II, III and IV years of R09/R13/R15/R16 regulations for want of attendance, shall be permitted to join the corresponding semester of R17 regulations and is required to complete the study of B. Pharmacy within the stipulated period of eight academic years from the date of first admission in I Year. The R17 Academic Regulations under which a student has been readmitted shall be applicable to that student from that semester.
- See rule (C) for further Transitory Regulations.
- B. For students detained due to shortage of credits:**
3. A student of R09/R13/R15/R16 Regulations who has been detained due to lack of credits, shall be promoted to the next semester of R17 Regulations only after acquiring the required credits as per the corresponding regulations of his/her first admission. The student is required to complete the study of B. Pharmacy within the stipulated period of

eight academic years from the year of first admission. The R17 Academic Regulations are applicable to a student from the year of readmission onwards.

See rule (C) for further Transitory Regulations.

C. For readmitted students in R17 Regulations:

4. A student who has failed in any subject under any regulation has to pass those subjects in the same regulations.
5. The maximum credits that a student acquires for the award of degree, shall be the sum of the total number of credits secured in all the regulations of his/her study including R17 Regulations. The performance evaluation of the student will be done after the exemption of two subjects if total credits acquired are ≤ 206 , three subjects if total credits acquired are > 206 (see R17 Regulations for exemption details).
6. If a student readmitted to R17 Regulations, has any subject with 80% of syllabus common with his/her previous regulations, that particular subject in R17 Regulations will be substituted by another subject to be suggested by the University.

Note: If a student readmitted to R17 Regulations, has not studied any subjects/topics in his/her earlier regulations of study which is prerequisite for further subjects in R17 Regulations, the College Principals concerned shall conduct remedial classes to cover those subjects/topics for the benefit of the students.

15.0 Student transfers

- 15.1** There shall be no branch transfers after the completion of admission process.
- 15.2** There shall be no transfers from one college/stream to another within the constituent colleges and units of Jawaharlal Nehru Technological University Hyderabad.
- 15.3** The students seeking transfer to colleges affiliated to JNTUH from various other Universities/institutions have to pass the failed subjects which are equivalent to the subjects of JNTUH, and also pass the subjects of JNTUH which the students have not studied at the earlier institution. Further, though the students have passed some of the subjects at the earlier institutions, if the same subjects are prescribed in different semesters of JNTUH, the students have to study those subjects in JNTUH in spite of the fact that those subjects are repeated.
- 15.4** The transferred students from other Universities/institutions to JNTUH affiliated colleges who are on rolls to be provide one chance to write the CBT (internal marks) in the **failed subjects and/or subjects not studied** as per the clearance letter issued by the university.
- 15.5** The autonomous affiliated colleges have to provide one chance to write the internal examinations in the **failed subjects and/or subjects not studied**, to the students transferred from other universities/institutions to JNTUH autonomous affiliated colleges who are on rolls, as per the clearance (equivalence) letter issued by the University.

16.0 Scope

- 16.1 The academic regulations should be read as a whole, for the purpose of any interpretation.
- 16.2 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- 16.3 The university may change or amend the academic regulations, course structure or syllabi at any time, and the changes or amendments made shall be applicable to all students with effect from the date notified by the university authorities.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Act No. 30 of 2008)

Kukatpally, Hyderabad, Telangana (India).

Academic Regulations for B.Pharm. (Lateral Entry Scheme) w.e.f the AY 2018-19

1. Eligibility for award of B. Pharm. Degree (LES)

The LES students after securing admission shall pursue a course of study for not less than three academic years and not more than six academic years.

2. The student shall register for 147 credits and secure 147 credits with CGPA ≥ 5 from II year to IV year B.Pharm. programme (LES) for the award of B.Pharm. degree. **Out of the 147 credits secured, the student can avail exemption up to 6 credits**, that is, two open elective subjects resulting in 141 credits for B.Pharm programme performance evaluation.
3. The students, who fail to fulfil the requirement for the award of the degree in six academic years from the year of admission, shall forfeit their seat in B.Pharm.
4. The attendance requirements of B. Pharm. (Regular) shall be applicable to B.Pharm. (LES).

5. Promotion rule

S. No	Promotion	Conditions to be fulfilled
1	Second year first semester to second year second semester	Regular course of study of second year first semester.
2	Second year second semester to third year first semester	(i) Regular course of study of second year second semester. (ii) Must have secured at least 29 credits out of 48 credits i.e., 60% of credits up

		to second year second semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
3	Third year first semester to third year second semester	Regular course of study of third year first semester.
4	Third year second semester to fourth year first semester	(i) Regular course of study of third year second semester. (ii) Must have secured at least 58 credits out of 96 credits i.e., 60% of credits up to third year second semester from all the relevant regular and supplementary examinations, whether the student takes those examinations or not.
5	Fourth year first semester to fourth year second semester	Regular course of study of fourth year first semester.

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

MALPRACTICES RULES

DISCIPLINARY ACTION FOR / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractice/Improper conduct	Punishment
	If the student:	
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 student is appearing but has not made use of (material shall include any marks on the body of the student 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 student orally or by any other body language methods or	Expulsion from the examination hall and cancellation of the performance in that subject only of all the students involved. In case of an

	communicates through cell phones with any student or persons in or outside the exam hall in respect of any matter.	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 student is appearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the student has already appeared including practical examinations and UG major project and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The hall ticket of the student is to be cancelled and sent to the university.
3.	Impersonates any other student in connection with the examination.	The student who has impersonated shall be expelled from examination hall. The student is also debarred and forfeits the seat. The performance of the original student who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and UG major project) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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.

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 student(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The students also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred for two consecutive semesters from class work and all university examinations. The continuation of the course by the student 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 student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student is also debarred and forfeits the seat.
9.	If student of the college, who is not a student for the particular examination or	Student of the colleges expulsion from the examination hall and cancellation of the

	any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	performance in that subject and all other subjects the student has already appeared including practical examinations and UG major project and shall not be permitted for the remaining examinations of the subjects of that semester/year. The student 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 student has already appeared including practical examinations and UG major project 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 and all other subjects the student has appeared including practical examinations and UG major project of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the university for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

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

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
(Established by Act No.30 of 2008)
Kukatpally, Hyderabad-500085, Telangana State (India)

Academic Regulations of M.Pharm. (Regular/Full Time) Programmes, 2022-23 (R22)
(CBCS)
(Effective for the students admitted into I year from the Academic Year 2022-23 and onwards)

1.0 Post-Graduate Degree Programmes in Pharmacy (PGP in Pharmacy) Jawaharlal Nehru Technological University Hyderabad (JNTUH) offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M.Pharm.) Degree programmes, under Choice Based Credit System (CBCS) at its constituent (non-autonomous) and affiliated colleges in different specializations.

2.0 Eligibility for Admissions

2.1 Admission to the PGPs shall be made subject to eligibility, qualification and specializations prescribed by the University from time to time, for each specialization under each M.Pharm. programme.

2.2 Admission to the post graduate programme shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant qualifying GPAT Examination/ the merit rank obtained by the qualified student in an entrance test conducted by Telangana State Government (PGE CET) for M.Pharm. programmes / an entrance test conducted by JNTUH/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.3 The medium of instructions for all PG Programmes will be **ENGLISH** only.

3.0 M.Pharm. Programme (PGP in Pharmacy) Structure

3.1 The M.Pharm. Programmes in Pharmacy of JNTUH are of Semester pattern, with **Four** Semesters consisting of **Two** academic years, each academic year having **Two** Semesters (First/Odd and Second/Even Semesters). Each Semester shall be of 23 weeks duration (inclusive of Examinations), with a minimum of **100** instructional days per Semester.

3.2 The student shall not take more than **four** academic years to fulfill all the academic requirements for the award of M.Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M.Pharm. programme.

3.3 **UGC/PCI** specified definitions/descriptions are adopted appropriately for various terms and abbreviations used in these PG academic regulations, as listed below:

3.3.1 Semester Scheme

Each Semester shall have 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester System (CBSS) are taken as 'references' for the present set of Regulations. The terms 'SUBJECT' and 'COURSE' imply the same meaning here and refer to 'Theory Subject', or 'Lab Course', or 'Design Subject', or 'Mini Project with Seminar', or 'Dissertation', as the case may be.

3.3.2 Credit Courses

All subjects/courses are to be registered by the student in a semester to earn credits which shall be assigned to each subject/course in an L: T: P: C (Lecture Periods: Tutorial Periods: Practical Periods:



Credits) structure based on the following general pattern:

- One credit for one hour/week/semester for theory/lecture (L) courses
- One credit for two hours/ week/semester for laboratory/ practical (P) courses or tutorials (T)

Other student activities like study tour, guest lecture, conference/workshop participations, technical paper presentations and mandatory courses (**Audit Courses**) will not carry any credits.

3.3.3 Subject Course Classification

All subjects/courses offered for the Post-Graduate Programme in Pharmacy (M.Pharm. Degree Programme) are broadly classified as follows. The University has followed in general the guidelines issued by UGC/PCI.

S.No.	Broad Course Classification	Course Group/ Category	Course Description
1	Core Courses (CoC)	PC- Professional Core	Includes subjects related to the Specialization in Pharmacy
		Dissertation	M.Pharm. Project or PG Project or Major Project
		Mini Project/ Seminar	Mini Project/Seminar based on core contents related to the Specialization in Pharmacy
2	Elective Courses (EiE)	PE - Professional Electives	Includes elective subjects related to the Specialization in Pharmacy
		OE - Open Electives	Elective subjects which include inter-disciplinary subjects or subjects in an area outside the Specialization in Pharmacy
3	Mandatory Courses	--	Non-Credit Audit Courses

4.0 Course Registration

- 4.1** A 'Faculty Advisor or Counselor' shall be assigned to each specialization, who will advise on the Post Graduate Programme (PGP), its Course Structure and Curriculum, Choice/Option for Subjects/ Courses, based on his competence, progress, pre-requisites and interest.
- 4.2** The Academic Section of the College invites 'Registration Forms' from students within 15 days from the commencement of class work through 'ON-LINE SUBMISSIONS', ensuring 'DATE and TIME Stamping'. The ON-LINE Registration Requests for any 'CURRENT SEMESTER' shall be completed BEFORE the commencement of SEEs (Semester End Examinations) of the 'PRECEDING SEMESTER'.
- 4.3** A Student can apply for ON-LINE Registration, ONLY AFTER obtaining the 'WRITTEN APPROVAL' from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).
- 4.4** If the Student submits ambiguous choices or multiple options or erroneous entries during ON-LINE Registration for the Subject(s) / Course(s) under a given/ specified Course Group/ Category as listed in the Course Structure, only the first mentioned Subject/ Course in that Category will be taken into consideration.



- 4.5 Subject/ Course Options exercised through ON-LINE Registration are final and CANNOT be changed, nor can they be inter-changed; further, alternate choices also will not be considered. However, if the Subject/ Course that has already been listed for Registration by the University in a Semester could not be offered due to unforeseen or unexpected reasons, then the Student will be allowed to have alternate choice either for a new Subject, if it is offered, or for another existing Subject (subject to availability of seats). Such alternate arrangements will be made by the Head of Department, with due notification and time-framed schedule, within the FIRST WEEK from the commencement of Class-work for that Semester.

5.0 Attendance Requirements

The programmes are offered based on a unit system with each subject being considered a unit. Attendance is calculated separately for each subject.

- 5.1 Attendance in all classes (Lectures/Laboratories) is compulsory. The minimum required attendance in each theory subject (**also mandatory audit courses**) including the attendance of mid-term examination / Laboratory etc. is **80%**. Two periods of attendance for each theory subject shall be considered, if the student appears for the mid-term examination of that subject. ***This attendance should also be included in the fortnightly upload of attendance to the University. The attendance of mandatory audit courses should be uploaded separately to the University.*** A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than **80%**.
- 5.2 A student's Seminar report and presentation on Mini Project shall be eligible for evaluation, only if he ensures a minimum of **80%** of his attendance in Seminar presentation classes on Mini Project during that Semester.
- 5.3 **Condoning of shortage of attendance** (between 70% and 80%) up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each subject (Theory/Lab/Mini Project with Seminar) of a semester shall be granted by the College Academic Committee on genuine reasons.
- 5.4 A prescribed fee per subject shall be payable for condoning shortage of attendance after getting the approval of College Academic Committee for the same. The College Academic Committee shall maintain relevant documents along with the request from the student.
- 5.5 Shortage of Attendance below 70% in any subject shall in **no case be condoned**.
- 5.6 A Student, whose shortage of attendance is not condoned in any Subject(s) (Theory/Lab/Mini Project with Seminar) in any Semester, is considered as 'Detained in that Subject(s), and is not eligible to write Semester End Examination(s) of such Subject(s), (in case of Mini Project with Seminar, his/her Mini Project with Seminar Report or Presentation are not eligible for evaluation) in that Semester; and he/she has to seek re-registration for those Subject(s) in subsequent Semesters, and attend the same as and when offered.
- 5.7 A student fulfills the attendance requirement in the present semester, shall not be eligible for readmission into the same class.
- 5.8 **a)** A student shall put in a minimum required attendance in at least **three theory subjects (excluding mandatory(audit) course)** in first Year I semester for promotion to first Year II Semester.
- b)** A student shall put in a minimum required attendance in at least **three theory subjects (excluding mandatory(audit) course)** in first Year II semester for promotion to second Year I Semester.



6.0 Academic Requirements

The following academic requirements must be satisfied, in addition to the attendance requirements mentioned in item no. 5. The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks per subject / course (theory / practical), based on Internal Evaluation and Semester End Examination.

- 6.1** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each subject/course, if he secures not less than **40%** of marks (**30** out of **75** marks) in the Semester End Examination, and a minimum of **50%** of marks in the sum total of CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together; in terms of Letter Grades and this implies securing '**D**' Grade or above in a subject.
- 6.2** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **Mini Project**, if student secures not less than **50%** marks (i.e. 50 out of 100 allotted marks). The student would be treated as failed, if student (i) does not submit a report on Mini Project or does not make a presentation of the same before the evaluation committee as per schedule or (ii) secures less than 50% marks in Mini Project evaluation. The failed student may reappear once for the above evaluation, as and when they are scheduled again; if the student fails in such 'one reappearance' evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.
- 6.3** A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **seminar & assignment**, if student secures not less than 50% marks i.e. 50 out of 100 allotted marks. **50** marks are allotted for **Seminar**, **50** marks are allotted for **Assignment**, **Total 50+50 = 100 marks**. The student would be treated as failed, if student (i) does not submit a report on seminar/does not submit the assignments as prescribed or does not make a seminar presentation before the evaluation committee as per schedule or (ii) secures less than 50% (i.e. < **25** marks out of **50**) marks in each of the seminar & assignment evaluations. The student failed in seminar evaluation may reappear once for it, as and when it is scheduled again; The student failed in assignment evaluation may submit the assignments once again for the evaluation, as and when the assignment submission is scheduled again. If the student fails in such 'one reappearance' evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.
- 6.4** A student shall register for all subjects for total of **98** credits as specified and listed in the course structure for the chosen specialization, put in required the attendance and fulfill the academic requirements for securing **98** credits obtaining a minimum of '**D**' Grade or above in each subject, and all **98** credits securing Semester Grade Point Average (**SGPA**) ≥ 6.0 (in each semester) and final Cumulative Grade Point Average (**CGPA**) (i.e., CGPA at the end of PGP) ≥ 6.0 , and shall **pass all the mandatory audit courses** to complete the PGP successfully.

Note: (1) The SGPA will be computed and printed on the marks memo only if the candidate passes in all the subjects offered and gets minimum '**D**' grade in all the subjects.

(2) CGPA is calculated only when the candidate passes in all the subjects offered in all the semesters

- 6.5** Marks and Letter Grades obtained in all those subjects covering the above specified **98** credits alone shall be considered for the calculation of final CGPA, which will be indicated in the Grade Card /Marks Memo of second year second semester.
- 6.6** If a student registers for extra subject(s) (in the parent specialization or other specializations of



Pharmacy) other than those listed subjects totaling to **98** credits as specified in the course structure, the performance in extra subject(s) (although evaluated and graded using the same procedure as that of the required **98** credits) will not be considered while calculating the SGPA and CGPA. For such extra subject(s) registered, percentage of marks and Letter Grade alone will be indicated in the Grade Card/Marks Memo, as a performance measure, subject to completion of the attendance and academic requirements as stated in items 5 and 6.1 - 6.4.

- 6.7** When a student is detained due to shortage of attendance in any subject(s) in any semester, no Grade allotment will be made for such subject(s). However, he is eligible for re-registration of such subject(s) in the subsequent semester(s), as and when next offered, with the academic regulations of the batch into which he is re-registered, by paying the prescribed fees per subject. In all these re-registration cases, the student shall have to secure a fresh set of internal marks and Semester End Examination marks for performance evaluation in such subject(s), and SGPA/CGPA calculations.
- 6.8** A student eligible to appear for the Semester End Examination in any subject, but absent from it or failed (failing to secure '**D**' Grade or above), may reappear for that subject at the supplementary examination as and when conducted. In such cases, his Internal Marks assessed earlier for that subject will be carried over, and added to the marks secured in the supplementary examination, for the purpose of evaluating his performance in that subject.
- 6.9** A Student who fails to earn **98** credits as per the specified course structure, and as indicated above, within **four** academic years from the date of commencement of his first year first semester, shall forfeit his seat in M.Pharm. programme and his admission **shall stand cancelled**.

7.0 Evaluation - Distribution and Weightage of Marks

The performance of a student in each semester shall be evaluated subject- wise (irrespective of credits assigned) for a maximum of 100 marks. The performance of a student in every theory subject/course will be evaluated for 100 marks, with 25 marks allotted for CIE (Continuous Internal Evaluation) and 75 marks for SEE (Semester End-Examination).

- 7.1** For theory subjects, 75 marks shall be awarded for the performance in the Semester End Examination and 25 marks shall be awarded for Continuous Internal Evaluation (CIE). The Continuous Internal Evaluation shall be made based on the average of the marks secured in the two Mid-Term Examinations conducted, first Mid-Term examinations in the middle of the Semester and second Mid-Term examinations during the last week of instruction. Each Mid-Term Examination shall be conducted for a total duration of 120 minutes with Part 'A' as compulsory consisting of 5 questions carrying 2 marks each (10 marks), and Part 'B' with 3 questions to be answered out of 5 questions, each question carrying 5 marks (15 marks). The details of the Question Paper pattern for Semester End Examination (Theory) are given below:
- The Semester End Examination will be conducted for 75 marks. It consists of two parts.
 - i) Part A for 25 marks, ii) Part B for 50 marks.
 - Part A is compulsory and consists of 5 questions, one from each unit and carrying 5 marks each.
 - Part B consists of 5 questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.
- 7.2** For practical subjects there shall be a Continuous Internal Evaluation (CIE) during the semester for 25 marks and 75 marks for semester end examination. Out of the 25 marks for internal evaluation:
1. A write-up on day-to-day experiment in the laboratory (in terms of aim, components/procedure, expected outcome) which shall be evaluated for 5 marks



2. 10 marks for viva-voce in the course concerned.
3. Internal practical examination conducted by the laboratory teacher concerned shall be evaluated for 10 marks.

The Semester End Examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University.

In the Semester End Examination held for 3 hours, total 75 marks are divided and allocated as shown below:

1. 10 marks for Synopsis
2. 50 marks for experiment
3. 15 marks for viva-voce on concerned laboratory course

A student has to secure 50 marks (i.e. 50% out of the 100 marks) allotted for CIE and SEE taken together.

7.3 There shall be Mini Project during I year II semester for **internal evaluation** of 100 marks. The Departmental Academic Committee (DAC) will review the progress of the mini project during the presentations and evaluate the same for 50 marks. Mini Project Viva Voce will be evaluated by the DAC for another 50 marks before the semester end examinations. Student shall carryout the mini project in consultation with the mini project supervisor which may include critically reviewing the literature, project implementation and submit it to the department in the form of a report and shall make an oral presentation before the DAC consisting of Head of the Department, Mini Project supervisor and two other senior faculty members of the department. The student has to secure a minimum of 50% of marks in i) mini project presentation and ii) mini project viva voce, to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.4 There shall be **seminar & assignment** during I Year I Semester & I Year II Semester for **internal evaluation** of **100** marks. **50** marks are allotted for **Seminar**, **50** marks are allotted for **Assignment**, **Total 50+50 = 100 marks**.

For **Seminar**, the student in consultation with the seminar supervisor shall collect the information on a specialized topic, prepare a report, and submit it to the department. The Departmental Academic Committee (DAC) consisting of Head of the Department, seminar supervisor and two other senior faculty members of the department will evaluate the seminar report for 50 marks before the semester end examinations. The student has to secure a minimum of 25 marks (i.e. 50% out of the 50 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

For **Assignment**, the student is required to submit **one assignment from each theory subject/course** in I Year I Semester & I Year II Semester before the commencement of Semester End Examinations.

- In I Year I Semester there are 5 theory courses and 5 assignments are to be submitted in total, one assignment each to the concerned theory subject teacher. The concerned theory subject teacher will evaluate the assignment for 10 marks. So 5 assignments will be evaluated for 50 marks in total.
- In I Year II Semester there are 4 theory courses and 4 assignments are to be submitted in total, one assignment each to the concerned theory subject teacher. The concerned theory subject teacher will evaluate the assignment for 12.5 marks. So 4 assignments will be evaluated for 50 marks in total.



The student has to secure a minimum of 25 marks (i.e. 50% out of the 50 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he may submit the assignments once again for the evaluation, as and when the assignment submission is scheduled again.

- 7.5** There shall be comprehensive viva-voce during II year I semester for **external evaluation** of 100 marks. It shall be evaluated by the committee consisting of an external examiner, Head of the Department, and two other senior faculty members of the department before the semester end examinations. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University. The student has to secure a minimum of 50 marks (i.e. 50% out of the 100 marks) allotted to be declared successful. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.
- 7.6** Every candidate shall be required to submit a dissertation on a topic approved by the Dissertation Review Committee.
- 7.7** A Dissertation Review Committee (DRC) shall be constituted with the Head of the Department as Chairperson, Dissertation Supervisor and one senior faculty member of the Department offering the M.Pharm. programme.
- 7.8** Registration of Dissertation Work: A candidate is permitted to register for the Dissertation Work after satisfying the attendance requirement in all the subjects, both theory and laboratory.
- 7.9** After satisfying 7.8, a candidate must present in Dissertation Work Review - I, in consultation with his Dissertation Supervisor, the title, objective and plan of action of his Dissertation work to the Dissertation Review Committee (DRC) for approval within four weeks from the commencement of Second year First Semester. Only after obtaining the approval of the DRC can the student initiate the Dissertation work.
- 7.10** If a candidate wishes to change his supervisor or topic of the Dissertation, he can do so with the approval of the DRC. However, the DRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of Dissertation proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.
- 7.11** A candidate shall submit his Dissertation progress report in two stages at least with a gap of **three** months between them.
- 7.12** The work on the Dissertation shall be initiated at the beginning of the II year and the duration of the Dissertation is two semesters. A candidate is permitted to submit Dissertation Thesis only after successful completion of all theory and practical courses with the approval of DRC not earlier than 40 weeks from the date of approval of the Dissertation work. For the approval of DRC the candidate shall submit the draft copy of thesis to the Head of the Department and make an oral presentation before the DRC.
- 7.13** The Dissertation Work Review - II in II Year I Sem. carries internal marks of 100. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and DRC will examine the Problem Definition, Objectives, Scope of Work, Methodology Adopted, Literature Survey in the same domain and progress of the Dissertation Work. A candidate has to secure a minimum of 50% of marks to be declared successful in Dissertation Work Review - II. If he fails to obtain the minimum required marks, he has to reappear for Dissertation Work Review - II as and when conducted.



- 7.14** The Dissertation Work Review - III in II Year II Sem. carries 100 internal marks. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The DRC will examine the overall progress of the Dissertation Work and decide whether or not the Dissertation is eligible for final submission. The evaluation shall be done as per the criteria given below:

Evaluation of Dissertation Book (Internal Evaluation):

Objective(s) of the work done	- 10 Marks
Methodology adopted	- 30 Marks
Results and Discussions	- 50 Marks
Conclusions and Outcomes	- 10 Marks
Total	- 100 Marks

A candidate has to secure a minimum of 50% of marks to be declared successful in Dissertation Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for Dissertation Work Review - III as and when conducted.

- 7.15** For Dissertation Evaluation (Viva Voce) in II Year II Sem. there are external marks of 100 and it is evaluated by the external examiner. The evaluation shall be done as per the criteria given below:

Evaluation of Presentation (External Evaluation):

Presentation of work	- 40 Marks
Communication skills	- 20 Marks
Viva-Voce	- 40 Marks
Total	- 100 Marks

The candidate has to secure a minimum of 50% marks in Dissertation Evaluation (Viva-Voce) examination. If he fails to obtain the required minimum marks, he has to reappear for the same as and when conducted.

- 7.16** Dissertation Work Reviews - II and III shall be conducted in phase I (Regular) and Phase II (Supplementary). Phase II will be conducted only for unsuccessful students in Phase I. The unsuccessful students in Dissertation Work Review - II (Phase II) shall reappear for it at the time of Dissertation Work Review - III (Phase I). These students shall reappear for Dissertation Work Review - III in the next academic year at the time of Dissertation Work Review - II only after completion of Dissertation Work Review - II, and then Dissertation Work Review - III follows. The unsuccessful students in Dissertation Work Review - III (Phase II) shall reappear for Dissertation Work Review - III in the next academic year only at the time of Dissertation Work Review - II (Phase I).
- 7.17** After approval from the DRC, a soft copy of the thesis should be submitted for ANTI-PLAGIARISM check and the plagiarism report should be submitted to the University and be included in the final thesis. The Thesis will be accepted for submission, if the similarity index is less than **30%**. If the similarity index has more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the thesis after one month. The maximum number of re-submissions of thesis after plagiarism check is limited to TWO. The candidate has to register for the Dissertation work and work for two semesters. After three attempts, the admission is liable to be cancelled. The college authorities are advised to make plagiarism check of every soft copy of theses before submissions.
- 7.18** Three copies of the Dissertation Thesis certified by the supervisor shall be submitted to the College/School/Institute, after submission of a research paper related to the Dissertation work in a UGC approved journal. A copy of the submitted research paper shall be attached to thesis.
- 7.19** The thesis shall be adjudicated by an external examiner selected by the University. For this, the



Principal of the College/School/Institute shall submit a panel of **three** examiners from among the list of experts in the relevant specialization as submitted by the supervisor concerned and Head of the Department.

- 7.20** If the report of the external examiner is unsatisfactory, the candidate shall revise and resubmit the Thesis. If the report of the examiner is unsatisfactory again, the thesis shall be summarily rejected. Subsequent actions for such dissertations may be considered, only on the specific recommendations of the external examiner and /or Dissertation Review Committee. No further correspondence in this matter will be entertained, if there is no specific recommendation for resubmission.
- 7.21** If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Dissertation Viva-Voce examination. The Dissertation Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the Thesis. The candidate has to secure a minimum of 50% of marks in Dissertation Evaluation (Viva-Voce) examination.
- 7.22** If he fails to fulfill the requirements as specified in 7.21, he will reappear for the Dissertation Viva-Voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree, unless he is asked to revise and resubmit his Dissertation Work by the board within a specified time period (within **four** years from the date of commencement of his first year first semester).
- 7.23** The Dissertation Viva-Voce External examination marks must be submitted to the University on the day of the examination.
- 7.24** For mandatory audit courses, a student has to secure 50 marks out of 100 marks (i.e. 50% of the marks allotted) in the continuous internal evaluation for passing the subject/course. These marks should also be uploaded along with the internal marks of other subjects.
- 7.25** No marks or letter grades shall be allotted for mandatory audit courses. Only Pass/Fail shall be indicated in Grade Card.

8.0 Re-Admission/Re-Registration

8.1 Re-Admission for Discontinued Student

A student, who has discontinued the M.Pharm. degree programme due to any reason whatsoever, may be considered for '**readmission**' into the same degree programme (with the same specialization) with the academic regulations of the batch into which he gets readmitted, with prior permission from the authorities concerned, subject to item 6.7.

- 8.2** If a student is detained in a subject (s) due to shortage of attendance in any semester, he may be permitted to **re-register** for the same subject(s) in the same category (core or elective group) or equivalent subject, if the same subject is not available, as suggested by the Board of Studies of that department, as and when offered in the subsequent semester(s), with the academic regulations of the batch into which he seeks re-registration, with prior permission from the authorities concerned, subject to item 3.2
- 8.3** ***A candidate shall be given only one-time chance to re-register and attend the classes for a maximum of two subjects in a semester***, if the internal marks secured by a candidate are less than 40% and failed in those subjects but fulfilled the attendance requirement. A candidate must re-register for failed subjects within four weeks of commencement of the class work and secure the required



minimum attendance. In the event of the student taking this chance, his Continuous Internal Evaluation (internal) marks and Semester End Examination marks obtained in the previous attempt stand cancelled.

9.0 Examinations and Assessment - The Grading System

- 9.1 Grades will be awarded to indicate the performance of each student in each Theory Subject, or Lab/Practicals, or Mini Project with Seminar, Dissertation, etc., based on the percentage of marks obtained in CIE + SEE (Continuous Internal Evaluation + Semester End Examination, both taken together) as specified in Item 7 above, and a corresponding Letter Grade shall be given.
- 9.2 As a measure of the student's performance, a 10-point Absolute Grading System using the following Letter Grades (PCI Guidelines) and corresponding percentage of marks shall be followed:

% of Marks Secured in a Subject/Course (Class Intervals)	Letter Grade (PCI Guidelines)	Grade Points
Greater than or equal to 90%	O (Outstanding)	10
80 and less than 90%	A (Excellent)	9
70 and less than 80%	B (Good)	8
60 and less than 70%	C (Fair)	7
50 and less than 60%	D (Average)	6
Below 50%	F (FAIL)	0
Absent	Ab	0

- 9.3 A student obtaining 'F' Grade in any Subject is deemed to have 'failed' and is required to reappear as 'Supplementary Candidate' for the Semester End Examination (SEE), as and when conducted. In such cases, his Internal Marks (CIE Marks) in those subjects will remain as obtained earlier.
- 9.4 If a student has not appeared for the examinations, 'Ab' Grade will be allocated to him for any subject and shall be considered 'failed' and will be required to reappear as 'Supplementary Candidate' for the Semester End Examination (SEE), as and when conducted.
- 9.5 A Letter Grade does not imply any specific marks percentage; it is only the range of percentage of marks.
- 9.6 In general, a student shall not be permitted to repeat any Subject/ Course (s) only for the sake of 'Grade Improvement' or 'SGPA/ CGPA Improvement'.
- 9.7 A student earns Grade Point (GP) in each Subject/ Course, on the basis of the Letter Grade obtained by him in that Subject/ Course. The corresponding 'Credit Points' (CP) are computed by multiplying the Grade Point with Credits for that particular Subject/ Course.

Credit Points (CP) = Grade Point (GP) x Credits For a Course

- 9.8 The student passes the Subject/ Course only when he gets **GP ≥ 6 (D Grade or above)**.
- 9.9 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points (ΣCP) secured from ALL Subjects/ Courses registered in a Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to TWO Decimal Places. SGPA is thus computed as

$$SGPA = \left\{ \sum_{i=1}^N C_i G_i \right\} / \left\{ \sum_{i=1}^N C_i \right\} \dots \text{For each Semester,}$$



where 'i' is the Subject indicator index (taking into account all Subjects in a Semester), 'N' is the no. of Subjects 'REGISTERED' for the Semester (as specifically required and listed under the Course Structure of the parent Department), C_i is the no. of Credits allotted to the i^{th} Subject, and G_i represents the Grade Points (GP) corresponding to the Letter Grade awarded for that i^{th} Subject.

- 9.10** The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all Semesters considered for registration. The CGPA is the ratio of the Total Credit Points secured by a student in ALL registered Courses in ALL Semesters, and the Total Number of Credits registered in ALL the Semesters. CGPA is rounded off to TWO Decimal Places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula

$$\text{CGPA} = \left\{ \sum_{j=1}^M C_j G_j \right\} / \left\{ \sum_{j=1}^M C_j \right\} \dots \text{for all } S \text{ Semesters registered}$$

(ie., upto and inclusive of S Semesters, $S \geq 2$),

where 'M' is the TOTAL no. of Subjects (as specifically required and listed under the Course Structure of the parent Department) the Student has 'REGISTERED' for from the 1st Semester onwards upto and inclusive of the Semester S (obviously $M > N$), 'j' is the Subject indicator index (taking into account all Subjects from 1 to S Semesters), C_j is the no. of Credits allotted to the j^{th} Subject, and G_j represents the Grade Points (GP) corresponding to the Letter Grade awarded for that j^{th} Subject. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	9	$4 \times 9 = 36$
Course 2	4	O	10	$4 \times 10 = 40$
Course 3	4	C	7	$4 \times 7 = 28$
Course 4	3	B	8	$3 \times 8 = 24$
Course 5	3	A	10	$3 \times 10 = 30$
Course 6	3	C	7	$3 \times 7 = 21$
	Total Credits = 21			Total Credit Points = 179

$$\text{SGPA} = 179/21 = 8.52$$

Illustration of calculation of CGPA

Course/Subject	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	9	$4 \times 9 = 36$
Course 2	4	A	9	$4 \times 9 = 36$
Course 3	4	B	8	$4 \times 8 = 32$
Course 4	3	O	10	$3 \times 10 = 30$
Course 5	3	B	8	$3 \times 8 = 24$



Course 6	3	D	6	$3 \times 6 = 18$
I Year II Semester				
Course 7	4	B	8	$4 \times 8 = 32$
Course 8	4	O	10	$4 \times 10 = 40$
Course 9	4	A	9	$4 \times 9 = 36$
Course 10	3	D	6	$3 \times 6 = 18$
Course 11	3	C	7	$3 \times 7 = 21$
Course 12	3	A	9	$3 \times 9 = 27$
	Total Credits = 42			Total Credit Points = 350

$$\text{CGPA} = 350/42 = 8.33$$

10.0 Award of Degree and Class

10.1 If a student who registers for all the specified Subjects/ Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire PG Programme (PGP), and secures the required number of **98 Credits** (with $\text{CGPA} \geq 6.0$), shall be declared to have 'QUALIFIED' for the award of the M.Pharm. Degree in the chosen specialization of Pharmacy that he was admitted into.

10.2 Award of Class

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

Class Awarded	CGPA
First Class with Distinction	≥ 7.50
First Class	$6.00 \leq \text{CGPA} < 7.49$
Second Class	$5.00 \leq \text{CGPA} < 5.99$

A student with final CGPA (at the end of the **PGP**) < 6.00 shall not be eligible for the Award of Degree.

11.0 Withholding of Results

If the student has not paid the dues, if any, to the University or if any case of indiscipline is pending against him, the result and degree of the student will be withheld and he will not be allowed into the next semester.

12.0 General

12.1 Credit: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

12.2 Credit Point: It is the product of grade point and number of credits for a course.

12.3 Wherever the words "he", "him", "his", occur in the regulations, they shall include "she", "her".



- 12.4** The academic regulation should be read as a whole for the purpose of any interpretation.
- 12.5** In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the University is final.
- 12.6** The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

**MALPRACTICES RULES****DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS**

S.No	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1.(a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject to 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. Incase 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 to 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 and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the 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	Expulsion from the examination hall and cancellation of performance in that subject and



	question paper during the examination or answer book or additional sheet, during or after the examination.	all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
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.	Incase of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
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 and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY IV YEAR COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2017-18 Admitted Batch

IV Year I Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS701	Instrumental Methods of Analysis	3	1	0	4
2	PS702	Industrial Pharmacy-II	3	1	0	4
3	PS703	Pharmacy Practice	3	1	0	4
4	PS704	Novel Drug Delivery Systems	3	1	0	4
5	PS705 PS706 PS707 PS708	Open Elective - III i. Pharmaceutical Marketing ii. Pharmaceutical Regulatory Science iii. Pharmacovigilance iv. Quality Control and Standardization of Herbals	3	1	0	4
6	PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	PS710	Practice School	0	0	4	2
8	PS711	Industrial Training	0	0	2	1
Total			15	5	10	25

IV Year II Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Pharmaceutical Jurisprudence	3	0	0	3
4	PS804 PS805 PS806 PS807	Open Elective - IV i. Computer Aided Drug Design ii. Nano Technology iii. Experimental Pharmacology iv. Advanced Instrumentation Techniques	3	1	0	4
5	PS808	Project Work	0	0	6	3
Total			12	3	6	18

PS701: INSTRUMENTAL METHODS OF ANALYSIS

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

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

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT – I**10 Hours****1. 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

2. Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT – II**10 Hours****1. 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, Thermistor, Pyroelectric detector and applications

2. Flame Photometry - Principle, interferences, instrumentation and applications**3. Atomic absorption spectroscopy** - Principle, interferences, instrumentation and applications**4. Nepheloturbidometry** - Principle, instrumentation and applications**UNIT – III****10 Hours****Introduction to chromatography****1. Adsorption and partition column chromatography**- Methodology, advantages, disadvantages and applications.**2. Thin layer chromatography**- Introduction, Principle, Methodology, R_f values, advantages, disadvantages and applications.**3. Paper chromatography**- Introduction, methodology, development techniques, advantages, disadvantages and applications**4. Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications**UNIT – IV****08 Hours****1. Gas chromatography** - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

2. **High performance liquid chromatography (HPLC)** - Introduction, theory, instrumentation, advantages and applications.

UNIT – V

07 Hours

1. **Ion exchange chromatography** - Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications
2. **Gel chromatography** - Introduction, theory, instrumentation and applications
3. **Affinity chromatography** - Introduction, theory, instrumentation and applications

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

PS702: INDUSTRIAL PHARMACY - II

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objectives: This course is designed to impart fundamental knowledge on pharmaceutical product Commercialization from laboratory to market

Course Outcomes: 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 in India and US
- 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: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing 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), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

UNIT – III**10 Hours**

1. **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
2. **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) 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, 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, Common Technical Document (CTD), 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' 2nd Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.
5. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition

PS703: PHARMACY PRACTICE

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objectives: 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 safe medication and patient counseling.

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Know pharmaceutical care services
- do patient counseling in community pharmacy

UNIT – I**10 Hours****1. Hospital and it's 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.

2. Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

3. 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**10 Hours****1. 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.

2. Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

3. Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT – III**10 Hours****1. Drug information services**

Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.

2. Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

3. 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.

UNIT – IV**08 Hours****1. 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.

2. Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

UNIT – V**07 Hours****Drug store management and inventory control**

Organization 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

Recommended Books (Latest Edition):

1. Merchant S. H. and Dr. J. S. Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman 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, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N. S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

PS704: NOVEL DRUG DELIVERY SYSTEMS

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objectives: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Course Outcomes: 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

UNIT – I**10 Hours**

1. **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
2. **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

UNIT – II**10 Hours**

1. **Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications
2. **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems
3. **Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump

UNIT – III**10 Hours**

1. **Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches
2. **Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications
3. **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**

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

UNIT – V**07 Hours**

1. **Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts
2. **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, 1st edition 1997 (reprint in 2001).
5. S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, 1st edition 2002.

PS705: PHARMACEUTICAL MARKETING (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objectives: The pharmaceutical industry not only needs highly qualified researchers, chemist, 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. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.

Course Outcome: Provide an understanding of marketing concepts and techniques and the application of the same 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**10 Hours**

Product decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

UNIT – III**10 Hours**

Promotion: Meaning and 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.

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 McGraw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw 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 Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

PS706: PHARMACEUTICAL REGULATORY SCIENCE (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objectives: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Course Outcomes: Upon completion of the subject student shall 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**10 Hours****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**10 Hours**

Regulatory Approval Process: Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.

Regulatory authorities and agencies: Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

UNIT – III**10 Hours**

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**08 Hours**

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**07 Hours**

Regulatory Concepts: Basic terminologies, 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, 2nd 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 Rodney K. Adams
8. Principles and Practices of Clinical Research, 2nd Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, 2nd Edition by Rick N

PS707: PHARMACOVIGILANCE (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objective: 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.

Course Outcomes: At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Data during pre-clinical, clinical and post approval.
- Pharmacovigilance Program of India (PvPI)
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

UNIT - I**10 Hours****Introduction to Pharmacovigilance:**

- a) History and development of Pharmacovigilance
- b) Importance of safety monitoring of Medicine
- c) WHO international drug monitoring programme
- d) Pharmacovigilance Program of India (PvPI)

Introduction to adverse drug reactions:

- a) Definitions and classification of ADRs
- b) Detection and reporting
- c) Methods in Causality assessment
- d) Severity and seriousness assessment
- e) Predictability and preventability assessment

Basic terminologies used in pharmacovigilance:

- a) Terminologies of adverse medication related events
- b) Regulatory terminologies

UNIT – II**10 hours****Drug and disease classification:**

- a) Anatomical, therapeutic and chemical classification of drugs
- b) International classification of diseases
- c) Daily defined doses

Drug dictionaries and coding in pharmacovigilance:

- a) WHO adverse reaction terminologies
- b) MedDRA and Standardized MedDRA queries
- c) WHO drug dictionary

Information resources in pharmacovigilance:

- a) Basic drug information resources

Establishing pharmacovigilance programme:

- a) Establishing in a hospital
- b) Establishment & operation of drug safety department in industry
- c) Contract Research Organizations (CROs)

UNIT – III

10 Hours

Vaccine safety surveillance:

- a) Vaccine Pharmacovigilance
- b) Vaccination failure
- c) Adverse events following immunization

Pharmacovigilance methods:

- a) Passive surveillance – Spontaneous reports and case series
- b) Stimulated reporting
- c) Active surveillance – Sentinel sites, drug event monitoring and registries
- d) Comparative observational studies – Cross sectional study, case control study and cohort study
- e) Targeted clinical investigations

UNIT – IV

08 Hours

Statistical methods for evaluating medication safety data

Safety data generation:

- a) Pre-clinical phase
- b) Clinical phase
- c) Post approval phase

ICH Guidelines for Pharmacovigilance:

- a) Organization and objectives of ICH
- b) Expedited reporting
- c) Individual case safety reports
- d) Periodic safety update reports
- e) Post approval expedited reporting
- f) Pharmacovigilance planning
- g) Good clinical practice in pharmacovigilance studies

UNIT – V

07 hours

Pharmacogenomics of adverse drug reactions:

Drug safety evaluation in special population

- a) Pediatrics
- b) Pregnancy and lactation
- c) Geriatrics

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, 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
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

PS708: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Open Elective - III)

B.Pharm. IV Year I Sem.

L/T/P/C
3/1/0/ 4

Course Objective: 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 Outcomes: 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**10 hours**

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**10 hours**

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**10 hours**

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

UNIT – IV**08 hours**

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**07 hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal 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. I, 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. 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. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
10. WHO. 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.
11. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

PS709: INSTRUMENTAL METHODS OF ANALYSIS LAB

B.Pharm. IV Year I Sem.

L/T/P/C
0/0/4/ 2

List of Experiments:

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 nephelo turbidometry
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

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

PS710: PRACTICE SCHOOL

B.Pharm. IV Year I Sem.

L/T/P/ C
0 /0/4/ 2

Course Objectives: Practice school is an educational innovation seeking to link industry/hospital/ pharmacy experience with university instruction. The student will:

- Meet the rapidly changing needs and challenges of a professional work place.
- Acquire knowledge and skills.
- Bear an economic relevance to the society.

Course Outcome: Institutionalized linkage between university/college and industry. Student's involvement in real life projects continues internal evaluation and monitoring the faculty help by student to understand the practical issues. After successful completion of 150 hrs, the students will submit the detailed report in the following field.

Note: Any domains relevant to pharmacy can be given to students. Following domains for reference

Industry oriented PS:

It comprises industry visits and interactions with executives to facilitate the process of learning by observations and discussions duly aided by the check list. It promotes learning by doing in various departments like production quality control and assurance, R&D etc. Taking one issue and working on it for prescribed hours and submit the report.

Hospital oriented PS:

The student is asked to visit the hospitals and work on some case studies like cardiovascular, diabetics, gastrointestinal, gynecological, pulmonary pediatric etc. related cases of some 5 to 6 to be studied and detailed data to be submitted.

Retail pharmacy-oriented PS:

The students have to visit different pharmacy shops and collect the data related to the most prescribed medicines in that area, prescription patterns, medical audit etc and submit the report.

Election of medicinal plants orientated PS:

The students have to visit medicinal plant gardens and collect some medicinal plants those are useful to various disorders and submit the report in detail about the plants they come across during their study period

Regulatory affairs: collect and analyse the regulatory affairs. Some important cases filed by drug control officers to be analysed and reported.

National poison centre: visit the local poison centre and write the relevant matter

Formulation aspects: Formulations using any equipments which otherwise are not usually used for regular practicals

PS801: BIOSTATISTICS AND RESEARCH METHODOLOGY

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies.

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

UNIT – I**10 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**10 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.

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

UNIT – III**10 Hours**

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, 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**8 Hours**

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**7 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

PS802: SOCIAL AND PREVENTIVE PHARMACY

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: 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 programmes. The roles of the pharmacist in these contexts are also discussed.

Course Outcomes: 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 health and pharmaceutical issues

UNIT – I**10 Hours**

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: Socio cultural 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**10 Hours**

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**10 Hours**

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

UNIT – IV**08 Hours**

National health intervention programme for mother and child, national family welfare programme, national tobacco control programme, national malaria prevention program, national programme for the health care for the elderly, social health programme; role of *who in indian national program

UNIT – V**07 Hours**

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. Short Textbook of Preventive and Social Medicine, Prabhakara G N, 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

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

PS803: PHARMACEUTICAL JURISPRUDENCE

B.Pharm. IV Year II Sem.

L/T/P/ C
3/0/0/ 3

Course Objectives: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

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

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

UNIT – I**10 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; its 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**08 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

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, 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

07 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 (Theory)

PS804: COMPUTER AIDED DRUG DESIGN (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

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**

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**08 Hours**

Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT – V**07 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 Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.

5. Koro Ikovas 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.

PS805: NANO TECHNOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

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

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

UNIT - I**Introduction to Nanotechnology**

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties of nanomaterials
- d. Classification of nanomaterials

UNIT - II**Synthesis of Nanomaterials**

Methods for synthesis of:

- a. Gold nanoparticles
- b. Magnetic nanoparticles
- c. Polymeric nanoparticles
- d. Self – assembly structures such as liposomes, Niosomes, micelles, aquasomes and nanoemulsions

UNIT - III**Biomedical applications of Nanotechnology**

- a. Nanotechnology products used for in vitro diagnostics
- b. Applications in imaging and targeting.

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary, nasal drug delivery, cardiovascular diseases and localized drug delivery systems.

UNIT - V

Characterization, drug release and stability studies of nanomaterials

Recommended Books (Latest Editions):

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfroms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P.J. Thomas and G.U. Kulakarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)

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

PS806: EXPERIMENTAL PHARMACOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines.

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals and newer screening methods used in the drug discovery
- Understand the Research methodology to be followed Bio-statistical data interpretation of the assays

UNIT - I

Laboratory 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

Preclinical screening models: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups

UNIT - III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and skeletal muscle relaxants.

UNIT - IV

Preclinical screening models for diuretics, anticoagulants and anticancer activities

UNIT - V

Research methodology and Bio-statistics, Selection of research topic, review of literature, research hypothesis and study design, Interpretation using Student's 't' test and One-way ANOVA. Graphical representation of data.

Recommended Books (Latest Editions):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Experimental Pharmacology for undergraduates by M C Prabhakara.
7. Drug discovery and Evaluation by Vogel H. G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta.
10. Handbook of Experimental Pharmacology, S K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.

PS807: ADVANCED INSTRUMENTATION TECHNIQUES (Open Elective - IV)

B.Pharm. IV Year II Sem.

L/T/P/ C
3/1/0/ 4

Course Objectives: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

UNIT – I**10 Hours****Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry - Principles, Fragmentation, Ionization techniques - Electron impact, chemical ionization, instrumentation and applications.

UNIT - II**10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction and applications.

UNIT - III**10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT – IV**08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction Techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT – V**07 Hours**

Hyphenated techniques - 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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY III YEAR COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2017-18 Admitted Batch

III Year I Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS501	Medicinal Chemistry II	3	1	0	4
2	PS502	Industrial Pharmacy - I	3	1	0	4
3	PS503	Pharmacology II	3	1	0	4
4	PS504	Pharmacognosy and Phytochemistry - II	3	1	0	4
5	PS505 PS506 PS507 PS508	Open Elective - I I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
6	PS509	Industrial Pharmacy lab	0	0	4	2
7	PS510	Pharmacology - II lab	0	0	4	2
8	PS511	Pharmacognosy and Phytochemistry - II lab	0	0	4	2
9	*MC500	Environmental sciences	1	0	0	0
		Total	16	05	12	26

III Year II Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS601	Medicinal Chemistry - III	3	1	0	4
2	PS602	Pharmacology - III	3	1	0	4
3	PS603	Herbal Drug Technology	3	1	0	4
4	PS604	Biopharmaceutics and Pharmacokinetics	3	1	0	4
5	PS605 PS606 PS607 PS608	Open Elective - II I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
6	PS609	Medicinal chemistry - III lab	0	0	4	2
7	PS610	Pharmacology - III lab	0	0	4	2
8	PS611	Herbal Drug Technology lab	0	0	4	2
9	*MC600	Human Values and Professional Ethics	1	0	0	0
		Total	16	05	12	26

PS501: MEDICINAL CHEMISTRY – II

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objective: 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, absorption, distribution and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Course Outcomes: 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 of different class of drugs
4. Study 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 (*)

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, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, 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, Thiotepea

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II

10 Hours

Anti-anginal:

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

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

Diuretics:

Carbonic anhydrase inhibitors: 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, Lorainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestamine 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

Sex hormones: Testosterone, Nandrolone, Progestones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

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.

UNIT – V

07 Hours

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: 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, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

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

Miscellaneous: Phenacaine, Dipiperodon, Dibucaine.*

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 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

PS502: INDUSTRIAL PHARMACY - I

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objective: 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 Outcomes: 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 (Crystalline and amorphous forms: Concepts of polymorphism and its significance in industrial setup), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient).

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

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:

- Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- Quality control tests: In process and finished product tests

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

UNIT – III

08 Hours

Capsules:

- Hard gelatin capsules:** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.
- Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets, Fluidised bed coater(FBC).

UNIT - IV

10 Hours

Parenteral Products:

- Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- Production procedure, production facilities and controls.

- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

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.

TEXT 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
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.
10. Pharmaceutical Technology 1 &11 BY Gaurav Agarwal CBS Publishers
11. Pharmaceutics Basic principles and Formulations by D.K. Tripathi Pharma med press

PS503: PHARMACOLOGY - II

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objective: 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 Outcomes: 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

10 hours

Pharmacology of drugs acting on cardio vascular 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

10 hours

1. Pharmacology of drugs acting on cardio vascular system

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

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT - III

10 hours

Autocoids and related drugs

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

UNIT - IV

08 hours

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.
- e. Insulin, Oral Hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

UNIT - V

07 hours

1. Pharmacology of drugs acting on endocrine system

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

2. Bioassay

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

TEXT BOOKS (Latest Editions)

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

PS504: PHARMACOGNOSY AND PHYTOCHEMISTRY - II

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objective: 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 Outcomes: 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 carryout isolation and identification of phytoconstituents

UNIT - I

7 Hours

Metabolic pathways in higher plants and their determination

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

UNIT - II

10 Hours

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites.

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

UNIT - III

10 Hours

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT - IV

10 Hours

Isolation, Identification and analysis of phytoconstituents

- a. Terpenoids: Menthol, Citral and Artemisin
- b. Glycosides: Glycyrrhetic acid and Rutin
- c. Alkaloids: atropine, Quinine, Reserpine and Caffeine
- d. Resins: Podophyllotoxin and Curcumin

UNIT - V 8 Hours

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine. Modern methods of extraction.

TEXT 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, 1st 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, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Boo of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R. C. Dubey.

PS505: GENERIC PRODUCT DEVELOPMENT
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

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

Course Outcome: The knowledge of the students is enhanced with the clear information about the generic product development.

UNIT - I

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

UNIT - II

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

UNIT - III

Analytical method development for verification and validation for active ingredient, in-process samples and finished dosage forms.

UNIT - IV

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

UNIT - V

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

REFERENCE BOOKS

1. Generic Drug product Development: Solid oral dosage forms-Leon Shargel.
2. ICH guidelines.

PS506: GREEN CHEMISTRY
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C
3 1/0/ 4

Course Objectives: To familiarize students about environment benign chemical synthesis. To make students familiarize with principles and importance of various green chemical synthesis. To provide adequate knowledge regarding green reactions, green solvents and other alternative green approaches. To impart adequate information regarding environment pollution, contributing factors and the concerns.

Course Outcomes: Upon completion of this course, the students should be able to: Explain the environment pollution factors. Understand the different greener approaches along with their principles.

UNIT - I

Introduction to green chemistry

Inception of green chemistry: history and development.

Principles of green chemistry: description with examples.

Synthetic approaches of green chemistry: in water, solvent less, microwave, ultrasonic, catalytic and synthesis.

UNIT - II

In water and solvent less organic reactions

In water reactions: principle and process involved in the Michael reaction and Wartz synthesis

Solvent less organic synthesis:

Alternative solvents used in green chemistry strategies

UNIT - III

Microwave and ultrasonic mediated reactions

Microwave reactions: principles and process involved in the Fries rearrangement, Diels Alder reaction and Metal halide reduction

Ultrasonic reaction: principle and process involved in the Strecker and Reformatsky reactions

UNIT - IV

Catalytic and solid supported reactions

Catalytic reactions: principle and process involved in the reactions catalyzed by metal catalysts, ionic liquids (Knovenegel condensation) and bio catalysts (Villegier reaction)

Solid supported reactions: principles and process

Alternative reagents used in green chemistry strategies.

UNIT - V

Greener synthesis of pharmaceuticals: Principle and procedure of the following synthesis

Nicotinic acid, Ibuprofen, paracetamol, Aspirin

Future trends in Green chemistry

REFERENCE BOOKS

1. Paul T Anastas, John Charles Warner. Green chemistry: theory and practice. Oxford university Press, 1988
2. Alluwalia V.K, Green chemistry : environmentally benign reactions. 2nd edn, Ane Books Pvt Ltd, New Delhi, 2012
3. Alluwalia V.K, M. Kidwai, New trends in green chemistry. 2nd edn, Anamaya Publishers, New delhi, 2004.

PS507: CELL AND MOLECULAR BIOLOGY
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C

3 1/0/ 4

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

UNIT – I

10 Hours

- a. Cell and Molecular Biology: Definitions theory and basics and Applications.
- b. Cell and Molecular Biology: History and Summation.
- c. Theory of the Cell? 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 Structure
- 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
- 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. Ananthanarayana and Panikers, Text book of microbiology, 10th edition by universities press.
2. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
3. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
6. Rose: Industrial Microbiology.
7. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
8. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
9. Peppler: Microbial Technology.
10. Edward: Fundamentals of Microbiology.
11. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
12. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
13. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
14. RA Goldshy et. al., Kuby Immunology.

PS508: COSMETIC SCIENCE
(Open Elective - I)

B.Pharm. III Year I Sem.

L T/P/ C

3 1/0/ 4

Course Objective: This subject deals with cosmetic products, cosmetic excipients, skin care products and their methods of preparation and evaluations.

Course Outcomes:

- Upon completion of the course the student shall be able to know the regulations pertaining to cosmetics and cosmetic excipients.
- They will be knowing the preparations of various skin care products like creams, anti-perspirants, deodorants, hair care products etc.
- They also know about the role of herbs in sunscreens.

UNIT – I

10 Hours

Classification of cosmetic and cosmeceutical products

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives.

Classification and application **Skin:** Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT – II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream their relative skin sensory, advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioners, antidandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT – III

10 Hours

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT – IV

08 Hours

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits.

UNIT – V**07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

REFERENCE BOOKS:

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Textbook of Cosmetics by Rajesh Kumar Nema, Kmal singh Rathore and BK Dubey
4. Textbook of Cosmetics by M. Vimaladevi

PS509: INDUSTRIAL PHARMACY LAB

B.Pharm. III Year I Sem.

**L T/P/ C
0 0/4/ 2**

List of Experiments:

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers (As per IP)

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
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.

PS510: PHARMACOLOGY - II LAB

B.Pharm. III Year I Sem.

L T/P/ C
0 0/4/ 2

List of Experiments:

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 abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis 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 PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 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

Recommended Books (Latest Editions)

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

PS511: PHARMACOGNOSY AND PHYTOCHEMISTRY II LAB

B.Pharm. III Year I Sem.

L T/P/ C
0 0/4/ 2

List of Experiments:

- (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

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, 1st 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, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

***MC500: ENVIRONMENTAL SCIENCES**

B.Pharm. III Year I Sem.

L T/P/ C
1 0/0/ 0

Course Objectives: 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.

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

- Create the 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 learner 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

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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

UNIT – II

Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

UNIT – III

Biodiversity and Biotic Resources: Introduction, Definition, genetic, species and ecosystem diversity.

Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic and optional values.

India as a mega diversity nation, Hot spots of biodiversity. Field visit. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts; conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

Unit – IV

Environmental Pollution: Air pollution; Water pollution; Soil pollution, Noise Pollution

UNIT -- V

Environmental Policy, Legislation & EIA: Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wild life Act.

Towards Sustainable Future: Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human health, Environmental Ethics, Concept of Green Building, Ecological Foot Print, Life Cycle assessment (LCA), Low carbon life style.

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. Text book of environmental science and technology, Dr. M. Anji Reddy.
5. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
6. Clark R.S., Marine Pollution, Clanderson Press Oxford
7. Cunningham, W.P. Cooper, T. H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
8. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
9. Down of Earth, Centre for Science and Environment

PS601: MEDICINAL CHEMISTRY – III

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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

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

Beta-Lactam antibiotics: Penicillin, Cephalosporins, Beta-Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 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.

UNIT – III

10 Hours

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

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

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

08 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, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

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 of combinatorial 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. The Organic Chemistry of Drug Synthesis by Lednicher, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

PS602; PHARMACOLOGY - III

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

Course Objectives: 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 Outcomes: 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 infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and appreciate correlation of pharmacology with related medical sciences.

UNIT- I

10 hours

1. 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

2. 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

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

UNIT – III

10 hours

Chemotherapy

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

UNIT – IV

08 hours

1. Chemotherapy

- a. Urinary tract infections and sexually transmitted diseases.
Chemotherapy of malignancy.

2. Immunopharmacology

- a. Immunostimulants
- b. Immunosuppressant
- c. Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT – V

07 hours

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, organophosphorus compound and lead, mercury and arsenic poisoning.

Recommended Books (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
- 2. Churchill Livingstone Elsevier
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 5. 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
- 6. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
- 7. K. D. Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 8. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher 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,
- 11. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

PS603: HERBAL DRUG TECHNOLOGY

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

UNIT – I

6 Hours

1. Herbs as raw materials

Definition of herb, herbal medicine, herbal drug preparation Source of Herbs

Selection, identification and authentication of herbal materials Processing of herbal raw material

2. Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

3. 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.

UNIT – II

7 Hours

1. 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

2. **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.

UNIT - III

10 Hours

1. Herbal Cosmetics

Principles and preparation of herbal cosmetics formulations- Shampoos, Dyes, face creams, tooth pastes and Bleaching agents.

2. Herbal excipients:

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

3. Herbal formulations :

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

UNIT – IV**10 Hours**

1. **Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.
2. **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.
3. **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**

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, standard operating procedures, health and hygiene, documentation and records.

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
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. Pharmacopoeal 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.
8. Herbal drug Technology. By SS Agrawal and M Paridhavi
9. Indian Medicinal Plants A compendium of 500 species Vol 1, 11, 111, 1V & V By Arya vaidys sala , Universities Press

PS604: BIOPHARMACEUTICS AND PHARMACOKINETICS

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

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

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics.
- Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
- Critically evaluate biopharmaceutic studies involving drug product equivalency
- Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

UNIT – I

10 Hours

Introduction to 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:** Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT – II

10 Hours

Metabolism & Excretion: Drug metabolism and basic understanding of 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: Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.

UNIT – III

10 Hours

Pharmacokinetics:

Introduction to Pharmacokinetics models, Compartment models, Non-compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of K_a , K_E . From plasma and urinary excretion data

UNIT – IV

08 Hours

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

- a). Repetitive Intravenous injections – One Compartment Open Model
- b). Repetitive Extravascular dosing – One Compartment Open model

UNIT – V

07 Hours

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Biotransformation 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 International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Fundamentals of Biopharmaceutics and pharmacokinetics by Dr. V. Venkateshwarlu
6. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
7. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
8. Biopharmaceutics; By Swarbrick
9. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
10. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
11. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
12. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
13. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.

PS605: BP605T PHARMACEUTICAL QUALITY ASSURANCE
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C

3 1/0/ 4

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

Course Outcomes: 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

- 1. Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP
- 2. Total Quality Management (TQM):** Definition, elements, philosophies
- 3. 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 4. (QbD):** Definition, overview, elements of QbD program, tools
- 5. ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration
- 6. NABL accreditation:** Principles and procedure

UNIT – II

10 Hours

- 1. 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.
- 2. Equipments and raw materials:** Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – II

10 Hours

- Quality Control:** Quality control test for containers, rubber closures and secondary packing materials.
- 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

- 1. Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
- 2. 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

- 1. 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.

2. 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 I WHO 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

PS606: PHARMACEUTICAL BIOTECHNOLOGY
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C

3 1/0/ 4

Course Objectives:

- 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 Outcomes: Upon completion of the subject student shall 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.
- 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 products:
- d. Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
- e. Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

UNIT – III

10 Hours

- 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

UNIT – IV

08 Hours

- a. Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b. Genetic organization of Eukaryotes and Prokaryotes
- c. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

- d. Introduction to Microbial biotransformation and applications.
- e. Mutation.

UNIT – V

07 Hours

- a. Types of mutation/mutants
- b. Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- c. Large scale production fermenter design and its various controls.
- d. Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

Recommended Books (Latest edition):

- 1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications
- 2. of Recombinant DNA: ASM Press Washington D.C.
- 3. RA Goldshy et. al., Kuby Immunology.
- 4. J. W. Goding: Monoclonal Antibodies.
- 5. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
- 6. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
- 7. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
- 8. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

PS607: BIOINFORMATICS
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C
3 1/0/ 4

Course Objective: This subject is design to impart fundamental knowledge on the principles of bioinformatics

Course Outcomes: Upon completion of the course the student able to understand

- Foundation of bioinformatics
- Sequence comparisons methods
- Genomic applications
- Proteomic and metabolic applications.

UNIT - I

Foundations of bioinformatics

- 1.1 Bioinformatics- a historical perspective
- 1.2 Bioinformatics data- nucleic acid sequence, protein sequence, protein structure, genome variation data, gene expression data, proteomic data, metabolic pathways and networks
- 1.3 Bioinformatics tools and resources- free online tolls, downloadable free tools, software pakags, bioinformatics web portals
- 1.4 Role of internet in Bioinformatics.

UNIT - II

Sequence comparison methods

- 2.1 Basics of sequence alignment: Match, mismatch, gaps, scoring an alignment (gap penalties (linear & affine gap penalties), sequence relationships (sequence identity, similarity, homology, orthologs, paralogs & xenologs)
- 2.2 DNA Vs protein sequence alignment (permissible replacement, similarity score, scoring matrices (PAM & BLOSUM)
- 2.3 multiple-sequence alignment (MSA): significance of MSA

UNIT - III

Genomic Applications:

- 3.1 Bioinformatics for genome sequencing, first and next generation methods of genome sequencing, de-novo and reference based genome sequencing, genome assembly (reads, contigs & scaffolds)
- 3.2 Transcript- profiling: expression microarrays (gene array& oligo array), transcriptome sequencing and RNA- seq analysis small RNA sequencing and analysis

UNIT - IV

- 4.1 Genome maps an markers: identification of molecular makers (SSR, STS & SNP markers), linkage Vs physical maps, displaying genome annotation using genome browsers
- 4.2 Medical application of bioinformatics –understanding diseases and identification of disease genes, disease diagnostics, overview of drug discovery, pharmacogenomics.

UNIT - V

Proteomic and metabolomic applications:

- 5.1 Protein profiling (2D gels, protein fingerprinting & identification), protein structure analysis
- 5.2 Protein structure: structure visualization
- 5.3 Protein: secondary and tertiary structure prediction (homology modelling)

Recommended Books (Latest edition):

1. Bioinformatics by B. G. Gurran, R. J. Walker, S.C. Bhatia. CBS Publishers.
2. Bioinformatics: Skills & applications by Rastogi, CBS Publishers
3. Bioinformatics: Sequence & genome analysis by Mount, CBS Publishers
4. Bioinformatics and bioprogramming by CN Chaveli
5. Bioinformatics (Basics, algorithms and applications by Ruchi singh and Richa Sharma
6. Essential Bioinformatics Jinxiong

PS608: SCREENING METHODS IN PHARMACOLOGY
(Open Elective - II)

B.Pharm. III Year II Sem.

L T/P/ C

3 1/0/ 4

Course Objectives: The student is going to study about various techniques involved in screening of drugs for various pharmacological activities and guidelines for handling animals

Course Outcomes: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines. The expected outcome are – the students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities and guidelines for regulations involved in screening of new drug molecules on animals.

UNIT - I

Care, handling and breeding technique of laboratory animals. Regulations for laboratory animals, CPSCEA guidelines, alternative to animal studies.

UNIT - II

Toxicity test: OECD guidelines, determination of LD₅₀, acute, sub-acute and chronic toxicity studies.

UNIT - III

Organization of screening for pharmacological activity of new substances with emphasis on the evaluation of antipsychotics, antiepileptics and antidepressants.

UNIT - IV

Screening methods for anti-diabetic, antiulcer, CHF and anti-hypertensive drugs.

UNIT - V

Screening methods for anti-inflammatory, analgesics and antipyretic drugs.

Recommended Books (Latest edition):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N.Bhagya Lakshmi
5. Fundamentals of experimental Pharmacology by M.N. Ghosh.
6. Experimental Pharmacology for undergraduates by M C Prabhakara.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta.
10. Handbook of Experimental Pharmacology, SK. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.

PS609: MEDICINAL CHEMISTRY- III LAB

B.Pharm. III Year II Sem.

L T/P/ C
0 0/4/ 2

1. Preparation of drugs and intermediates

- a. Sulphanilamide
- b. 7-Hydroxy, 4-methyl coumarin
- c. Chlorobutanol
- d. Triphenyl imidazole
- e. Tolbutamide
- f. Hexamine

2. Assay of drugs

- a. Isonicotinic acid hydrazide
- b. Chloroquine
- c. Metronidazole
- d. Dapsone
- e. Chlorpheniramine maleate
- f. Benzyl penicillin

3. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
4. Drawing structures and reactions using chem draw®
5. 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)

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.

PS610: PHARMACOLOGY - III LAB

B.Pharm. III Year II Sem.

L T/P/ C
0 0/4/ 2

List of Experiments:

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)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

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 Modern Pharmacology with 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,
10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

PS611: HERBAL DRUG TECHNOLOGY LAB

B.Pharm. III Year II Sem.

**L T/P/ C
0 0/4/ 2**

List of Experiments:

1. To perform preliminary phytochemical screening of crude drugs.
2. Evaluation of excipients of natural origin
3. Incorporation of prepared and standardized extract in cosmetics formulations like creams, lotions, Shampoos and their evaluation.
4. Incorporation of prepared and standardized extract in cosmetics formulations like Syrups, Mixtures and tablets and their evaluations as per pharmacopoeial requirements
5. Monograph analysis of herbal drugs from recent Pharmacopoeias
6. Determination of Aldehyde content
7. Determination of phenolic content
8. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
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. Pharmacopoeal 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.

***MC600: HUMAN VALUES AND PROFESSIONAL ETHICS**

B.Pharm. III Year II Sem.

L T/P/ C
1 0/0/ 0

Course Objective: To enable the students to imbibe and internalize the Values and Ethical Behavior in the personal and Professional lives.

Course Outcome: The students will understand the importance of Values and Ethics in their personal lives and professional careers. The students will learn the rights and responsibilities as an employee, team member and a global citizen.

UNIT - I

Introduction to Professional Ethics: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

UNIT - II

Basic Theories: Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

UNIT - III

Professional ethics in pharmacy: general introduction to code of pharmaceutical ethics, objectives, pharmacists in relation to his job, his trade, to his profession and relation to medicinal professions. Pharmacists oath.

UNIT - IV

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.

Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

UNIT - V

Global issues in Professional Ethics: Introduction – Current Scenario, Technology Globalization of MNCs, International Trade, World Summits, Issues, Business Ethics and Corporate Governance, Sustainable Development Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights.

TEXT BOOKS:

1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.

REFERENCE BOOKS

1. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
2. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.
3. Forensic Pharmacy by Dr.Kokate
4. Forensic Pharmacy by Bhaskar Chaurasia

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
BACHELOR OF PHARMACY
COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2022-23 Admitted Batch

I Year I semester

S. No	Course Code	Subject	L	T	P	Credits
1	PS101	Human Anatomy and Physiology I	3	1	-	4
2	PS102	Pharmaceutical Analysis I	3	1	-	4
3	PS103	Pharmaceutics	3	1	-	4
4	PS104	Pharmaceutical Inorganic Chemistry	3	1	-	4
5	HS105	Communication skills	2	-	-	2
6	BS106/BS107	Remedial Biology [#] / Remedial Mathematics [§]	2 [#] /3 [§]	-	-	2 [#] /3 [§]
7	PS108	Human Anatomy and Physiology-I lab	-	-	4	2
8	PS109	Pharmaceutical Analysis I lab	-	-	4	2
9	PS110	Pharmaceutics lab	-	-	4	2
10	PS111	Pharmaceutical Inorganic Chemistry lab	-	-	4	2
11	HS112	Communication skills lab	-	-	2	1
12	BS113	Remedial Biology lab	-	-	2	1
Total			16/17	4	20	30[#]/30

[#]Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course.

[§]Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

I Year II semester

S. No	Course Code	Subject	L	T	P	Credits
1	PS201	Human Anatomy and Physiology II	3	1	-	4
2	PS202	Pharmaceutical Organic Chemistry-I	3	1	-	4
3	BS203	Biochemistry	3	1	-	4
4	BS204	Pathophysiology	3	1	-	4
5	CS205	Computer Applications in Pharmacy	3	-	-	3
6	PS206	Human Anatomy and Physiology II lab	-	-	4	2
7	PS207	Pharmaceutical Organic Chemistry-I Lab	-	-	4	2
8	BS208	Biochemistry lab	-	-	4	2
9	CS209	Computer Applications in Pharmacy lab	-	-	2	1
10	*MC200	NSS	-	-	-	-
Total			15	4	14	26

II YEAR I SEMESTER

S. No	Course Code	Course Title	L	T	P	Credits
1	PS301	Pharmaceutical Organic Chemistry-II	3	1	0	4
2	PS302	Physical Pharmaceutics-I	3	1	0	4
3	BS303	Pharmaceutical Microbiology	3	1	0	4
4	PC304	Pharmaceutical Engineering	3	1	0	4

5	PS305	Pharmaceutical Organic Chemistry-II Lab	0	0	4	2
6	PS306	Physical Pharmaceutics-I Lab	0	0	4	2
7	BS307	Pharmaceutical Microbiology Lab	0	0	4	2
8	PC308	Pharmaceutical Engineering Lab	0	0	4	2
10	*MC300	NSO	0	0	0	0
		Total Credits	12	04	16	24

II YEAR II SEMESTER

S. No	Course Code	Course Title	L	T	P	Credits
1	PS401	Pharmaceutical Organic Chemistry-III	3	1	0	4
2	PC402	Physical Pharmaceutics-II	3	1	0	4
3	PS403	Pharmacology-I	3	1	0	4
4	PC404	Pharmacognosy and Phytochemistry-I	3	1	0	4
5	PS405	Pharmaceutical Jurisprudence	3	1	0	4
6	PC406	Physical Pharmaceutics-II Lab	0	0	4	2
7	PS407	Pharmacology-I Lab	0	0	4	2
8	PC408	Pharmacognosy and Phytochemistry-I Lab	0	0	4	2
9	*MC400	Gender Sensitization Lab	1	0	0	0
		Total Credits	16	05	12	26

III Year I Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS501	Medicinal Chemistry I	3	1	0	4
2	PS502	Industrial Pharmacy - I	3	1	0	4
3	PS503	Pharmacology II	3	1	0	4
4	PS504	Pharmacognosy and Phytochemistry - II	3	1	0	4
5	PS505 PS506 PS507 PS508	Open Elective - I I. Generic Product Development II. Green Chemistry III. Cell and Molecular Biology IV. Cosmetic science	3	1	0	4
6	PC509	Medicinal Chemistry I Lab	0	0	4	2
7	PS510	Industrial Pharmacy – I lab	0	0	4	2
8	PS511	Pharmacology - II lab	0	0	4	2
9	PS512	Pharmacognosy and Phytochemistry - II lab	0	0	4	2
10	*MC500	Environmental sciences	1	0	0	0
		Total	16	05	16	28

III Year II Semester

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS601	Medicinal Chemistry - II	3	1	0	4
2	PS602	Pharmacology - III	3	1	0	4
3	PS603	Herbal Drug Technology	3	1	0	4
4	PS604	Biopharmaceutics and Pharmacokinetics	3	1	0	4
5	PS605 PS606 PS607 PS608	Open Elective - II I. Pharmaceutical Quality Assurance II. Pharmaceutical Biotechnology III. Bioinformatics IV. Screening Methods in Pharmacology	3	1	0	4
6	PS609	Medicinal chemistry - II lab	0	0	4	2

7	PS610	Pharmacology - III lab	0	0	4	2
8	PS611	Herbal Drug Technology lab	0	0	4	2
9	PS612	Biopharmaceutics and Pharmacokinetics Lab	0	0	4	2
10	*MC600	Human Values and Professional Ethics	1	0	0	0
Total			16	05	16	28

IV Year I Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS701	Instrumental Methods of Analysis	3	1	0	4
2	PS702	Industrial Pharmacy-II	3	1	0	4
3	PS703	Pharmacy Practice	3	1	0	4
4	PS704	Medicinal Chemistry - III	3	1	0	4
5	PS705 PS706 PS707 PS708	Open Elective - III i. Pharmaceutical Marketing ii. Pharmaceutical Regulatory Science iii. Pharmacovigilance iv. Quality Control and Standardization of Herbals	3	1	0	4
6	PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	PS710	Practice School	0	0	4	2
8	PS711	Industrial Training	0	0	4	2
Total			15	5	12	26

IV Year II Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Novel Drug Delivery System	3	1	0	4
4	PS804 PS805 PS806 PS807	Open Elective - IV i. Computer Aided Drug Design ii. Nano Technology iii. Experimental Pharmacology iv. Advanced Instrumentation Techniques	3	1	0	4
5	PS808	Novel Drug Delivery System Lab	0	0	4	2
6		Project Work	0	0	6	3
Total			12	4	10	21

*MC - Mandatory Course - Satisfactory/ Unsatisfactory.

PS101: HUMAN ANATOMY AND PHYSIOLOGY - I**B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

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.

Course 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 human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

UNIT –I**10 hours****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 extracellular 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**10 hours****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**10 hours****Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, 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 – IV**08 hours****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**07 hours****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.

TEXT 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. Text book 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. Text book 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

PS102: PHARMACEUTICAL ANALYSIS - I**B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

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

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

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

UNIT - I**10 Hours****(a) Pharmaceutical analysis-** Definition and scope

- Different techniques of analysis
- Methods of expressing concentration
- Primary and secondary standards.
- 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****10 Hours**

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**10 Hours**

Precipitation titrations: Mohr's method, Volhard's, ModifiedVolhard'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.

UNIT – IV**08 Hours****Redox titrations:**

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

UNIT – V**07 Hours****Electrochemical methods of analysis:**

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

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

TEXT BOOKS: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. Introduction to Pharmaceutical Analysis by Badwaik Hemant R. published by Pharma Med Press
3. A.I. Vogel, Text Book of Quantitative Inorganic analysis
4. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. John H. Kennedy, Analytical chemistry principles
7. Indian Pharmacopoeia.
8. Badwaik Hemant R., Introduction to Pharmaceutical Analysis, Pharma Med Press

PS103: PHARMACEUTICS**B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

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

Course Objectives: Upon completion of this course the student 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**10 Hours**

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 Pharmacopoeia.

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**10 Hours**

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**08 Hours**

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**08 Hours**

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.

UNIT – V**07 Hours**

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

TEXT BOOKS: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, 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 Text Book 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. Françoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.
13. Tripathi Dulal Krishna, Pharmaceutics: Basic Principles and Formulations, Pharma Med Press

PS104: PHARMACEUTICAL INORGANIC CHEMISTRY**B. Pharm. I Year I Sem**

L	T	P	C
3	1	0	4

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

Course 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**10 Hours**

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**10 Hours**

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**10 Hours****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**08 Hours****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, Sodiumnitrite333

Astringents: Zinc Sulphate, Potash Alum

UNIT – V**07 Hours**

Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131} , Storage conditions, precautions & pharmaceutical application of radioactive substances.

TEXT 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, Text Book of Quantitative Inorganic analysis
3. P. GunduRao, 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. IndianPharmacopoeia
8. Algarsamy V. Pharmaceutical Inorganic Chemistry, 2nd Ed. Pharma Med Press
9. Rao Somasekhar, Pharmaceutical Inorganic Chemistry, Pharma Med Press

HS105: COMMUNICATION SKILLS**B. Pharm. I Year I Sem**

L	T	P	C
2	0	0	2

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.

Course 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**07****Hours**

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**07****Hours**

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**07****Hours**

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**05****Hours**

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

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

UNIT – V**04 Hours**

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

TEXT BOOKS: (Latest Editions)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen. P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, GopalaSwamy Ramesh, 5th Edition, 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, Konarnira, 2nd Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning India pvt. Ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, McGraw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, McGraw Hill, 1999
13. Rao Bhaskara, Communication Skills, BS Publications

BS106: REMEDIAL BIOLOGY**B. Pharm. I Year I Sem**

L	T	P	C
2	0	0	2

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

Course 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 plant
- know understand the basic components of anatomy & physiology animal with special reference to human

UNIT - I**07 Hours****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**07 Hours****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 glands, 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**07 Hours****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, 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**05 Hours****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

04

Hours

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.

TEXT BOOKS:

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

REFERENCE BOOKS:

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

BS107: REMEDIAL MATHEMATICS**B. Pharm. I Year I Sem**

L	T	P	C
3	0	0	3

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 Laplace transform.

Course 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**06 Hours****Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using Gauss Elimination method.

UNIT- II**06 Hours****Logarithms:**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

Function:

Real Valued function, Classification of real valued functions

UNIT – III**06 Hours****Calculus****Limits and continuity:**

Introduction, Limit of a function, Definition of limit of a function

Differentiation:

Introductions, properties of derivatives, Finding derivative of a function using Standard Derivatives, 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**. Related problem.

UNIT – IV**06 Hours****Integration:**

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

UNIT – V**06 Hours****Differential Equations:**

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

TEXT BOOKS: (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Intermediate telugu academy mathematics text book
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S. Grewal
5. A Text Book of Remedial Mathematics by P seshagiri Rao, Pharmamed Press.

PS108: HUMAN ANATOMY AND PHYSIOLOGY- I Lab**B. Pharm. I Year I Sem**

L	T	P	C
0	0	4	2

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.

List of Experiments:

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. To study the integumentary and special senses using specimen, models, etc.,
7. To study the nervous system using specimen, models, etc.,
8. To study the endocrine system using specimen, models, etc
9. To demonstrate the general neurological examination
10. To demonstrate the function of olfactory nerve
11. To examine the different types of taste.
12. To demonstrate the visual acuity
13. To demonstrate the reflex activity
14. Recording of body temperature
15. To demonstrate positive and negative feedback mechanism.

PS109: PHARMACEUTICAL ANALYSIS - I Lab**B. Pharm. I Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:**1. Preparation and standardization of**

- 1) Sodium hydroxide
- 2) Sulphuric acid
- 3) Sodium thiosulfate
- 4) Potassium permanganate
- 5) Ceric ammonium sulphate

2. Assay of the following compounds 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

3. 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

REFERENCE:

1. Pharmaceutical Analysis: A Practical Manual by Randhir Singh Dahiya, Navpreet Kaur, Lalit Kishore, Pharmamed.

PS110: PHARMACEUTICS LAB**B. Pharm. I Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:**1. Syrups**

- a) Syrup IP
- b) Paracetamol pediatric syrup

2. Elixirs

- a) Piperazine citrate elixir
- b) Paracetamol pediatric elixir

3. Linctus a) Simple Linctus BPC**4. Solutions**

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution

5. Suspensions

- a) Calamine lotion
- b) Magnesium Hydroxide mixture

5. Emulsions

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

6. Powders and Granules

- a) ORS powder (WHO)
- b) Effervescent granules c) Dusting powder

7. Suppositories

- a) Glycero gelatin suppository
- b) Soap glycerin suppository

8. Semisolids

- a) Sulphur ointment
- b) Non-staining iodine ointment with methyl salicylate
- c) Bentonite gel

9. Gargles and Mouthwashes

- a) Potassium chlorate gargle
- b) Chlorhexidine mouthwash

REFERENCES BOOKS:

- 1. Pharmaceutics-I (General Pharmacy) A Practical Manual by Mishra Vijay, Pharmamed Press
- 2. Pharmaceutics: A Practical Manual for B PHARM & PHARM D Courses, Abraham Sindhu by Pharmamed Press.

PS111: PHARMACEUTICAL INORGANIC CHEMISTRY - LAB**B. Pharm. I Year I Sem****L T P C**
0 0 4 2**Limit tests for following ions**

- a) Limit test for Chlorides and Sulphates Modified limit test for Chlorides and Sulphates Limit test for Iron
- b) Limit test for Heavy metals Limit test for Lead
- c) Limit test for Arsenic

Identification test Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

Test for purity

- a) Swelling power of Bentonite
- b) Neutralizing capacity of aluminum hydroxide gel
- c) Determination of potassium iodate and iodine in potassium Iodide

Preparation of inorganic pharmaceuticals

- a) Boric acid
- b) Potash alum
- c) Ferrous sulphate

REFERENCE BOOK:

1. Practical Pharmaceutical In-Organic Chemistry, by Bayya Subba Rao, Pharmamed Press.

HS112: COMMUNICATION SKILLS - LAB**B. Pharm. I Year I Sem**

L	T	P	C
0	0	2	1

The following learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech
Figures of Speech
Effective Communication
Writing Skills
Effective Writing
Interview Handling Skills
E-Mail etiquette
Presentation Skills

REFERENCE BOOK:

1. Successful Career Soft Skills and Business English Personality Development and Career Path
by Varanasi Bhaskara Rao, Y. Kameswari

BS113: REMEDIAL BIOLOGY LAB**B. Pharm. I Year I Sem**

L	T	P	C
0	0	2	1

List of Experiments:

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 and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

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. Shrivastava.
3. Biology practical manual according to National core curriculum. Biology forum of Karnataka. Prof. M. J. H. Shafi

PS201: HUMAN ANATOMY AND PHYSIOLOGY-II**B. Pharm. I Year II Sem**

L	T	P	C
3	1	0	4

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.

Course 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 human body.
- Perform the hematological tests like blood cell counts, hemoglobin 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**10 hours****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, Reticulo endothelial system.

Lymphatic system

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

UNIT – II**10 hours****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 heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

UNIT – III**06 hours****Digestive system**

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.

Respiratory system

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

UNIT – IV**10 hours****Respiratory system**

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 – V**09 hours****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

TEXT 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. Text book 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. Human Anatomy and Physiology-II by Singh Amteshwar Jaggi, Pharmamed Press

REFERENCE BOOKS:

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Text book 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. Chatterje, Academic Publishers Kolkata

PS202: PHARMACEUTICAL ORGANIC CHEMISTRY –I**B. Pharm. I Year II Sem**

L	T	P	C
4	1	0	4

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 on mechanisms and orientation of reactions.

Course 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 compound

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**07 Hours****Classification, nomenclature and isomerism**

Brief review of structural theory of organic chemistry, hybridization, bond length, bond angle, bond energy; inductive effect, electromeric effect, resonance, hyperconjugation and their application in the analysis of strength of organic acids, bases and stability of organic compounds; structure, shape and reactivity of nucleophiles, electrophiles and free radicals; cleavage of bonds-homolysis and heterolysis

Classification of Organic Compounds: Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

Types of organic reactions: Addition reactions-electrophilic, nucleophilic and free radical; Substitution reactions-electrophilic, nucleophilic and free radical; elimination and rearrangement reactions

UNIT – II**10 Hours****Alkanes*, Alkenes* and Conjugated dienes***

Functional group approach for the following reactions (preparations & reactions) to be studied in context to their structure

Alkanes: Preparation: Catalytic hydrogenation, Wurtz reaction, Kolbe's synthesis, from Grignard reagent. Reactions: Free radical Substitution: Halogenation, Synthesis of cycloalkanes and different kinds of strains in cycloalkanes

Alkenes: Preparation: Elimination reactions: Dehydration of alkenes and dehydrohalogenation of alkyl halides (Saytzeff's rule); cis alkenes (Partial catalytic hydrogenation) and trans alkenes (Birch reduction). Reactions: cis-addition (alk. KMnO₄) and trans-addition (bromine), Addition of HX (Markownikoff's and anti-Markownikoff's addition), Hydration, Ozonolysis, oxymercuration-demercuration, Hydroboration-oxidation, stability of alkenes

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

Alkynes: Preparation: Acetylene from CaC₂ and conversion into higher alkynes; by dehalogenation of tetra halides and dehydrohalogenation of vicinal-dihalides. Reactions: formation of metal acetylides, addition of bromine and alkaline KMnO₄, ozonolysis and oxidation with hot alk. KMnO₄

UNIT – III**10 Hours****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, Preparation: from alkenes and alcohols. Reactions: hydrolysis, nitrite & nitro formation, nitrile & isonitrile formation.

Alcohols: Preparation of alcohols: using Grignard reagent, Ester hydrolysis, Reduction of aldehydes, ketones, carboxylic acid and esters. Reactions: With sodium, HX (Lucas test), esterification, oxidation reactions.

UNIT – IV**10 Hours****Carbonyl compounds* (Aldehydes and ketones)**

Preparation: from acid chlorides and from nitriles. Reactions: Reaction with HCN, ROH, NaHSO₃, NH₂-G derivatives. Aldol Condensation, Cannizzaro's reaction, Wittig reaction, Benzoin condensation, Clemmensen reduction and Wolff Kishner reduction, Meerwein-Ponndorf Verley reduction, Analysis of aldehydes and ketones: haloform test, 2,4-DNP test, Tollens and Fehling test.

UNIT - V**08 Hours****Carboxylic acids***(aliphatic and aromatic)

Preparation and reactions of carboxylic acids.

Carboxylic acid derivatives (aliphatic): Preparation: Acid chlorides, Anhydrides, Esters and Amides from acids and their interconversion.

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Aliphatic amines* -

Preparation: from alkyl halides, Gabriel's Phthalimide synthesis, Hofmann Bromamide reaction.

Reactions: Hofmann vs. Saytzeff elimination, Quaternary ammonium salts, Carbylamine test.

Basicity, effect of substituent on Basicity. Qualitative tests.

TEXT BOOKS: (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar, Volume-I
3. Algarsamy V., Pharmaceutical organic Chemistry, Pharma Med Press
4. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
5. Organic Chemistry by P.L. Soni
6. Practical Organic Chemistry by Mann and Saunders.
7. Vogel's text book of Practical Organic Chemistry
8. Advanced Practical organic chemistry by N.K. Vishnoi.
9. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
10. Pharmaceutical organic Chemistry-1, Pooja Chawla.
11. McMurry E. John, Organic Chemistry, Cengage

BS203: BIOCHEMISTRY**B. Pharm. I Year II Sem**

L	T	P	C
3	1	0	4

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.

Course 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**10 Hours****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 level phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT – II**10 Hours****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.

UNIT – III**10 Hours****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, alpeptonuria, tyrosinemia)

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

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT – IV**08 Hours**

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 inhibitors

UNIT – V

07 Hours

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

TEXT BOOKS: (Latest Editions)

1. Principles of Biochemistry by Lehninger
2. Algarsamy V. Pharmaceutical Biochemistry, Pharma Med Press.
3. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
4. Biochemistry by Stryer.
5. Biochemistry by D. Satyanarayan and U. Chakrapani
6. Textbook of Biochemistry by Rama Rao.
7. Textbook of Biochemistry by Deb.
8. Outlines of Biochemistry by Conn and Stumpf
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)

BS204: PATHOPHYSIOLOGY**B. Pharm. I Year II Sem**

L	T	P	C
3	1	0	4

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.

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

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

UNIT – I**10 Hours****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**10 Hours****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**10 Hours****Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, 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**08 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

UNIT – V**07 Hours**

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections, SARS virus including COVID 19, Conjunctivitis, Measles

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

TEXT 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. Sujesh M., Pathophysiology for Pharmacy - A Concise Review, Pharma Med Press
5. 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;
6. William and Wilkins, Baltimore; 1991 [1990 printing].
7. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
8. Guyton A, John. E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
9. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
10. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

CS205: COMPUTER APPLICATIONS IN PHARMACY**B. Pharm. I Year II Sem**

L	T	P	C
3	0	0	3

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

Course 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**06 hours**

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

Concept of Information Systems and Software: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II**06 Hours**

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**06 Hours**

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**06 hours**

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

UNIT-V**06 hours**

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

TEXT 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 – Wiley-Interscience, A John Wiley 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)
4. 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
5. Mohiddin S. D. Computer Applications in Pharmaceutical Sciences, Pharma Med Press.

PS206: HUMAN ANATOMY AND PHYSIOLOGY –II LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	4	2

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.

List of Experiments:

1. Introduction to hemocytometry.
2. Enumeration of white blood cell (WBC) count
3. Enumeration of total red blood corpuscles (RBC) count
4. Determination of bleeding time
5. Determination of clotting time
6. Estimation of hemoglobin content
7. Determination of blood group.
8. Determination of erythrocyte sedimentation rate (ESR).
9. Determination of heart rate and pulse rate.
10. Recording of blood pressure.
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 analyser
16. Permanent slides of vital organs and gonads.

REFERENCE BOOKS:

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

PS207: PHARMACEUTICAL ORGANIC CHEMISTRY -I LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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

RECOMMENDED BOOKS (Latest Editions)

- 1. Practical Organic Chemistry by Mann and Saunders.
- 2. Advanced Practical organic chemistry by N.K. Vishnoi.

BS208: BIOCHEMISTRY LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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) Biochemistry: A Practical Manual, Bose Sharad Chandra
- 2) Practical Biochemistry by R.C. Gupta and S. Bhargavan.
- 3) Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
- 4) Practical Biochemistry by Harold Varley.

CS209: COMPUTER APPLICATIONS IN PHARMACY LAB**B. Pharm. I Year II Sem**

L	T	P	C
0	0	2	1

List of Experiments:

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a 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

PS301: PHARMACEUTICAL ORGANIC CHEMISTRY – II**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

Course Objectives: 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 on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Course Outcomes: 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,
- prepare organic compounds

UNIT - I**10 Hours****Benzene and its derivatives**

A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule

B. Preparations of benzene, Reactions of benzene - nitration, sulphonation, halogenation reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.

C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

UNIT - II**10 Hours**

Phenols* - preparation and reactions, Acidity of phenols, effect of substituents on acidity, qualitative tests.

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

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

UNIT – III**10 Hours**

Nitro Compounds: Preparations and reactions, Classification, Reactivity: Halogenation using nitrous acid, Nef reaction, Michael Addition, Henry Reaction, Aromatic Nitro hydrocarbons, Preparation of Nitrobenzene from diazonium salt and direct nitration, Reactivity and reduction of nitrobenzene in different media.

Ethers (aliphatic and aromatic): Introduction, synthesis and reactions of ethers

UNIT – IV**08 Hours****Polynuclear hydrocarbons:**

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

UNIT – V**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

RECOMMENDED BOOKS (Latest Editions)

- Organic Chemistry by Morrison and Boyd
- Organic Chemistry by I.L. Finar, Volume-I
- Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

4. Pharmaceutical organic Chemistry by V Algarsamy, Pharmamed Press
5. Organic Chemistry by P.L. Soni
6. Practical Organic Chemistry by Mann and Saunders.
7. Vogel's text book of Practical Organic Chemistry
8. Advanced Practical organic chemistry by N.K. Vishnoi.
1. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

PS302: PHYSICAL PHARMACEUTICS - I**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

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

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

- Understand various physicochemical properties of drug molecules in the designing the dosage form.
- Know the principles of chemical kinetics & to use them in assigning expiry date for formulation.
- Demonstrate use of physicochemical properties in evaluation of dosage forms.
- Appreciate physicochemical properties of drug molecules in formulation research and development.

UNIT – I**10 Hours**

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 – II**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, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. Partially miscible liquids, Critical solution temperature (CST) and applications. Distribution law, its limitations and applications

UNIT - III**10 Hours**

Micromeretics: Particle size and distribution, average 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 – IV**08 Hours**

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**

pH, 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. Isotonicity, Colligative properties and determination of tonicity of a system.

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 1-3, 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.
8. Manavalan et. Al, Physical Pharmaceutics, Pharma Med Press

BS303: PHARMACEUTICAL MICROBIOLOGY**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

Course Objectives: In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms. Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc. Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

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

- Understand methods of identification, cultivation and preservation of various microorganisms
- Importance of sterilization in microbiology. and pharmaceutical industry
- Learn sterility testing of pharmaceutical products.
- Microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

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 and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.

UNIT – III**10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus. 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. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic and testing of antimicrobial activity of a new substance. General aspects-environmental cleanliness.

UNIT – V**07 Hours**

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. Rafi MD, Text book of biochemistry for undergraduates, 3rd edition, Universities press, 2017.
2. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
3. Prescott and Dunn, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
6. Rose: Industrial Microbiology.
7. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
8. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
9. Peppler: Microbial Technology.
10. I.P., B.P., U.S.P.- latest editions.
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
14. Ananthanarayan and Paniker's textbook of Microbiology tenth edition
15. Ravi Kumar, Pharmaceutical Microbiology: A Comprehensive Approach, 2nd Ed. Pharma Med Press

PC304: PHARMACEUTICAL ENGINEERING**B. Pharm. II Year I Sem**

L	T	P	C
3	1	0	4

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

Course Outcomes: Upon completion of the course student shall be able:

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

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**

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 & Silverson Emulsifier,

Crystallization: Objectives, applications, & theory of crystallization. Solubility curves, principles, construction, working, uses, merits and demerits of Agitated batch crystallizer, Swenson Walker Crystallizer, Krystal crystallizer, Vacuum crystallizer. Caking of crystals, factors affecting caking & prevention of caking.

UNIT – III**10 Hours**

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.

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. List of equipment by name and their functions.

UNIT – IV**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.

Distillation: Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced

pressure, steam distillation & molecular distillation

UNIT - V**07 Hours**

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. HEPA filters for controlled pollution.

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.

RECOMMENDED BOOKS: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, 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 DK Tripathi, Pharma Med Press
5. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
6. Remington practice of pharmacy- Martin, Latest edition.
7. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
8. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
9. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.
10. Derle, Essentials of Pharmaceutical Engineering (Unit Operations), 2nd Ed. Pharma Med Press

PS305: PHARMACEUTICAL ORGANIC CHEMISTRY - II LAB**B. Pharm. II Year I Sem**

L	T	P	C
0	0	4	2

I Experiments involving laboratory techniques

Recrystallization
Steam Distillation

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

Acid value
Saponification value
Iodine value

III Preparation of compounds

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

RECOMMENDED BOOKS: (Latest Editions)

1. Practical Organic Chemistry by Mann and Saunders.
2. Durai Ananda Kumar T., Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press.
3. A Microscale Approach to Organic Laboratory Techniques, Pavia, Lampman, Cengage BSP Books.

PS306: PHYSICAL PHARMACEUTICS – I LAB**B. Pharm. II Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments

1. Determination the solubility of drug at room temperature at different pH conditions
2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch 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 particle size, particle size distribution using sieving method
7. Determination of particle size, particle size distribution using Microscopic method
8. Determination of bulk density, true density and porosity
9. Determine the angle of repose and influence of lubricant on angle of repose
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

RECOMMENDED BOOKS: (Latest Editions)

1. Experimental pharmaceuticals by Eugene, Parott.
2. Pharmaceutical Calculation, D K Tripathi.
3. Laboratory manual of physical pharmaceuticals, C.V.S. Subramanyam, J. Thimma settee
4. Mohanta Guru Prasad. Physical Pharmacy Practical text, 3rd Revised Ed., Pharma Med Press

BS307: PHARMACEUTICAL MICROBIOLOGY LAB**B. Pharm. II Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:

1. Introduction and study of different equipments 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, Grams 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 (IMViC reactions)
11. Revision Practical Class

RECOMMENDED BOOKS (Latest edition)

1. Jyostna, Manual of Practical Microbiology, Pharma Med Press
2. Pharmaceutical Microbiology: A Laboratory manual by Prasad G.Shyam & K.Srisailam,

PC308: PHARMACEUTICAL ENGINEERING LAB**B. Pharm. II Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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.

RECOMMENDED BOOKS (Latest edition)

1. Pharmaceutical Engineering : Practical Manual (Unit Operations), Sudhakara Reddy, Pharmamed Press.
2. Remington practice of pharmacy- Martin, Latest edition.

PS401: PHARMACEUTICAL ORGANIC CHEMISTRY – III**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

Course Objectives: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Course Outcomes: At the end of the course, the student shall be able to:

- Understand the methods of preparation and properties of organic compounds
- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- Know the medicinal uses and other applications of organic compounds

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT - I**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

UNIT – II**10 Hours****Geometrical isomerism**

Nomenclature of geometrical isomers (Cis Trans, EZ, 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

UNIT – III**10 Hours****Heterocyclic compounds with one hetero atom**

Nomenclature and classification

Synthesis, reactions and medicinal uses of compounds/derivatives: Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT – IV**08 Hours****Heterocyclic compounds with two hetero atoms**

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

UNIT – V**07 Hours****Reactions of 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, Pinacol-Pinacolone rearrangement Claisen-Schmidt condensation

RECOMMENDED BOOKS (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist
6. Rama Rao Nadendla, Principles of Pharmaceutical Organic Chemistry, 2nd Ed., Pharma Med Press

PS402: PHYSICAL PHARMACEUTICS - II**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

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

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

- Understand various physicochemical properties of drug molecules in the designing the dosage form
- Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
- Demonstrate use of physicochemical properties in evaluation of dosage forms.
- Appreciate physicochemical properties of drug molecules in formulation research and Development

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

UNIT - II**10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, 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 suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsion formulation.

UNIT - IV**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, solubilisation, detergency, adsorption at solid interface.

UNIT – V**07 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.

RECOMMENDED BOOKS: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceuticals 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 1-3, 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.
8. Vidyadhara et al. Physical Pharmaceutics – II, Pharma Med Press.

PC403: PHARMACOLOGY - I**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

Course Objectives: 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.

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

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

UNIT – I**08 hours****1. General Pharmacology**

- Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration.
- 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.
- Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT – II**10 Hours****Adverse Drug Reactions and Drug Interactions**

- Agonists, antagonists (competitive and noncompetitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- Adverse drug reactions.
- Drug interactions (pharmacokinetic and pharmacodynamic)
- 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 peripheral nervous system**

- Organization and function of ANS.
- Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- Local anesthetic agents.
- Drugs used in myasthenia gravis and glaucoma

UNIT – IV**10 Hours****3. Pharmacology of central nervous system - I**

- 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**07 Hours****Pharmacology of central nervous system - II**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. 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. A Pharmacology Primer: Theory Applications and Methods, 3rd edition, Terry P. Kenakin, Elsevier
3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
6. 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
7. 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
11. Ravishankar. K & Kiranmayi G.V.N, Pharmacology: A Comprehensive Approach, Pharma Med Press

PC404: PHARMACOGNOSY AND PHYTOCHEMISTRY - I**B. Pharm. II Year II Sem**

L	T	P	C
3	1	0	4

Course Objective: 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.

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

- to know the techniques in the cultivation and production of crude drugs
- to know the crude drugs, their uses and chemical nature
- know the evaluation techniques for the herbal drugs
- to carry out the microscopic and morphological evaluation of crude drugs

UNIT - I**10 Hours**

Introduction to Pharmacognosy: Definition, history, scope and development of Pharmacognosy

(a) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(b) 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 classification of drugs

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.

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 – III**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, serratiopeptidase, urokinase, streptokinase, pepsin).

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

Marine Drugs:

Novel medicinal agents from marine sources

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 naturopathy.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT - V

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

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, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, 11nd edition, Birla publications, New Delhi, 2007
8. Anatomy of Crude Drugs by M.A. Iyengar
9. SL Deore, Pharmacognosy and Phytochemistry – I, Pharma Med Press

PS405: PHARMACEUTICAL JURISPRUDENCE**B.Pharm. II Year II Sem.**

L	T	P	C
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Course Objectives: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

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

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

UNIT – I**10 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; its 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**08 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

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, 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**07 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 (Theory)
10. Kokate C. K. Textbook of Forensic Pharmacy, 2nd Ed. Pharma Med Press

PC406: PHYSICAL PHARMACEUTICS – II LAB**B. Pharm. II Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
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
12. Preparation and evaluation of Colloids

RECOMMENDED BOOKS: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceuticals by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Physical Pharmacy Practical text, 3rd Revised Ed.by Mohanta Guru Prasad
5. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

PS407: PHARMACOLOGY – I LAB**B. Pharm. II Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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 oesophagus
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 softwares and videos

RECOMMENDED BOOKS (Latest Editions)

- 1) Essentials of Experimental Pharmacology, General Concepts by Bothra Sunil

PC408: PHARMACOGNOSY AND PHYTOCHEMISTRY – I LAB**B. Pharm. II Year II Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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 length and width of Phloem fibres of Cinchona & Cinnamon.
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
11. Determination of acid value, ester value, Saponification value and iodine lab of fixed oils mentioned in theory.

RECOMMENDED BOOKS: (Latest Editions)

1. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
2. Practical Pharmacognosy, T. E. Wallis, Pharmamed Press
3. Anatomy of Crude Drugs by M.A. Iyengar

MC400: GENDER SENSITIZATION LAB**B. Pharm. II Year II Sem**

L	T	P	C
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COURSE DESCRIPTION

This course offers an introduction to Gender Studies, an interdisciplinary field that asks critical questions about the meanings of sex and gender in society. The primary goal of this course is to familiarize students with key issues, questions and debates in Gender Studies, both historical and contemporary. It draws on multiple disciplines – such as literature, history, economics, psychology, sociology, philosophy, political science, anthropology and media studies – to examine cultural assumptions about sex, gender, and sexuality.

This course integrates analysis of current events through student presentations, aiming to increase awareness of contemporary and historical experiences of women, and of the multiple ways that sex and gender interact with race, class, caste, nationality and other social identities. This course also seeks to build an understanding and initiate and strengthen programmes combating gender-based violence and discrimination. The course also features several exercises and reflective activities designed to examine the concepts of gender, gender-based violence, sexuality, and rights. It will further explore the impact of gender-based violence on education, health and development.

Objectives of the Course

- To develop students' sensibility with regard to issues of gender in contemporary India.
- To provide a critical perspective on the socialization of men and women.
- To introduce students to information about some key biological aspects of genders.
- To expose the students to debates on the politics and economics of work.
- To help students reflect critically on gender violence.
- To expose students to more egalitarian interactions between men and women.

Learning Outcomes

- Students will have developed a better understanding of important issues related to gender in contemporary India.
- Students will be sensitized to basic dimensions of the biological, sociological, psychological and legal aspects of gender. This will be achieved through discussion of materials derived from research, facts, everyday life, literature and film.
- Students will attain a finer grasp of how gender discrimination works in our society and how to counter it.
- Students will acquire insight into the gendered division of labor and its relation to politics and economics.
- Men and women students and professionals will be better equipped to work and live together as equals.
- Students will develop a sense of appreciation of women in all walks of life.
- Through providing accounts of studies and movements as well as the new laws that provide protection and relief to women, the textbook will empower students to understand and respond to gender violence.

Unit-I: UNDERSTANDING GENDER

Introduction: Definition of Gender-Basic Gender Concepts and Terminology-Exploring Attitudes towards Gender-Construction of Gender-Socialization: Making Women, Making Men
- Preparing for Womanhood. Growing up Male. First lessons in Caste.

Unit – II: GENDER ROLES AND RELATIONS

Two or Many? -Struggles with Discrimination-Gender Roles and Relations-Types of Gender Roles-Gender Roles and Relationships Matrix-Missing Women-Sex Selection and Its Consequences-Declining Sex Ratio. Demographic Consequences-Gender Spectrum: Beyond the Binary

Unit – III: GENDER AND LABOUR

Division and Valuation of Labour-Housework: The Invisible Labor- “My Mother doesn’t Work.” “Share the Load.”-Work: Its Politics and Economics -Fact and Fiction. Unrecognized and Unaccounted work. - Gender Development Issues-Gender, Governance and Sustainable Development-Gender and Human Rights-Gender and Mainstreaming

Unit – IV: GENDER - BASED VIOLENCE

The Concept of Violence- Types of Gender-based Violence-Gender-based Violence from a Human Rights Perspective-Sexual Harassment: Say No!-Sexual Harassment, not Eve-teasing- Coping with Everyday Harassment- Further Reading: “*Chupulu*”. Domestic Violence: Speaking Out/Is Home a Safe Place? -When Women Unite [Film]. Rebuilding Lives. Thinking about Sexual Violence Blaming the Victim-“I Fought for my Life....”

Unit – V: GENDER AND CULTURE

Gender and Film-Gender and Electronic Media-Gender and Advertisement-Gender and Popular Literature- Gender Development Issues-Gender Issues-Gender Sensitive Language-Gender and Popular Literature - Just Relationships: Being Together as Equals Mary Kom and Onler. Love and Acid just do not Mix. Love Letters. Mothers and Fathers. Rosa Parks-The Brave Heart.

Note: Since it is Interdisciplinary Course, Resource Persons can be drawn from the fields of English Literature or Sociology or Political Science or any other qualified faculty who has expertise in this field from engineering departments.

- **Classes will consist of a combination of activities: dialogue-based lectures, discussions, collaborative learning activities, group work and in-class assignments. Apart from the above prescribed book, Teachers can make use of any authentic materials related to the topics given in the syllabus on “Gender”.**

- ☞ **ESSENTIAL READING:** The Textbook, “*Towards a World of Equals: A Bilingual Textbook on Gender*” written by A. Suneetha, Uma Bhargubanda, Duggirala Vasanta, Rama Melkote, Vasudha Nagaraj, Asma Rasheed, Gogu Shyamala, Deepa Sreenivas and Susie Tharu published by Telugu Akademi, Telangana Government in 2015.

ASSESSMENT AND GRADING:

- Discussion & Classroom Participation: 20%
- Project/Assignment: 30%
- End Term Exam: 50%

PS501: MEDICINAL CHEMISTRY – I**B. Pharm. III Year I Sem**

L	T	P	C
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Course Objectives: 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 Outcomes: Upon completion of the course the student shall be able to

- understand the chemistry of drugs with respect to their pharmacological activity
- understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- know the Structural Activity Relationship (SAR) of different class of drugs
- write the chemical synthesis of some 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 (*)

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, significance of Isomerism in biological activity, Structural modifications in drug discovery. Prodrugs: Basic concepts & application of prodrug design

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.

Indirect acting agents: Hydroxyamphetamine, 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

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

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

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolatehydrochloride, 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

08 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.

Fluoro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, 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

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

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

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

Dissociative anesthetics: Ketamine hydrochloride. *

Narcotic and non-narcotic analgesics

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

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

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, 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. Rama Rao Nadendla, Medicinal Chemistry, 2nd Revised Ed. Pharma Med Press

PS502: INDUSTRIAL PHARMACY - I**B.Pharm. III Year I Sem.**

L	T	P	C
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Course Objective: 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 Outcomes: 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 (Crystalline and amorphous forms: Concepts of polymorphism and its significance in industrial setup), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient).

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

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:**

- Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- Quality control tests: In process and finished product tests

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

UNIT – III**08 Hours****Capsules:**

- Hard gelatin capsules:** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.
- Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets, Fluidised bed coater (FBC)/ extrusion spheronization technique.

UNIT – IV**10 Hours****Parenteral Products:**

- Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- Production procedure, production facilities and controls.
- Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals

and lyophilized products, Sterilization.

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

Ophthalmic/Otic Preparations: Introduction, formulation considerations; formulation of eye drops, ear 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 aerosolsystems; 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.

TEXT 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
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.
10. Pharmaceutical Technology 1 &11 BY Gaurav Agarwal CBS Publishers
11. Pharmaceutics Basic principles and Formulations by D.K. Tripathi Pharma med press
12. Semalty Ajay, Industrial Pharmacy - I, Pharma med press

PS503: PHARMACOLOGY - II**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

Course Objective: 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 Outcomes: 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**10 hours****Pharmacology of drugs acting on cardio vascular system - I**

- 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**10 hours****1. Pharmacology of drugs acting on cardio vascular system - II**

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

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT - III**10 hours****Autocoids and related drugs**

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

UNIT - IV**08 hours****Pharmacology of drugs acting on endocrine system - I**

- 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.
- e. Insulin, Oral Hypoglycemic agents and glucagon.
- f. ACTH and corticosteroids.

UNIT - V**07 hours****1. Pharmacology of drugs acting on endocrine system - II**

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

2. Bioassay

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

TEXT BOOKS (Latest Editions)

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
- 2. Churchill Livingstone Elsevier
- 3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
- 4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
- 5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
- 6. 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.
- 7. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
- 8. K. D. Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
- 9. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- 10. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert.
- 11. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
- 12. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

PS504: PHARMACOGNOSY AND PHYTOCHEMISTRY - II**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

Course Objective: 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 Outcomes: 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 carryout isolation and identification of phytoconstituents

UNIT - I**07 Hours****Metabolic pathways in higher plants and their determination**

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

UNIT - II**10 Hours**

- General introduction, general methods of extraction (Maceration, Percolatio, Chromatographic methods) and isolation of alkaloids, glycosides, flavanoids and volatile oils.
- Biological source, microscopical characters, composition, chemistry, analysis, therapeutic uses and commercial applications of the following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

UNIT - III**10 Hours**

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biological sources, therapeutic uses and commercial applications of following secondary metabolites

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT - IV**10 Hours****Isolation, Identification, analysis of phytoconstituents and commercial applications of following**

- Terpenoids: Menthol, Citral and Artemisin
- Glycosides: Glycyrrhetic acid and Rutin
- Alkaloids: atropine, Quinine, Reserpine and Caffeine
- Resins: Podophyllotoxin and Curcumin

UNIT - V**08 Hours**

- Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.

b. Modern methods of extraction (Super critical fluid extraction, counter current extraction, Microwave assisted extraction, ultra sonication assisted extraction)

TEXT 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, 1st 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, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Boo of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R. C. Dubey.
14. SL Deore, Pharmacognosy and Phytochemistry – II, Pharma Med Press
15. Kulkarni A. Vishaka, Pharmacognosy and Phytochemistry – II, Pharma Med Press

PS505: GENERIC PRODUCT DEVELOPMENT (Open Elective - I)**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

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

Course Outcome: The knowledge of the students is enhanced with the clear information about the generic product development.

UNIT - I

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

UNIT - II

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

UNIT - III

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

UNIT - IV

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

UNIT - V

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

REFERENCE BOOKS:

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

PS506: GREEN CHEMISTRY (Open Elective - I)**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

Course Objectives: To familiarize students about environment benign chemical synthesis. To make students familiarize with principles and importance of various green chemical synthesis. To provide adequate knowledge regarding green reactions, green solvents and other alternative green approaches. To impart adequate information regarding environment pollution, contributing factors and the concerns.

Course Outcomes: Upon completion of this course, the students should be able to: Explain the environment pollution factors. Understand the different greener approaches along with their principles.

UNIT – I**Introduction to green chemistry**

Inception of green chemistry: history and development.

Principles of green chemistry: description with examples.

Synthetic approaches of green chemistry: in water, solvent less, microwave, ultrasonic, catalytic and synthesis.

UNIT – II**In water and solvent less organic reactions**

In water reactions: principle and process involved in the Michael reaction and Wartz synthesis

Solvent less organic synthesis:

Alternative solvents used in green chemistry strategies

UNIT – III**Microwave and ultrasonic mediated reactions**

Microwave reactions: principles and process involved in the Fries rearrangement, Diels Alder reaction and Metal halide reduction

Ultrasonic reaction: principle and process involved in the Strecker and Reformatsky reactions

UNIT – IV**Catalytic and solid supported reactions**

Catalytic reactions: principle and process involved in the reactions catalyzed by metal catalysts, ionic liquids (Knovenegel condensation) and bio catalysts (Viliger reaction)

Solid supported reactions: principles and process

Alternative reagents used in green chemistry strategies.

UNIT – V

Greener synthesis of pharmaceuticals: Principle and procedure of the following synthesis

Nicotinic acid, Ibuprofen, paracetamol, Aspirin

Future trends in Green chemistry

REFERENCE BOOKS

1. Paul T Anastas, John Charles Warner. Green chemistry: theory and practice. Oxford university Press, 1988
2. Alluwalla V. K, Green chemistry: environmentally benign reactions. 2nd edn, Ane Books Pvt Ltd, New Delhi, 2012
3. Alluwalla V.K, M. Kidwai, New trends in green chemistry. 2nd edn, Anamaya Publishers, New Delhi, 2004.

PS507: CELL AND MOLECULAR BIOLOGY (Open Elective - I)**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

UNIT – I**10 Hours**

- a. Cell and Molecular Biology: Definitions theory and basics and Applications.
- b. Cell and Molecular Biology: History and Summation.
- c. Theory of the Cell? Properties of cells and cell membrane.
- d. Prokaryotic versus Eukaryotic
- e. Cellular Reproduction

UNIT – II**10 Hours**

- a. DNA and the Flow of Molecular Structure
- b. DNA Functioning
- c. DNA and RNA
- d. Types of RNA
- e. Transcription and Translation

UNIT – III**10 Hours**

- a. Proteins: Definition **and** Amino Acids
- 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. Ananthanarayana and Panikers, Text book of microbiology, 10th edition by universities press.
2. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
3. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
4. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
5. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
6. Rose: Industrial Microbiology.
7. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
8. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
9. Pepler: Microbial Technology.
10. Edward: Fundamentals of Microbiology.
11. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
12. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
13. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
14. RA Goldshy et. al., Kuby Immunology.

PS508: COSMETIC SCIENCE (Open Elective - I)**B.Pharm. III Year I Sem.**

L	T	P	C
3	1	0	4

Course Objective: This subject deals with cosmetic products, cosmetic excipients, skin care products and their methods of preparation and evaluations.

Course Outcomes:

- Upon completion of the course the student shall be able to know the regulations pertaining to cosmetics and cosmetic excipients.
- They will be knowing the preparations of various skin care products like creams, anti-perspirants, deodorants, hair care products etc.
- They also know about the role of herbs in sunscreens.

UNIT – I**10 Hours**

Classification of cosmetic and cosmeceutical products

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application **Skin:** Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT – II**10 Hours****Principles of formulation and building blocks of skin care products:**

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream their relative skin sensory, advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioners, antidandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT – III**10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT – IV**08 Hours**

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits.

UNIT – V**07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturization. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Introduction, classification and mechanism of action

REFERENCE BOOKS:

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Textbook of Cosmetics by Rajesh Kumar Nema, Kamal Singh Rathore and BK Dubey
4. Textbook of Cosmetics by M. Vimaladevi
5. Rao Madhusudan, Cosmeceuticals, Pharma Med Press
6. Vinita kale, Textbook of Cosmetic science and technology, Pharma Med Press

PC509: MEDICINAL CHEMISTRY – I LAB**B. Pharm. III Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:**I. Preparation of drugs/ intermediates**

- 1,3-pyrazole
- 1,3-oxazole
- Benzimidazole
- Benztriazole
- 2,3- diphenyl quinoxaline
- Phenothiazine
- Barbiturate

II Assay of drugs

- Chlorpromazine
- Phenobarbitone
- Atropine
- Ibuprofen
- Aspirin
- Furosemide

III Determination of Partition coefficient for any two drugs**RECOMMENDED BOOKS (Latest Editions)**

- Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
- Foye's Principles of Medicinal Chemistry.
- Burger's Medicinal Chemistry, Vol I to IV.
- Introduction to principles of drug design- Smith and Williams.
- Remington's Pharmaceutical Sciences.
- Martindale's extra pharmacopoeia.
- rganic Chemistry by I.L. Finar, Vol. II.
- The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
- Indian Pharmacopoeia.
- Text book of practical organic chemistry- A.I. Vogel
- Raghuprasad, et al., Advanced Medicinal Chemistry – A Laboratory Guide, Pharma Med Press

PS510: INDUSTRIAL PHARMACY LAB**B. Pharm. III Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers (As per IP)

PS511: PHARMACOLOGY - II LAB**B. Pharm. III Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:

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 abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis 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 PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 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

RECOMMENDED BOOKS (Latest Editions)

1. A Practical book of Pharmacology by Dr. Ramesh Alluri
2. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
3. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

PS512: PHARMACOGNOSY AND PHYTOCHEMISTRY II LAB**B. Pharm. III Year I Sem**

L	T	P	C
0	0	4	2

List of Experiments:

- (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

MC500: ENVIRONMENTAL SCIENCES*B. Pharm. III Year I Sem**

L	T	P	C
1	0	0	0

Course Objectives: 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.

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

- Create the 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 learner 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

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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

UNIT – II**Ecosystems**

Concept of an ecosystem.

Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

UNIT – III

Biodiversity and Biotic Resources: Introduction, Definition, genetic, species and ecosystem diversity.

Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic and optional values.

India as a mega diversity nation, Hot spots of biodiversity. Field visit. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts; conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

UNIT – IV

Environmental Pollution: Air pollution; Water pollution; Soil pollution, Noise Pollution

UNIT – V

Environmental Policy, Legislation & EIA: Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wild life Act.

Towards Sustainable Future: Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human health, Environmental Ethics, Concept of Green Building, Ecological Foot Print, Life Cycle assessment (LCA), Low carbon life style.

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. Text book of environmental science and technology, Dr. M. Anji Reddy.
5. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
6. Clark R.S., Marine Pollution, Clanderson Press Oxford
7. Cunningham, W.P. Cooper, T. H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
8. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
9. Down of Earth, Centre for Science and Environment
10. Manoharachary C. Principles of Environmental Studies, Pharma Med Press

PS601: MEDICINAL CHEMISTRY – II**B. Pharm. III Year II Sem**

L	T	P	C
3	1	0	4

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

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

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

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, 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:

Alkylatingagents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II**10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole.

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

Diuretics:

Carbonic anhydrase inhibitors: 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, Lorainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholestamine and Cholestipol

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

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

UNIT - IV**08 Hours****Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: 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.*

UNIT – V**07 Hours****Introduction to Drug Design:**

Introduction to molecular modeling tools, molecular representations, file formats, parameters used in QSAR, QSAR methods, Pharmacophore modeling, Docking studies.

Combinatorial Chemistry: Concept and applications of combinatorial 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. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A. I. Vogel.
11. Jenkins, The Chemistry of Organic Medicinal Products, Pharma Med Press.

PS602; PHARMACOLOGY - III**B.Pharm. III Year II Sem.****L T P C**
3 1 0 4

Course Objectives: 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 Outcomes: 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 infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and appreciate correlation of pharmacology with related medical sciences.

UNIT- I**10 hours****1. Pharmacology of drugs acting on Respiratory system**

- Anti -asthmatic drugs
- Drugs used in the management of COPD
- Expectorants and antitussives
- Nasal decongestants
- Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

- Antiulcer agents.
- Drugs for constipation and diarrhoea.
- Appetite stimulants and suppressants.
- Digestants and carminatives.
- Emetics and anti-emetics.

UNIT – II**10 hours****Antimicrobial agents**

- General principles of chemotherapy.
- Sulfonamides and cotrimoxazole.
- Antibiotics - Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

UNIT – III**10 hours****Chemotherapy**

- Antitubercular agents
- Antifungal agents
- Antiviral drugs
- Antileprotic agents
- Anthelmintics
- Antimalarial drugs
- Antiamoebic agents
- Urinary tract infections and sexually transmitted diseases.

UNIT – IV**08 hours****1. Antimalignancy & Immunotherapy**

Types of malignancy.
Chemotherapy of cancer.

2. Immunopharmacology

- a. Immunostimulants
- b. Immunosuppressant
- c. Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT – V

07 hours

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, organophosphorus compound and lead, mercury and arsenic poisoning.

RECOMMENDED BOOKS (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,
2. Churchill Livingstone Elsevier
3. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
4. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
5. Basic Knowledge of Pharmacology BY Roland Seifert, Springer
6. 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
7. Mycek M. J, Gelnet S. B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
8. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
9. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
10. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
11. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,
12. N. Udapa and P.D. Gupta, Concepts in Chronopharmacology.
13. Essentials of Experimental Pharmacology, General Concepts by Sunil Bothra, Pharmamed Press.

PS603: HERBAL DRUG TECHNOLOGY**B.Pharm. III Year II Sem.**

L	T	P	C
3	1	0	4

Course Objectives: 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 Outcomes: 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**6 Hours****1. Herbs as raw materials**

Definition of herb, herbal medicine, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

2. Good Agricultural Practices

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

3. General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions/ research organizations involved in production and research on medicinal and aromatic plants in India.

UNIT – II**7 Hours****1. Nutraceuticals**

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

Study of following herbs as health food: Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina, Tinospora cordifolia, Linseed.

2. Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification.

Study of following drugs and their possible side effects and interactions: Hypercium, Ginkobiloba, Ginseng, Garlic, Pepper.

UNIT - III**10 Hours****1. Herbal Cosmetics**

Principles and preparation of herbal cosmetics formulations- Shampoos, Dyes, face creams, perfumes, tooth pastes and Bleaching agents.

2. Herbal excipients:

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

3. Herbal formulations:

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

4. Introduction to herbal pharmacopeia

UNIT – IV**10 Hours**

1. **Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.
2. **Patenting and Regulatory requirements of natural products:**
 - a. Introduction to Herbal Pharmacopeia
 - b. Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
 - c. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.
3. **Regulatory Issues** - Regulations in India (ASU DTAB – Ayurvedic Sidda Unani Drugs technical advisory board, ASU DCC - Ayurvedic Sidda Unani drugs Consultative Committee), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT – V**07 Hours****Schedule T– Good Manufacturing Practice for herbal drug industry**

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation and records.

RECOMMENDED BOOKS: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
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. Pharmacopoeal 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.
8. Herbal drug Technology. By SS Agrawal and M Paridhavi
9. Indian Medicinal Plants A compendium of 500 species Vol 1, 11, 111, 1V & V By Arya vaidys sala, Universities Press
10. SL Deore, Herbal Drug Technology, Pharma Med Press

PS604: BIOPHARMACEUTICS AND PHARMACOKINETICS**B.Pharm. III Year II Sem.**

L	T	P	C
3	1	0	4

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

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics.
- Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
- Critically evaluate biopharmaceutic studies involving drug product equivalency
- Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

UNIT – I**10 Hours****Introduction to Biopharmaceutics**

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from extra-vascular routes (Transmucosal & Transdermal), **Distribution:** Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT – II**10 Hours**

Metabolism & Excretion: Drug metabolism and basic understanding of 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: Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, bioequivalence studies.

UNIT – III**10 Hours****Pharmacokinetics:**

Introduction to Pharmacokinetics models, Compartment models, Non-compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of K_a , K_E . From plasma and urinary excretion data

UNIT – IV**08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens: Repetitive Intravenous injections – One Compartment Open Model

UNIT – V**07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Biotransformation 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 International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Venkateswarlu V. Biopharmaceutics and Pharmacokinetics, Pharma Med Press
6. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei Dekker Inc.
7. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
8. Biopharmaceutics; By Swarbrick
9. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
10. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
11. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
12. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
13. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
14. Experimental approaches to Biopharmaceutics and Pharmacokinetics by Suresh Banari, Pharmamed Press
15. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Sarfaraz Niazi, Pharmamed Press.

PS605: PHARMACEUTICAL QUALITY ASSURANCE (Open Elective - II)**B.Pharm. III Year II Sem.**

L	T	P	C
3	1	0	4

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

Course Outcomes: 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**

- 1. Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP
- 2. Total Quality Management (TQM):** Definition, elements, philosophies
- 3. ICH Guidelines:** purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines.
- 4. Quality by design (QbD):** Definition, overview, elements of QbD program
- 5. ISO 9000 & ISO14000:** Overview, Benefits, Elements
- 6. NABL accreditation:** Brief introduction and Principles

UNIT – II**10 Hours**

- 1. 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.
- 2. Equipments and raw materials:** Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III**10 Hours**

- Quality Control:** Quality control test for containers (Glass & Plastic) and rubber closures
- 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**

- 1. Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
- 2. 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**

- 1. 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 and UV-Visible spectrophotometer.
- 2. Warehousing:** Good warehousing practices.

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 I WHO 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
10. Pharmaceutical Quality Assurance by Dr. Sohan Chiltlange
11. Chowdary KPR, A Textbook of Pharmaceutical Quality Assurance, Pharma Med Press
12. Pharmaceutical Quality Assurance and Management by K. P. Bhusari, Pharma Med Press

PS606: PHARMACEUTICAL BIOTECHNOLOGY (Open Elective - II)**B.Pharm. III Year II Sem.**

L	T	P	C
3	1	0	4

Course Objectives:

- 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 Outcomes: Upon completion of the subject student shall 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**

- Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- Brief introduction to Protein Engineering.
- Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- Basic principles of genetic engineering.

UNIT – II**10 Hours**

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

UNIT – III**10 Hours**

- Structure of Immunoglobulins
- Structure and Function of MHC (Major Histocomp
- Types of immunity- humoral immunity, cellular immunity
- Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- Storage conditions and stability of official vaccines
- Hybridoma technology- Production, Purification and Applications

UNIT – IV**08 Hours**

- Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- Genetic organization of Eukaryotes and Prokaryotes
- Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- Introduction to Microbial biotransformation and applications.
- Mutation.

UNIT – V**07 Hours**

- a. Types of mutation/mutants
- b. Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- c. Large scale production fermenter design and its various controls.
- d. Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

RECOMMENDED BOOKS (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications
2. of Recombinant DNA: ASM Press Washington D.C.
3. RA Goldshy et. al., Kuby Immunology.
4. J. W. Goding: Monoclonal Antibodies.
5. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
6. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
7. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
8. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi
9. Nagori, Foundations in Pharmaceutical Biotechnology, Rev. Ed. Pharma Med Press
10. Pharmaceutical Biotechnology by Ravi Kumar Maddali, Pharma Med Press

PS607: BIOINFORMATICS (Open Elective - II)**B.Pharm. III Year II Sem.****L T P C**
3 1 0 4

Course Objective: This subject is design to impart fundamental knowledge on the principles of bioinformatics

Course Outcomes: Upon completion of the course the student able to understand

- Foundation of bioinformatics
- Sequence comparisons methods
- Genomic applications
- Proteomic and metabolic applications.

UNIT – I**Foundations of bioinformatics**

- 1.1 Bioinformatics- a historical perspective
- 1.2 Bioinformatics data- nucleic acid sequence, protein sequence, protein structure, genome variation data, gene expression data, proteomic data, metabolic pathways and networks
- 1.3 Bioinformatics tools and resources- free online tolls, downloadable free tools, software pakags, bioinformatics web portals
- 1.4 Role of internet in Bioinformatics.

UNIT - II**Sequence comparison methods**

- 2.1 Basics of sequence alignment: Match, mismatch, gaps, scoring an alignment (gap penalties (linear & affine gap penalties), sequence relationships (sequence identity, similarity, homology, orthologs, paralogs & xenologs)
- 2.2 DNA Vs protein sequence alignment (permissible replacement, similarity score, scoring matrices (PAM & BLOSUM)
- 2.3 multiple-sequence alignment (MSA): significance of MSA

UNIT – III**Genomic Applications:**

- 3.1 Bioinformatics for genome sequencing, first and next generation methods of genome sequencing, de-novo and reference based genome sequencing, genome assembly (reads, contigs & scaffolds)
- 3.2 Transcript- profiling: expression microarrays (gene array& oligo array), transcriptome sequencing and RNA- seq analysis small RNA sequencing and analysis

UNIT – IV

- 4.1 Genome maps an markers: identification of molecular makers (SSR, STS & SNP markers), linkage Vs physical maps, displaying genome annotation using genome browsers
- 4.2 Medical application of bioinformatics –understanding diseases and identification of disease genes, disease diagnostics, overview of drug discovery, pharmacogenomics.

UNIT – V**Proteomic and metabolomic applications:**

- 5.1 Protein profiling (2D gels, protein fingerprinting & identification), protein structure analysis
- 5.2 Protein structure: structure visualization
- 5.3 Protein: secondary and tertiary structure prediction (homology modelling)

RECOMMENDED BOOKS (Latest edition):

1. Bioinformatics by B. G. Gurran, R. J. Walker, S.C. Bhatia. CBS Publishers.
2. Bioinformatics: Skills & applications by Rastogi, CBS Publishers
3. Bioinformatics: Sequence & genome analysis by Mount, CBS Publishers
4. Bioinformatics and bioprogramming by CN Chaveli
5. Bioinformatics (Basics, algorithms and applications by Ruchi Singh and Richa Sharma
6. Essential Bioinformatics Jinxiong
7. Durai Ananda Kumar T. Elementary Pharmacoinformatics, Pharma Med Press
8. Khan Imtiyaz Alam, Elementary Bioinformatics, Pharma Med Press

PS608: SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)**B.Pharm. III Year II Sem.****L T P C**
3 1 0 4

Course Objectives: The student is going to study about various techniques involved in screening of drugs for various pharmacological activities and guidelines for handling animals

Course Outcomes: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines. The expected outcome are – the students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities and guidelines for regulations involved in screening of new drug molecules on animals.

UNIT – I

Care, handling and breeding technique of laboratory animals. Regulations for laboratory animals, CPSCEA guidelines, alternative to animal studies.

UNIT – II

Toxicity test: OECD guidelines, determination of LD₅₀, acute, sub-acute and chronic toxicity studies.

UNIT – III

Organization of screening for pharmacological activity of new substances with emphasis on the evaluation of antipsychotics, antiepileptics and antidepressants.

UNIT – IV

Screening methods for anti-diabetic, antiulcer, CHF and anti-hypertensive drugs.

UNIT – V

Screening methods for anti-inflammatory, analgesics and antipyretic drugs.

RECOMMENDED BOOKS (Latest edition):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
5. Fundamentals of experimental Pharmacology by M.N. Ghosh.
6. Experimental Pharmacology for undergraduates by M C Prabhakara.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta.
10. Pharmacological Screening methods and Toxicology by A. Srinivasa Rao
11. Handbook of Experimental Pharmacology, SK. Kulkarni.
12. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
13. Screening Methods in Pharmacology, Robert A. Turner.
14. Bodakhe H. Surendra, Guidelines and Screening Methods of Pharmacology, Pharma Med Press

PS609: MEDICINAL CHEMISTRY- II LAB**B.Pharm. III Year II Sem.****L T P C**
0 0 4 2**1. Preparation of drugs and intermediates**

- a. Benzocaine
- b. Sulphanilamide
- c. 7-Hydroxy, 4-methyl coumarin
- d. Triphenyl imidazole
- e. Tolbutamide
- f. Phenytoin Sodium
- g. Diphenhydramine HCl
- h. 6-methyl Uracil
- i. Procaine
- j. Promethazine HCl

2. Assay of drugs

- a. Isonicotinic acid hydrazide
- b. Metronidazole
- c. Chlorpheniramine maleate
- d. Quinidine Sulphate
- e. Acetazolamide
- f. Omeprazole

3. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
4. Drawing structures and reactions using chem draw®
5. 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)

RECOMMENDED BOOKS (Latest Editions)

1. Indian Pharmacopoeia.
2. Text book of practical organic chemistry- A.I. Vogel.
3. Durai Ananda Kumar T. Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press.

PS610: PHARMACOLOGY - III LAB**B.Pharm. III Year II Sem.****L T P C**
0 0 4 2**List of Experiments:**

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)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

RECOMMENDED BOOKS (Latest Editions)

1. A Practical book of Pharmacology by Dr. Ramesh Alluri
2. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
3. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,

PS611: HERBAL DRUG TECHNOLOGY LAB**B.Pharm. III Year II Sem.****L T P C**
0 0 4 2**List of Experiments:**

1. To perform preliminary phytochemical screening of crude drugs.
2. Evaluation of excipients of natural origin
3. Incorporation of prepared and standardized extract in cosmetics formulations like creams, lotions, Shampoos and their evaluation.
4. Incorporation of prepared and standardized extract in cosmetics formulations like Syrups, Mixtures and tablets and their evaluations as per pharmacopoeial requirements
5. Monograph analysis of herbal drugs from recent Pharmacopoeias
6. Determination of Aldehyde content
7. Determination of phenolic content
8. Determination of total alkaloids

RECOMMENDED BOOKS: (Latest Editions)

1. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
2. Mandal Vivekananda, Quick Review on Herbal Drug Technology, Pharma Med Press

PS612: BIOPHARMACEUTICS AND PHARMACOKINETICS LAB**B.Pharm. III Year II Sem.****L T P C**
0 0 4 2**List of Experiments:**

1. Dissolution experimental study of influence of disintegration
2. Drug release from semisolids (Agar diffusion using petri dishes, Salicylic acid release from semisolid dosage form)
3. Study of permeability of drugs using dialysis tubes/Sac
4. Drug permeation across membranes using diffusion cells (franz diffusion cells)
5. Calculation of all Pharmacokinetic parameters following the below rate of administration
 - a) IV bolus/Plasma
 - b) IV bolus/Urine
 - c) Extravascular/Plasma
 - d) Extravascular/Urine
 - e) Non compartment Pharmacokinetics Extravascular/Plasma

Reference Books

- 1) Experimental approaches to Biopharmaceutics and Pharmacokinetics by Bandari Suresh
- 2) Biopharmaceutics and Pharmacokinetics lab manual, by Dachinamurthy

MC600: HUMAN VALUES AND PROFESSIONAL ETHICS*B.Pharm. III Year II Sem.**

L	T	P	C
1	0	0	0

Course Objective: To enable the students to imbibe and internalize the Values and Ethical Behavior in the personal and Professional lives.

Course Outcome: The students will understand the importance of Values and Ethics in their personal lives and professional careers. The students will learn the rights and responsibilities as an employee, team member and a global citizen.

UNIT - I

Introduction to Professional Ethics: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

UNIT – II

Basic Theories: Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

UNIT – III

Professional ethics in pharmacy: general introduction to code of pharmaceutical ethics, objectives, pharmacists in relation to his job, his trade, to his profession and relation to medicinal professions. Pharmacists' oath.

UNIT – IV

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.

Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

UNIT – V

Global issues in Professional Ethics: Introduction – Current Scenario, Technology Globalization of MNCs, International Trade, World Summits, Issues, Business Ethics and Corporate Governance, Sustainable Development Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights.

TEXT BOOKS:

1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.
3. Indian Culture Values and Professional Ethics by P. S. R. Murty, BS Publications

REFERENCE BOOKS:

1. Engineering Ethics, Concepts Cases: Charles E Harris Jr., Michael S Pritchard, Michael J Rabins, 4e , Cengage learning, 2015.
2. Business Ethics concepts & Cases: Manuel G Velasquez, 6e, PHI, 2008.
3. Forensic Pharmacy by Dr. Kokate
4. Forensic Pharmacy by Bhaskar Chaurasia

PS701: INSTRUMENTAL METHODS OF ANALYSIS**B.Pharm. IV Year I Sem.**

L	T	P	C
3	1	0	4

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

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT – I**10 Hours****1. 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

2. Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT – II**10 Hours****1. 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, Thermistor, Pyroelectric detector and applications

2. Flame Photometry - Principle, interferences, instrumentation and applications**3. Atomic absorption spectroscopy** - Principle, interferences, instrumentation and applications**4. Nepheloturbidometry** - Principle, instrumentation and applications**UNIT – III****10 Hours****Introduction to chromatography****1. Adsorption and partition column chromatography**- Methodology, advantages, disadvantages and applications.**2. Thin layer chromatography**- Introduction, Principle, Methodology, R_f values, advantages, disadvantages and applications.**3. Paper chromatography**- Introduction, methodology, development techniques, advantages, disadvantages and applications**4. Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications**UNIT – IV****08 Hours****1. Gas chromatography** - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications**2. High performance liquid chromatography (HPLC)** - Introduction, theory, instrumentation, advantages and applications.

UNIT – V**07 Hours**

1. **Ion exchange chromatography** - Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications
2. **Gel chromatography** - Introduction, theory, instrumentation and applications
3. **Affinity chromatography** - Introduction, theory, instrumentation and applications

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
11. Vidya Sagar, Instrumental Methods of Drug Analysis, Pharma Med Press

PS702: INDUSTRIAL PHARMACY - II**B.Pharm. IV Year I Sem.****L T P C**
3 1 0 4

Course Objectives: This course is designed to impart fundamental knowledge on pharmaceutical product Commercialization from laboratory to market

Course Outcomes: 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 in India and US
- 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

Plant location, industrial hazards and plant safety: Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.

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 there prevention. Ferrous and nonferrous metals, inorganic and organic non metals.

Material handling systems: Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.

UNIT – II**10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing 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), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

UNIT – III**10 Hours**

1. **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
2. **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) 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, 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, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

RECOMMENDED BOOKS: (Latest Editions)

1. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
2. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' 2nd Edition.
3. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.
4. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition
5. Industrial Pharmacy: A Comprehensive Approach by Tripathi DK, Pharmamed Press

PS703: PHARMACY PRACTICE**B.Pharm. IV Year I Sem.****L T P C**
3 1 0 4

Course Objectives: 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 safe medication and patient counselling.

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Know pharmaceutical care services
- do patient counselling in community pharmacy

UNIT – I**10 Hours****1. Hospital and it's 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.

2. Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

3. 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**10 Hours****1. 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.

2. Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

3. Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT – III**10 Hours****1. Drug information services**

Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.

2. Patient counselling

Definition of patient counselling; steps involved in patient counseling, and Special cases that require the pharmacist

3. 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.

UNIT – IV**08 Hours****1. 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.

2. Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

UNIT – V**07 Hours****Drug store management and inventory control**

Organization 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

RECOMMENDED BOOKS (Latest Edition):

1. Merchant S. H. and Dr. J. S. Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman 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, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N. S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributors; 2008.
7. Balasubramanian, Pharmacy Practice, Pharma Med Press
8. Bari B. Sanjay, Pharmacy Practice: Essentials of Hospital, Clinical and Community Pharmacy, Pharma Med Press
9. Patient Assessment in Pharmacy, by Yolanda M H
10. Patient Communication for Pharmacy: A Case-Study Approach on Theory and Practice, Min Liu, Lakesha M. Butler
11. Fundamental Skills for Patient Care in Pharmacy Practice by Colleen Doherty Lauster, Sneha Baxi Srivastava

PS704: MEDICINAL CHEMISTRY – III**B.Pharm. IV Year I Sem.**

L	T	P	C
3	1	0	4

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

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

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

Beta-Lactam antibiotics: Penicillin, Cephalosporins, Beta-Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II**10 Hours****Antibiotics II:**

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

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.

UNIT – III**10 Hours****Anti-tubercular Agents**

Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

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

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**08 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, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V**07 Hours****Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandrolone, Progestones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

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 Lednicher, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I. Vogel.
11. S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, 1st edition 2002.
12. Durai Ananda Kumar T. Experimental Organic and Medicinal Chemistry Principles & Practice, Pharma Med Press

PS705: PHARMACEUTICAL MARKETING (Open Elective - III)**B.Pharm. IV Year I Sem.****L T P C
3 1 0 4**

Course Objectives: The pharmaceutical industry not only needs highly qualified researchers, chemist, 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. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.

Course Outcome: Provide an understanding of marketing concepts and techniques and the application of the same 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**10 Hours**

Product decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

UNIT – III**10 Hours**

Promotion: Meaning and 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.

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 McGraw Hill, New Delhi.
3. Subba Rao Changanti, Pharmaceutical Marketing in India, Pharma Med Press

4. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill
5. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
6. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
7. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
8. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
9. Smarta Raja B. Strategic Pharmaceutical Marketing, Pharma Med Press

PS706: PHARMACEUTICAL REGULATORY SCIENCE (Open Elective - III)**B.Pharm. IV Year I Sem.**

L	T	P	C
3	1	0	4

Course Objectives: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Course Outcomes: Upon completion of the subject student shall 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**10 Hours****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**10 Hours**

Regulatory Approval Process: Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.

Regulatory authorities and agencies: Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

UNIT – III**10 Hours**

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**08 Hours**

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**07 Hours**

Regulatory Concepts: Basic terminologies, 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, 2nd 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 Rodney K. Adams
8. Principles and Practices of Clinical Research, 2nd Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, 2nd Edition by Rick N
10. Clinical Research: Principles, Practices, Perspective, by Bikash Medhi, Pharmamed Press

PS707: PHARMACOVIGILANCE (Open Elective - III)**B.Pharm. IV Year I Sem.****L T P C**
3 1 0 4

Course Objective: 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.

Course Outcomes: At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Data during pre-clinical, clinical and post approval.
- Pharmacovigilance Program of India (PvPI)
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

UNIT - I**10 Hours****Introduction to Pharmacovigilance:**

- a) History and development of Pharmacovigilance
- b) Importance of safety monitoring of Medicine
- c) WHO international drug monitoring programme
- d) Pharmacovigilance Program of India (PvPI)

Introduction to adverse drug reactions:

- a) Definitions and classification of ADRs
- b) Detection and reporting
- c) Methods in Causality assessment
- d) Severity and seriousness assessment
- e) Predictability and preventability assessment

Basic terminologies used in pharmacovigilance:

- a) Terminologies of adverse medication related events
- b) Regulatory terminologies

UNIT – II**10 hours****Drug and disease classification:**

- a) Anatomical, therapeutic and chemical classification of drugs
- b) International classification of diseases
- c) Daily defined doses

Drug dictionaries and coding in pharmacovigilance:

- a) WHO adverse reaction terminologies
- b) MedDRA and Standardized MedDRA queries
- c) WHO drug dictionary

Information resources in pharmacovigilance:

- a) Basic drug information resources

Establishing pharmacovigilance programme:

- a) Establishing in a hospital
- b) Establishment & operation of drug safety department in industry
- c) Contract Research Organizations (CROs)

UNIT – III**10 Hours****Vaccine safety surveillance:**

- a) Vaccine Pharmacovigilance
- b) Vaccination failure
- c) Adverse events following immunization

Pharmacovigilance methods:

- a) Passive surveillance – Spontaneous reports and case series
- b) Stimulated reporting
- c) Active surveillance – Sentinel sites, drug event monitoring and registries
- d) Comparative observational studies – Cross sectional study, case control study and cohort study
- e) Targeted clinical investigations

UNIT – IV**08 Hours****Statistical methods for evaluating medication safety data****Safety data generation:**

- a) Pre-clinical phase
- b) Clinical phase
- c) Post approval phase

ICH Guidelines for Pharmacovigilance:

- a) Organization and objectives of ICH
- b) Expedited reporting
- c) Individual case safety reports
- d) Periodic safety update reports
- e) Post approval expedited reporting
- f) Pharmacovigilance planning
- g) Good clinical practice in pharmacovigilance studies

UNIT – V**07 hours****Pharmacogenomics of adverse drug reactions:****Drug safety evaluation in special population**

- a) Pediatrics
- b) Pregnancy and lactation
- c) Geriatrics

RECOMMENDED BOOKS (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, 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
10. Text Book of Medicine by Yashpal Munjal

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna, Pharmamed Press.
12. A Textbook of Clinical Research and Pharmacovigilance, KPR Chowdary, Pharmamed Press.
13. <http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
14. <http://www.ich.org/>
15. <http://www.cioms.ch/>
16. <http://cdsco.nic.in/>
17. http://www.who.int/vaccine_safety/en/
18. http://www.ipc.gov.in/PvPI/pv_home.html

PS708: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Open Elective - III)**B.Pharm. IV Year I Sem.****L T P C**
3 1 0 4

Course Objective: 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 Outcomes: 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**10 hours**

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**10 hours**

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**10 hours**

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

UNIT – IV**08 hours**

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**07 hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal 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. I , 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. 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. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
10. WHO. 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.
11. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.
12. Deore S L, Quality Control of Herbal Drugs, Pharma Med Press

PS709: INSTRUMENTAL METHODS OF ANALYSIS LAB**B.Pharm. IV Year I Sem.****L T P C**
0 0 4 2**List of Experiments:**

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 nephelo turbidometry
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

RECOMMENDED BOOKS (Latest Editions):

1. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
2. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
3. Quantitative Analysis of Drugs by D. C. Garrett
4. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

PS710: PRACTICE SCHOOL**B.Pharm. IV Year I Sem.****L T P C**
0 0 4 2

Course Objectives: Practice school is an educational innovation seeking to link industry/hospital/ pharmacy experience with university instruction. The student will:

- Meet the rapidly changing needs and challenges of a professional work place.
- Acquire knowledge and skills.
- Bear an economic relevance to the society.

Course Outcome: Institutionalized linkage between university/college and industry. Student's involvement in real life projects continues internal evaluation and monitoring the faculty help by student to understand the practical issues. After successful completion of 150 hrs, the students will submit the detailed report in the following field.

Note: Any domains relevant to pharmacy can be given to students. Following domains for reference

Industry oriented PS:

It comprises industry visits and interactions with executives to facilitate the process of learning by observations and discussions duly aided by the check list. It promotes learning by doing in various departments like production quality control and assurance, R&D etc. Taking one issue and working on it for prescribed hours and submit the report.

Hospital oriented PS:

The student is asked to visit the hospitals and work on some case studies like cardiovascular, diabetics, gastrointestinal, gynaecological, pulmonary paediatric etc. related cases of some 5 to 6 to be studied and detailed data to be submitted.

Retail pharmacy-oriented PS:

The students have to visit different pharmacy shops and collect the data related to the most prescribed medicines in that area, prescription patterns, medical audit etc and submit the report.

Election of medicinal plants orientated PS:

The students have to visit medicinal plant gardens and collect some medicinal plants those are useful to various disorders and submit the report in detail about the plants they come across during their study period

Regulatory affairs: collect and analyse the regulatory affairs. Some important cases filed by drug control officers to be analysed and reported.

National poison centre: visit the local poison centre and write the relevant matter

Formulation aspects: Formulations using any equipments which otherwise are not usually used for regular practicals

PS801: BIOSTATISTICS AND RESEARCH METHODOLOGY**B.Pharm. IV Year II Sem.**

L	T	P	C
3	1	0	4

Course Objectives: To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies.

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

UNIT – I**10 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**10 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.

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

UNIT – III**10 Hours**

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, 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**8 Hours**

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**7 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. Bayya Subba Rao, Pharmaceutical Research Methodology and Bio-Statistics: Theory & Practice, Pharma Med Press
6. Chowdary KPR, A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, Pharma Med Press

PS802: SOCIAL AND PREVENTIVE PHARMACY**B.Pharm. IV Year II Sem.****L T P C**
3 1 0 4

Course Objectives: 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 programmes. The roles of the pharmacist in these contexts are also discussed.

Course Outcomes: 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 health and pharmaceutical issues

UNIT – I**10 Hours**

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: Socio cultural 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**10 Hours**

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**10 Hours**

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

UNIT – IV**08 Hours**

National health intervention programme for mother and child, national family welfare programme, national tobacco control programme, national malaria prevention program, national programme for the health care for the elderly, social health programme; role of *who in indian national program

UNIT – V**07 Hours**

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. Short Textbook of Preventive and Social Medicine, Prabhakara G N, 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

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
7. K. Ravi Shankar, Social and Preventive Pharmacy, Pharma Med Press.

PS803: NOVEL DRUG DELIVERY SYSTEMS**B.Pharm. IV Year II Sem.****L T P C**
3 1 0 4

Course Objectives: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Course Outcomes: 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

UNIT – I**10 Hours**

1. **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
2. **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

UNIT – II**10 Hours**

1. **Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications
2. **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems
3. **Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump

UNIT – III**10 Hours**

1. **Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches
2. **Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high-density systems, inflatable and gastroadhesive systems and their applications
3. **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**

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

UNIT – V**07 Hours**

1. **Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts
2. **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, 1st edition 1997 (reprint in 2001).
5. Tripathi Dulal Krishna, Novel Drug Delivery Systems, Pharma Med Press

PS804: COMPUTER AIDED DRUG DESIGN (Open Elective - IV)**B.Pharm. IV Year II Sem.**

L	T	P	C
3	1	0	4

Course Objectives: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modelling software

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**

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**08 Hours**

Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT – V**07 Hours**

Molecular Modelling: 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 Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.

5. Koro Ikavas 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.
10. Durai Ananda Kumar T. Current Concepts in Drug Design. Pharma Med Press

PS805: NANO TECHNOLOGY (Open Elective - IV)**B.Pharm. IV Year II Sem.****L T P C**
3 1 0 4

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

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

UNIT – I**Introduction to Nanotechnology**

- a. Definition of nanotechnology
- b. History of nanotechnology
- c. Unique properties of nanomaterials
- d. Classification of nanomaterials

UNIT – II**Synthesis of Nanomaterials**

Methods for synthesis of:

- a. Gold nanoparticles
- b. Magnetic nanoparticles
- c. Polymeric nanoparticles
- d. Self – assembly structures such as liposomes, Niosomes, micelles, aquasomes and nanoemulsions

UNIT – III**Biomedical applications of Nanotechnology**

- a. Nanotechnology products used for in vitro diagnostics
- b. Applications in imaging and targeting.

UNIT – IV

Design of nanomaterials for drug delivery, pulmonary, nasal drug delivery, cardiovascular diseases and localized drug delivery systems.

UNIT – V

Characterization, drug release and stability studies of nanomaterials

RECOMMENDED BOOKS (Latest Editions):

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfroms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P.J. Thomas and G.U. Kulakarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)

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

PS806: EXPERIMENTAL PHARMACOLOGY (Open Elective - IV)**B.Pharm. IV Year II Sem.****L T P C**
3 1 0 4

Course Objectives: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines.

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals and newer screening methods used in the drug discovery
- Understand the Research methodology to be followed Bio-statistical data interpretation of the assays

UNIT – I

Laboratory 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

Preclinical screening models: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups

UNIT - III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasymphomimetics, parasympholytics and skeletal muscle relaxants.

UNIT - IV

Preclinical screening models for diuretics, anticoagulants and anticancer activities

UNIT – V

Research methodology and Bio-statistics, Selection of research topic, review of literature, research hypothesis and study design, Interpretation using Student's 't' test and One-way ANOVA. Graphical representation of data.

RECOMMENDED BOOKS (Latest Editions):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Experimental Pharmacology for undergraduates by M C Prabhakara.
7. Drug discovery and Evaluation by Vogel H. G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta.
10. Handbook of Experimental Pharmacology, S K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.
13. Guidelines and Screening Methods of Pharmacology, Surendra H. Bodakhe, Pharmamed Press.

PS807: ADVANCED INSTRUMENTATION TECHNIQUES (Open Elective - IV)**B.Pharm. IV Year II Sem.****L T P C**
3 1 0 4

Course Objectives: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

UNIT – I**10 Hours****Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry - Principles, Fragmentation, Ionization techniques - Electron impact, chemical ionization, instrumentation and applications.

UNIT - II**10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction and applications.

UNIT - III**10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT – IV**08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction Techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT – V**07 Hours**

Hyphenated techniques - 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
11. Liptak, Analytical Instrumentation, T&F

PS808: NOVEL DRUG DELIVERY SYSTEMS LAB**B.Pharm. IV Year II Sem.****L T P C**
0 0 4 2

1. Study on diffusion of drugs through various polymeric membranes
2. Study on polymeric properties
3. Preparation and Evaluation of Microencapsules by different methods
4. Preparation and Evaluation of Mucosal Drug Delivery Systems
5. Preparation and Evaluation of Transdermal Drug Delivery Systems
6. Preparation and Evaluation of Gastroretentive Drug Delivery Systems
7. Preparation and Evaluation of Buccal Drug Delivery Systems
8. Preparation and Evaluation of Osmotic Drug Delivery Systems
9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles

PROJECT WORK

The student should select a project work from the following areas and should work in respective industries/departments to complete project. The project work done has to be presented as a report. The student should present the findings of the project work in the college for final evaluation.

1. Formulation Development
2. Analytical Development
3. Chemical synthesis/Natural products
4. Pharmacological / toxicological screening
5. Pharmacovigilance
6. Herbal drugs, formulations and Analysis
7. Regulatory Affairs
8. Bioavailability, Bioequivalence, clinical students
9. Intellectual property management
10. Hospital Pharmacy
11. Community Pharmacy
12. Any project work related to Pharmacy profession

Reference Books

- 1) Tripathi Dulal Krishna, Novel Drug Delivery Systems, Pharma Med Press