Kakatiya University, Warangal

Syllabus for the Bachelor of Pharmacy (B. Pharm) Four Years Course

From the academic year 2017-2018 onwards

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2017-18. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
	Total	**32/34$/36#**	**4**	**27/29$/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.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*****Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	**28**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	**31**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	**27**	**5**	**26**

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial PharmacyII – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	**28**	**5**	**24**

***** Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	**Elective – 1**	3	1	4
I	Pharmaceutical Marketing			
II	Pharmaceutical Regulatory Science			
III	Pharmacovigilance			
IV	Quality Control and Standardizations of Herbals			
V	Computer Aided Drug Design			
BP804ET	**Elective – 2**	3	1	4
I	Cell and Molecular Biology			
II	Cosmetic Science			
III	Experimental Pharmacology			
IV	Advanced Instrumentation Techniques			
V	Dietary Supplements and Nutraceuticals			
BP805PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$/30#**
II	29
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**211/213$/214#**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the university from time to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course**.**

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course**.**

10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$^{\$}$/80$^{\#}$**	**115/125$^{\$}$/130$^{\#}$**	**23/24$^{\$}$/26$^{\#}$ Hrs**	**185/200$^{\$}$/210$^{\#}$**	**490/525$^{\$}$/ 540$^{\#}$**	**31.5/33$^{\$}$/ 35$^{\#}$ Hrs**	**675/725$^{\$}$/ 750$^{\#}$**

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

$^{\$}$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course**.**

***** Non University Examination(NUE)

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

***** The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial PharmacyI– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial PharmacyI– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

***** The subject experts at college level shall conduct examinations

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total
		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803E	**Elective -1**	10	15	1 Hr	25	75	3 Hrs	100
I	Pharmaceutical Marketing – Theory							
II	Pharmaceutical Regulatory Science – Theory							
III	Pharmacovigilance – Theory							
IV	Quality Control and Standardizations of Herbals – Theory							
V	Computer Aided Drug Design – Theory							
BP804ET	**Elective – 2**	10	15	1 Hr	25	75	3 Hrs	100
I	Cell and Molecular Biology – Theory							
II	Cosmetic Science – Theory							
III	Experimental Pharmacology – Theory							
IV	Advanced Instrumentation Techniques – Theory							
V	Dietary Supplements and Nutraceuticals - Theory							
BP805PW	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI:Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs) = 10 x 1 = 10

OR OR

Objective Type Questions (5 x 2) = 05 x 2 = 10

(Answer all the questions)

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10

II. Short Answers (Answer 2 out of 3) = 2 x 5 = 10

Total = 30 marks

For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 4 out of 6)	=	4 x 5 = 20

Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05

Total	=	40 marks
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12. Promotion and award of grades

A student shall be declared PASSand eligible for getting gradein a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment.For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a studentfails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examinationof that course. However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs) = 20 x 1 = 20
OR OR
Objective Type Questions (10 x 2) = 10 x 2 = 20
(Answer all the questions)
II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

Total = 75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2) = 1 x 10 =10
II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks

Question paper pattern for end semester practical examinations

I. Synopsis = 5
II. Experiments = 25
III. Viva voce = 5

Total = 35 marks

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16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who hasgiven more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

Note: Grade ABshould be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in anysemester.

17. Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of ABand a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade pointsin these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any semester shall take into consideration the F and ABSgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO} + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where $C_1, C_2, C_3,\ldots$ is the total number of credits for semester I,II,III,…. and $S_1,S_2, S_3,\ldots$is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a projectunder 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:

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:

Presentation of work		25 Marks
Communication skills		20 Marks
Question and answer skills		30 Marks
	Total	**75 Marks**

Explanation: 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.

22. Industrial training (Desirable)

Every candidate 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 Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

23. Practice School

In the VII semester, every candidate shall undergo 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 program 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). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college leveland grade point shall be awarded.

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

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**

- **Body fluids and blood**
- Body fluids, composition and functions of blood, hemopoeisis, 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 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**

- **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.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology byTortora 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 Tailor. 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. Chatterrje ,Academic Publishers Kolkata

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

(a) Pharmaceutical analysis- Definition and scope

i) Different techniques of analysis

ii) Methods of expressing concentration

iii) Primary and secondary standards.

iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

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

(c) Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

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, Modified Volhard's, Fajans method, estimation of sodium chloride.
- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

- Basic Principles,methods and application of diazotisation titration.

UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **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

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following

(1) Chloride
(2) Sulphate
(3) Iron
(4) Arsenic

II Preparation and standardization of

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

III 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

IV Determination of Normality by electro-analytical methods

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

Recommended Books: (Latest Editions)

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

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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.

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

Course Content:

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 ofEmulsion, 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.

UNIV – 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

BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

5. Suspensions

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended 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. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

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, Sodium nitrite333

  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.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I **Limit tests for following ions**

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

II **Identification test**

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

III **Test for purity**

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

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

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

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

Objectives:

Upon completion of the course the student shall be able to

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

Course content:

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

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing 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

Recommended Books: (Latest Edition)

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

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

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

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of 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, Potista, 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 & Dicotylidones.

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
- Rennin 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

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

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

Reference Books

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

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

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

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

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

Course Content:

UNIT – I **06 Hours**

- **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- **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,

- **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1$,

UNIT –II **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, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equations

UNIT – III **06 Hours**

- **Calculus**

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

UNIT – IV **06 Hours**

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,

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

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**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy byPanchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

Unit I **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 II **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.

- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

- **Respiratory system** **10 hours**

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

  Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

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

Unit IV **10 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.

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

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

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

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology byTortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. 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. Chatterrje ,Academic Publishers Kolkata

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

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

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**

  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

UNIT-II10 Hours

- **Alkanes*, Alkenes* and Conjugated dienes***

  SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

  Stabilities of alkenes, SP^2 hybridization in alkenes

  E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

UNIT-III10 Hours

- **Alkyl halides***

  SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

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

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

UNIT-IV10 Hours

- **Carbonyl compounds* (Aldehydes and ketones)**

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

UNIT-V **08 Hours**

- **Carboxylic acids***

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

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

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

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. 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.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

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

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course student shell able to

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

Course Content:

UNIT I **08 Hours**

- **Biomolecules**

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

- **Bioenergetics**

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

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

UNIT II **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 III **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.

- **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 (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

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

  Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 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

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

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

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

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

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

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

Course content:

Unit I **10Hours**

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

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

Unit II **10Hours**

- **Cardiovascular System:**
  Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure .

Unit II **10Hours**

- **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 **8 Hours**

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

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

Recommended Journals

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

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

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

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

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

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 dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

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

Recommended books (Latest edition):

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

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

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

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

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

Course content:

Unit-I **10hours**

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 **10hours**

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 **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

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 Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

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

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I **10 Hours**

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

UNIT II **10 Hours**

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

- **Fats and Oils**

a. Fatty acids – reactions.

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

- **Polynuclear hydrocarbons:**

a. Synthesis, reactions
b. 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 only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

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-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

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

UNIT-II **10Hours**

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

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

UNIT-III **08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV **08Hours**

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

UNIT-V **07 Hours**

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.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

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

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

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

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

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

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

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

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

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

Classification and mode of action of disinfectants

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

Evaluation of bactericidal & Bacteriostatic.

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

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

Unit V **07Hours**

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

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

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

Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

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.

Recommended Books (Latest edition)

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

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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

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

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

Course content:

UNIT-I **10 Hours**

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II **10 Hours**

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

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

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

UNIT- III **08 Hours**

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

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

UNIT-IV **08 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 Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V **07 Hours**

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

Recommended Books: (Latest Editions)

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

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient by heat exchanger.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
IX. 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.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: 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.

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

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

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:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV **8 Hours**

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.

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

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT- I **10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

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

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II **10 Hours**

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

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

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

- 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, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

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

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:**

Phenytoin*, Mephenytoin, Ethotoin **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 barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

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

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

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

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

1 1,3-pyrazole

2 1,3-oxazole

3 Benzimidazole

4 Benztriazole

5 2,3- diphenyl quinoxaline

6 Benzocaine

7 Phenytoin

8 Phenothiazine

9 Barbiturate

II Assay of drugs

1 Chlorpromazine

2 Phenobarbitone

3 Atropine

4 Ibuprofen

5 Aspirin

6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. 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.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

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

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

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

Course Content:

UNIT-I **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.

UNIT-II **10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III **10 Hours**

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

UNIT-IV **10Hours**

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

UNIT-V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

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

Recommended Books: (Latest Editions)

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

BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

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

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

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

Course Content:

UNIT-I **08 hours**

1. General Pharmacology

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

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

UNIT-II **12 Hours**

General Pharmacology

a. 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.
b. Adverse drug reactions.
c. Drug interactions (pharmacokinetic and pharmacodynamic)
d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III **10 Hours**

2. Pharmacology of drugs acting on peripheral nervous system

a. Organization and function of ANS.

b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV **08 Hours**

3. Pharmacology of drugs acting on central nervous system

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

b. General anesthetics and pre-anesthetics**.**

c. Sedatives, hypnotics and centrally acting muscle relaxants.

d. Anti-epileptics

e. Alcohols and disulfiram

UNIT-V **07 Hours**

3. Pharmacology of drugs acting on central nervous system

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.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog 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. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R.Craig&Robert,

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

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

Quality control of Drugs of Natural Origin:

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

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

UNIT-II **10 Hours**

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III **07 Hours**

Plant tissue culture:

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

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

UNIT IV **10 Hours**

Pharmacognosy in various systems of medicine:

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

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V **08 Hours**

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

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

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

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, 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

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (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 paliside ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

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

SEMESTER V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

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

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

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

Course Content:

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

UNIT- I **10 Hours**

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline 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

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

Alkylating agents: 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, Isosorbide dinitrite*, 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, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

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

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide,

Bosentan, Tezosentan.

UNIT- IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.
Drugs for erectile dysfunction: Sildenafil, Tadalafil.
Oral contraceptives: Mifepristone, Norgestril, 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: Acrabose, 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, Diperodon, 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. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. Industrial PharmacyI (Theory)

45 Hours

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

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

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

Course content:

3 hours/ week

UNIT-I **07 Hours**

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

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

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

UNIT-II **10 Hours**

Tablets:

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

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

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

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

UNIT-III **08 Hours**

Capsules:

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

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

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

UNIT-IV **10 Hours**

Parenteral Products:

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

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

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

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

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

UNIT-V **10 Hours**

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

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

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

BP 506 P. Industrial PharmacyI (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (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.

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **10hours**

1. 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 **10hours**

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 **10hours**

3. 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 **08hours**

5. Pharmacology of drugs acting on endocrine system

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

UNIT-V **07hours**

5. Pharmacology of drugs acting on endocrine system

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

6. Bioassay

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

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

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

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

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

UNIT-II **14 Hours**

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

secondary metabolites:

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

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

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

UNIT-IV **10 Hours**

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

UNIT V **8 Hours**

Basics of Phytochemistry

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

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

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 phytoconstitutents 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. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd 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.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I **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; 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, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **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** D efinition, 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)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: 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.

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

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

Course Content:

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

UNIT – I **10 Hours**

Antibiotics

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

β-Lactam antibiotics: Penicillin, Cepholosporins, β- 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, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, 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 Tioconozole, 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, Sulfamethoxaole*, 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, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

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

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

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.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

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 **10hours**

3. Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V **07hours**

5. 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, organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

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, Churchil 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. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

Objectives: 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 .

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

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

Biodynamic Agriculture

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

Indian Systems of Medicine

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

UNIT-II **7 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

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

UNIT-III **10 Hours**

Herbal Cosmetics

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

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

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

UNIT- IV **10 Hours**

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

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

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

UNIT-V **07 Hours**

General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. 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.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I **10 Hours**

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

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

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

UNIT- III **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

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

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

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. 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 production of:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

d) Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

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

Unit IV **08Hours**

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: Types of mutation/mutants.

Unit V **07 Hours**

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

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol 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

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV **08 Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

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

UNIT –V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

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

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought bylearning plus, inc. available at http.//www.cgmp.com/ra.htm.

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

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

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I: **10 Hours**

a) 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.

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II: 10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

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

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: 10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

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

c) Patient counseling

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

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV 8 Hours

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

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

Unit V 7 Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah 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*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I **10 Hours**

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

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

Unit-II **10 Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implantsand osmotic pump

Unit-III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

Objectives: 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**.**

Course content:

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

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

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**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels

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 **7Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. 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. NewYork.
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

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

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

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

- Acquire high consciousness/realization of current issuesrelated 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 tohealth and pharmaceutical issues

Course content:

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 GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

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

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I **10 Hours**

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **10 Hours**

Product decision:

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:

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; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan 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.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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

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

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10Hours**

Regulatory Approval Process

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

Regulatory authorities and agencies

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

Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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

Objectives:

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

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

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

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

Unit IV **8 Hours**

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

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

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: 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 Pharmacoepidemiolog 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 NyfortHansen,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

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

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

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. 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.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

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

Objectives: 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

Course Content:

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, Hammet's substituent constant and Tafts 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 Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas 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.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

Objectives: 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

Course content:

Unit I **10Hours**

a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

a) DNA and the Flow of Molecular Information
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III **10 Hours**

a) Proteins: Defined **and** Amino Acids
b) Protein Structure

c) Regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

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

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 and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene 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**.

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 benfits.

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

References

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) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. **b. Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's,antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart 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.

Objectives: 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.

Course Content:

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, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (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, structural elucidation 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

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 **Tutorial:1** **Credit point:4**

Scope :

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

Objective:

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

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I **07 hours**

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

UNIT II **15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
b) Sulfides: Diallyl sulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III **07 hours**

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV **10 hours**

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

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

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 Tutorial:1 Credit points:4

Unit-I **10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Solvents and solubilizers
ii. Cyclodextrins and their applications
iii. Non - ionic surfactants and their applications
iv. Polyethylene glycols and sorbitols
v. Suspending and emulsifying agents
vi. Semi solid excipients

Unit-III **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Tablet and capsule excipients
ii. Directly compressible vehicles
iii. Coat materials
iv. Excipients in parenteral and aerosols products
v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV **08 Hours**

Optimization techniques in pharmaceutical product development.A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development.

Unit-V **07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.
13. Advanced Review Articles related to the topics.

RULES, REGULATIONS AND SYLLABUS FOR

B.PHARM (FOUR YEAR COURSE)
KAKATIYA UNIVERSITY, WARANGAL – 506 009

From the academic year 2008 – 2009 onwards

(Applicable to the UCPSc and other Pharmacy colleges
Affiliated to KU, Warangal)

I. GENERAL RULES AND REGULATIONS

1. Eligibility for admission:

Candidates for admission to the Degree of Bachelor of Pharmacy shall be required to have passed the Intermediate Examination of the Board of Intermediate Education, Andhra Pradesh or an Examination recognized as equivalent there to with Physics, Chemistry and Mathematics or biology as subjects.

OR

The Diploma in Pharmacy Examination from an Institute in AP recognized by the Pharmacy Council of India (or a local candidate with a Diploma in Pharmacy from outside AP).

2. The degree of Bachelor of Pharmacy will be conferred on the candidates who have subsequently undergone the prescribed course of study of the Kakatiya University for a period of not less than four academic years.
3. The course and Examination for the four year shall be designated as I-B Pharm, II-B.Pharm, III-B.Pharm, IV-B.Pharm. The examination for each year shall be on the basis of the Scheme of Examination.
4. The distribution of marks shall be as indicated in the Scheme of Examination and the scope of subjects as indicated in the syllabus.
5. In every academic year there shall be one annual examination, ordinarily in April/May and one supplementary examination in October/November or on such dates as may be fixed by the University.
6. Candidates admitted to any year of the course of study shall pursue in each academic year, the regular courses of lecturers, tutorials, practicals etc, as mentioned in the Scheme of Instructions and after satisfying the conditions laid down in these ordinances will be eligible to appear for the examinations on such dates as may be fixed by the University.
7. A candidate to be eligible to take an examination specified in paragraph [4] shall prosecute a regular course of study in the course prescribed for the examination concerned, for not less then one academic year in the University College of Pharmaceutical Sciences and affiliated colleges of Kakatiya University.

8. A student shall be deemed to have pursued a regular course of study in a subject during each academic session, if he/she attended at least 75% of the classes held in each subject of examination and had produced a certificate of good conduct from the Principal of University College of Pharmaceutical Sciences/other affiliate Pharmacy colleges. Provided that the Vice-Chancellor of the university may condone shortage in attendance not exceeding 10% in each subject due to one or more of the following reasons involving absence from classes.

a. Participation in NCC camp duly supported by a certificate to that effect from the Officer-Commanding, NCC.

b. Participation in University or College team in games or cultural activities at Inter-state or Inter-University level duly supported by the certificate from the Office concerned.

c. Participation in Educational excursions conducted on working days certified by the principal of the College. No credit will be given for excursions conducted on holidays.

d. University deputation for youth festival certified by the Principal of the College.

e. Prolonged illness duly certified by the Medical Officer of the University Hospital or any Government Hospital.

9. In order to pass an examination, the candidate (i) shall obtain not less then 45 (forty five)% of the Marks allotted for the examination in each paper and (ii) shall obtain not less than 50 (fifty)% of all papers of examination for that particular year.

10. A candidate, who fails in four papers or less, may be promoted to next higher class. Such candidate may take the examination in the papers in which he/she failed, at the subsequent annual or supplementary examination.

11. The candidates of II, III and IV year B.Pharm, who failed in some of the I, II, or III year papers, respectively may be permitted to appear for these papers at the Annual/Supplementary examinations together with II, III or IV year examinations provided, however, that the total number of papers in which they have failed is not more than four at any time for the promotion to next higher class. However D.Pharm lateral entry students in B.Pharm II year may be promoted to III year, even if they failed in five subjects, provided if these students have to appear for more papers in total than the regular students of II year in annual exams.

12. The award of division shall be based on the aggregate marks obtained by a candidate in B.Pharm. I, II, III and IV, years examinations put together. Those who obtain 50% marks and more but less than 60% will be awarded Second Division and those who obtain 60% and above will be awarded First Division. Candidates securing 75% and the above in the aggregate of all examinations of B.Pharm. I, II, III and IV in first attempt shall be declared to have passed in First Division with Distinction. Any candidate, who carries a backlog at any stage, will not be eligible for distinction and rank.

13. A candidate shall be ranked on the basis of his/her grand total provided he/she has passed in all the papers of his/her I, II, III and IV year examinations in first attempt.

14. i. A candidate who fail to secure 50% in aggregate, but has passed in all papers shall be allowed to appear at a supplementary examination in any theory papers of his/her choice of that particular year.

ii. A candidate who fails to secure 50% in aggregate and also fails in not more than one paper shall be allowed to appear at a supplementary examination in the paper failed and two theory papers of his/her choice.

15. The college, if possible will organize an Educational and Industrial tour for 15 days during III year B.Pharm. Students as a part of the teaching program, may take part accompanied by faculty members deputed by the college.

16. Industrial/Hospital training: It is compulsory that every student of B.Pharm shall undergo training for a period of 6 weeks during final B.Pharm (in summer vacation) in Pharmaceutical Company or in a Hospital.

SCHEME OF INSTRUCTIONS AND EXAMINATIONS

B.PHARM. I YEAR

THEORY PAPERS:

Sl.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	Dispensing & General Pharmacy	3	20	80	100	3
2	Pharmaceutical Inorganic and. Analytical chemistry	3	20	80	100	3
3	Pharmaceutical Organic Chem-1	4	20	80	100	3
4	Remedial Maths/Remedial Biology	2	20/10	80/40	100/50	3/1.5
5	Biochemistry	2	20	80	100	3
6	Communicative skills in English	2	20	80	100	3
7	Tutorials	5				
	Total	21	120/110	480/440	600/110	

PRACTICAL PAPERS:

Sl.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam duration (hrs)
1	Dispensing & General Pharmacy	3	20	80	100	3
2	Pharmaceutical Inorganic and. Analytical chemistry	3	20	80	100	3
3	Pharmaceutical Organic Chem-1	3	20	80	100	3
4	Remedial Biology	3	10	40	50	2
5	Biochemistry	3	20	80	100	3
	Total	15	80/90	320/360	450	

B.PHARM – FIRST YEAR

I.T.I. DISPENSING AND GENERAL PHARMACY

(Theory) [3hrs/Week]

UNIT- I

History of Pharmacy: Development of Pharmacy Education, Industries and Research.

a) Pharmacy literature: History of I.P., B.P., U.S.P., B.P.C, and N.F. of India and Extra Pharmacopoeia.

b) Pharmacy Ethics: Introduction to code of Ethics of Pharmacy.

Galenicals: Methods of preparation, storage and packing of Infusions, Decoctions, Tinctures, Liquid extracts, Dry extracts, Study in detail of extraction processes like Maceration and Percolation.

UNIT - II

Principles and various methods involved in the preparation of the following: Solutions, Aromatic Waters, Syrups, Mucilages, Spirits, Elixirs, Magmas and Glycerines.

UNIT - III

Pharmaceutical calculations (only in C.G.S system): Percentage calculations, Proportional calculations, alligations, isotonic solutions, Proof spirits and Displacement values.

Principles of dispensing: The form of prescription Handling, Pricing and Refilling of prescription, Prescription containers, Labelling and Packing.

UNIT -IV

Principles involved and procedures adopted in the dispensing of the following classes of Pharmaceutical preparations: Mixtures, Emulsions, Powders, Lotions, Liniments, Ointments, Creams, Pastes and jellies, Suppositories, Pessaries, Nasal bougies, Inhalations, Eye drops, Ear drops, Throat paints and Gargles.

UNIT -V

Posology: Calculation of doses and a general know-how of the doses.

Incompatibility: Scope, Classes of incompatibility, Correction of incompatibilities, Handling of incompatible prescriptions pertaining to: alkaloidal incompatibility, Incompatibility of soluble iodides, soluble salicylates and benzoates with acids, ferric salts and alkaline substances, incompatibility causing evolution of carbon dioxide of soluble barbiturates and emulsifying agents.

I.P.I. DISPENSING AND GENERAL PHARMACY

(Practicals) [3hrs/Week]

I. Preparations: A minimum 50 preparations having at least one from each class is compulsory.

Galenicals **:** Demonstration of maceration; Percolation; Sox halation.

Solutions **:** Normal saline solution, Dextrose solution, Benzoic acid solution, Copper sulphate and zinc sulphate solution, Aqueous iodine solution.

Aromatic waters **:** Chloroform Water, Camphor Water, Peppermint Water.

Syrups **:** Simple syrup, Flavoured syrup, Artificial syrup.

Elixirs **:** At least one

Glycerine **:** Phenol glycerin, Tannic acid glycerin.

Spirits **:** Chloroform spirit

Emulsions **:** Liquid paraffin emulsion, Arachis oil emulsion

Lotions **:** Calamine lotion, Salicylic acid lotion, compound sulphur lotion.

Liniments **:** Methyl salicylate liniment, Camphor liniment, Terpentine oil liniment.

Ointments **:** Sulphur ointment (Hydrocarbon base)

Whitfield ointment (Water miscible base),

Boric acid ointment

Creams : Cetrimide cream, Barrier cream

Pastes : Zinc oxide paste

Gels : Zinc oxide gel (Bentonite gel)

Suppositories : One each with PEG and Cocoa butter as bases.

Ear drops : Boric acid ear drops, Sodium bicarbonate ear drops.

Eye drops : Atropine sulphate eye drops, Zinc sulphate eye drops

Mouth wash : Peppermint mouth rinse, Zinc sulphate, Zinc chloride mouth wash.

Inhalation : Menthol and Eucalyptus inhalation

Paints : Mandle's paint

Powders : Dusting powder, Divided power

Gargles : Potassium chlorate gargle; Tannic acid Gargles.

II. Important preparations: Compulsory.

- Soft soap
- Lysol (cresol with soap solution)
- Milk of magnesia (mixture)
- Chemical incompatibilities (Some representative examples)
-

III. Some information regarding incompatibilities (can be a demonstration).

IV. Prescription reading (Minimum of three Prescriptions).

V. Study of some marketed preparations (Minimum of three).

I.T.2. PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY

(Theory) [3 hrs/week]

PART – A (Inorganic)

UNIT – I

(a) **Limit tests** for Arsenic, heavy metals, lead, Iron, chloride and Sulphate and Pharmacopoeial standards.

(b) **Electrolytes:** Sodium, Potassium and Calcium replenishers.
Sodium and Potassium Replenishers: Sodium chloride, compound

Sodium chloride solution (Ringer solution), Potassium chloride, ORS.

Calcium Replenishers: Calcium chloride, Calcium gluconate, Dibasic calcium phosphate.

(c) Gastro-intestinal agents:

(1) **Acidifiers and Antacids**: IP: Dilute hydrochloric acid, sodium acid phosphate, sodium bicarbonate, sodium citrate, Potassium citrate, Aluminium hydroxide gel, Dried Aluminium hydroxide gel, Magnesium oxide (Magnesia), Magnesium-hydroxide mixture, Magnesium carbonate, Magnesium trisilicate, Calcium carbonate.

(2) **Adsorbents and related drugs**: Light kaolin, Heavy kaolin, Activated charcoal.

(d) Acid base Regulators: Sodium bicarbonate, Sodium lactate, Sodium citrate/Potassium citrate, and Sodium acetate, Ammonium chloride.

(e) Dialysis fluids: Haemodialysis fluids and intraperitoneal dialysis fluids.

UNIT-II

(a) **Mineral Nutrients/Supplements**

(1) **Haematinics –** Ferrous sulphate, Ferrous fumarate, Ferrous gluconate, Ferric ammonium citrate, iron and dextrose injection.

(2) **Halogens:** Iodine and Iodides or fluorides.

(b) Pharmaceutics aids:

(1) **Excipients:** Dicalcium phosphate, Tricalcium phosphate, Magnesium stearate, Talc and Calcium carbonate (Precipitated chalk).

(2) **Suspending agents:** Bentonite, Colloidalsilica, Aluminium stearate.

(3) **Colourants:** Titanium oxide, Ferric oxide.

(c) Expectorants: Ammonium chloride, Potassium iodide.
(d) Emetics: Potassium antimony tartarate, Copper sulphate, Zinc sulphate.
(e) Antidotes: Sodium thiosulphate, Sodium nitrite.

UNIT – III

Definition, Preparation, Properties, Assay methods, Limits and Uses

(a) Topical agents:

1) **Astringents:** Zinc sulphate, Zinc oxide, Calcium hydroxide, Copper sulphate, Bismuth sub carbonate.
2) **Topical protectants:** Zinc oxide, Calamine, Zinc stearate, Talc, Titanium-dioxide, Heavy kaolin and Light kaolin (only uses).
3) **Silicone polymers:** Activated Dimethicone.
4) **Anti infectives:** Hydrogen peroxide solution, Potassium permanganate, Silver nitrate (Silver protein), Iodine, (solutions of Iodine, povidone – iodine), Boric acid, Zinc – undecylenate, Mercury compounds (Yellow mercuric oxide, Ammoniated mercury), Sulphur, Selenium sulphide.

(b) Dental products:

1) **Fluorides:** Sodium fluoride, Sodium monofluorophosphate and stannous fluoride.
2) **Oral antiseptics and Astringents:** Hydrogen peroxide, Sodium peroxide (BP), Magnesium peroxide, Zinc peroxide and Mouth washes.
3) **Dentifrices:** Calcium carbonate, Dibasic calcium phosphate, Calcium phosphate, Sodium metaphosphate and Strontium chloride.
4) **Cements & fillers :** Zinc oxide (only uses).

(c) Other Medicinal agents:

1) **Antineoplastic agents:** Cisplatin
2) **Antidepressants:** Lithium carbonate
3) **Diagnostic agent:** Barium sulphate.
4) **Surgical aid:** Plaster of Paris.

PART – B (Analytical)

Unit – IV

a) **Theory of Neutralization Titration:** Acidimetry, Alkalimetry, Acid-base concept, Common ion effect and Solubility product, pH, Buffers and indicators.

b) **General Principles and theory of** oxidation-reduction methods, and precipitation methods. An account of the indicators used in these titrations.
Application of the above methods in the analysis of drugs, as under IP 1996.

Unit – V

a) **Complexometric titration:** Theory, types and application in pharmaceutical analysis. Masking and demasking and their applications.

b) **Non-aqueous Titration:** Theory, types, solvents used and application in Pharmaceutical analysis.
Application of the above methods in the analysis of drugs, as under IP 1996 (including the latest addenda).

C) Karl-Fisher method of estimation of water and other methods of moisture determination and Picnometry.

I.P. 2. PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY

(Practicals) [3hrs/week]

List of experiments:

A) Limit tests for the following as per the procedure given in Indian Pharmacopoeia (1996 – including the latest addenda)

1) Chlorides
2) Sulphates
3) Heavy metals
4) Iron
5) Arsenic (demonstration)

B)
6) Balances and Weighing, Calibration of weight, Pipette and Burette.
7) Preparation and standardization of Hydrochloric acid solution (0.1N).
8) Preparation and standardization of Potassium permanganate solution (0.1N & 0.1M).
9) Preparation of a primary standard solution of 0.1N Potassium hydrogen-phthalate.
10) Preparation and standardization of 0.1N EDTA solution.
11) Preparation and purification of Boric acid.
12) Preparation and purification of Sodium citrate.
13) Preparation and purification of Potash alum.

14) Preparation and purification of yellow mercuric oxide.
15) Preparation and purification of Ammoniated mercury.
16) Preparation and purification of Magnesium stearate.
17) Assay of sodium bicarbonate and assay of Boric acid (Neutralisation).
18) Assay of Calcium gluconate (or) any calcium compounds (Complexometry).
19) Assay of Copper sulphate (Redox titration).
20) Assay of Sodium acetate (Non-aqueous titration).
21) Assay of Ferrous sulphate (Oxidation-reduction / Redox titration).
22) Assay of Hydrogen peroxide solution (Permanganometry).
23) Exercises related assay by Gravimetric method.

I.T. 3. PHARMACEUTICAL ORGANIC CHEMISTRY-I

(Theory) [4hrs/week]

Unit – I

Structure and Activity of Organic Molecules: Shapes of organic molecules, Bond lengths, Bond angles and Bond dissociation energies. Electronic effects in organic molecules: Inductive effect, Electromeric or Mesomeric effect, Hyper conjugation, concept of resonance; Types of organic reagents and reactions.

A Study of Hydrocarbons:

Aliphatic/Alicyclic Hydrocarbons: Nomenclature, Isomerism (Chain, conformational and geometrical) Relative stabilities (Heats of Combustion and Hydrogenation), Ring stabilities of cyclohexane, chair-boat conformation, Bayer's strain theory and Sachse-Mohr theory. Free radical substitution reactions (Halogenation) of Alkanes, Selectivity of Halogen.

Alkenes: Electrophilic addition reactions of alkenes, Markovnikov's Rule, Kharasch effect, Bayer's Oxidation (Cis-Hydroxylation, Polymerisation).

Alkadienes: 1,4 addition reactions.

Aromtic Hydrocarbons:

Kekule's structure of Benzene, Bond lengths, Heats of hydrogenation and stability, Molecular orbital picture of Benzene, Aromaticity, Huckel's rule, Nomenclature of Benzene derivatives, characteristic reactions of Benzene, theory of reactivity and orientation in monosubstituted benzenes.

Unit – II

Halogen Compounds-Aliphatic: Nomenclature, two major methods of preparation, characteristic nucleophilic substitution reactions, Factors that play role in SN1 and SN2, Walden inversion, elimination reaction and Saytzef's rule.

Halogen Compounds-Aromatic: Nomenclature, Low reactivity of halo benzenes towards nucleophilic substitution, Benzyne ion concept.

Alcohols: Nomenclature, classification, two important methods of preparation, physical properties, Hydrogen bonding, characteristic nucleophilic substitution reactions (replacement of -OH by -Cl), elimination reactions, Reimer Tiemann reaction and relative reactivities of 1^o, 2^o and 3^o alcohols.

Ethers: Nomenclature, Williamson's synthesis, Action of HI on ethers (Ziesel's Method).

Alkynes: Acidity of 1-alkynes, Formation of metal acetylides. Stereo specific reduction of alkynes. Addition of hydrogen halide (HCl) addition of water and keto-enol Tautomerism.

Unit – III

Carbonyl Compounds: Nomenclature, two important methods of preparation, polarity of carbonyl group, relative reactivities of carbonyl compounds, nucleophilic addition and addition-elimination reactions, oxidation-reduction reactions, aldol condensation, Cannizzaro reaction, Benzoin condensation, Perkins reactions, Reformatsky reaction.

Phenols: Nomenclature, two important methods of preparation, physical properties, acidity of phenols, stability of phenoxide ion, reactions of phenols, Kolbe-Schmidt reaction stability of conjugated dienes, and Fries rearrangement.

Unit – IV

Carboxylic acids and their derivatives:

Carboxylic acids: Nomenclature, Intermolecular association, stability of carboxylate anion, Two important methods of preparation, Decarboxylation, functional groups reactions, Reduction of carboxylic acids. A note on dicarboxylic acids.

Acid derivatives: (Acid chlorides, anhydrides, esters and amides). Nomenclature, Reactions like hydrolysis, Reduction of esters and amides, Hofmann's degradation of amides. Brief account of Malonic and acetoacetic esters. Their importance in synthesis.

Unit – V

Nitrogen Compounds:

Nitro compounds: Nomenclature, acidity of nitro compounds containing α-hydrogens, reductive reactions of aromatic nitro compounds.

Amines: Nomenclature, Basicity of amines, Classification, Relative reactivity, Hinsberg method of separation, Acylation reactions

Diazotisation and Reactions of Diazonium salts.

Nitriles and isonitriles : Nomenclature, two methods of synthesis, reactivity and functional reactions.

Polynuclear aromatic hydrocarbons: Nomenclature, structure and aromatic character of Naphthalene and Anthracene. Resonance structures, electron density and reactivity. Electrophilic substitution, Oxidation and reduction reactions.

I.P. 3. PHARMACEUTICAL ORGANIC CHEMISTRY-I

(Practicals) [3hrs/week]

Introduction to: Equipment & Glassware, Recrystallization method, details of M.P, B.P and distillation

I. Preparation of organic compounds (each involving a specific organic reaction covered in theory)

1.	N-Acetylation	:	Preparation of Acetanilide from Aniline
2.	O-Acetylation		Preparation of Aspirin from Salicylic acid
3.	Nuclear Bromination	:	Preparation of p-Bromoacetanilide from Acetanilide
4.	Hydrolysis	:	Preparation of p-Bromoaniline from p-Bromoacetanilide
5.	Nuclear Nitration	:	Preparation of m-Dinitroaniline from Benzene
6.	Reduction	:	Preparation of m-Nitroaniline from m-Dinitrobenzene
7.	Oxidation	:	Preparation of Benzoic acid from
		:	Benzyl chloride
8.	Esterification	:	Preparation of n-Butylacetate from n-Butylalcohol
9.	Etherification	:	Preparation of β-Naphthyl methyl ether from β-Naphthol
10.	Addition-Elimination	:	Preparation of Phenyl hydrozone or Oxime from benzaldehyde
11.	α-Halogenation–cum-Oxidation	:	Preparation of Iodoform from Ethanol or Acetone
12.	Extensive Nuclear Bromination	:	Preparation of Tribromophenol or Tribromoaniline from Phenol or Aniline

II. Systematic qualitative Analysis (Identification) of Monofunctional Organic Compounds:

Avoid water-soluble compounds, and compounds containing more than one functional group.

III. An Experimental Determination of Relative Reactivities of the Following

a) Differentiation between Parafinic, Olefinic and Acetylinic Hydrocarbons using

i) Test for unsaturation with bromine-carbon tetrachloride and/ or dil.aq. Potassium permanganate, and

ii) Ammonical silver nitrate.

b) Differentiation between Benzene, Toulene and Nitrobenzene (Relative aromaticity) using conc. Sulphuric acid (sulfonation).

c) Differentiation between Aniline (1°), N-Methylation (2°) and N, N-Dimethyl (3°) using tosyl chloride (Hinsberg's Method)

d) Differentiation between: n-Propyl alcohol (1°), isopropyl alcohol (2°) and tert.butyl alcohol (3°) using the Lucas Reagent.

e) Differentiation between: Formaldehyde, Acetaldehyde, and Benzaldehyde using Tollen's Reagent.

I.T.4. REMEDIAL MATHEMATICS

(Only for student's admitted under B.P.C and D.Pharm streams)

(Theory)[2hrs/Week]

An introductory review of elementary mathematics:

UNIT - I

Algebra: Arithmetic and geometric progression. Permutations and combinations. Binomial theorem. Partial fractions. Logarithms. Matrices: types, addition, multiplication of matrices, Determinant of second and third order. Adjoint and inverse of non-singular matrix. Application of determinant to solve simultaneous equations by Cramer's rule.

UNIT - II

Trigonometry: Trigonometric ratios and the relation between them. Sin (A±B), Cos (A±B) and Tan (A±B) formulae only. Trigonometric ratios of multiple angles. Height and distances with simple problems only.

UNIT - III

Analytical geometry: Distance between two points, Area of a triangle. Co-ordinates of a point dividing a given segment in a given ratio. Locus. Equation to a straight line in different forms. Angle between straight lines. Point of intersection.

UNIT - IV

Differential calculus: Continuity and limits, differentiation, derivability and deviation, RH derivatives and LH derivatives, differential general theorems and derivation, derivatives of trigonometric functions (including reverse trigonometric functions), logarithmic differentiation, partial differentiation, maxima and minima (elemental).

Integral calculus: integration as reverse process of differentiation, definite integrals, integration by substitution and by parts, integration of algebraic functions, evaluation of area and volume in simple cases.

UNIT - V

Differential equations: Formulation and derivation, order and degree, first order and degree, linear equation with constant co-efficiency, homogeneous linear equations (first method of solution only); simultaneous differential equations which are linear and of first order.

I.T.4. REMEDIAL BIOLOGY

(Only for students admitted under M.P.C. stream)

(Theory)[2Hrs/Week]

Section – A (Botany)

UNIT I

Plant Cell and Tissues: Plant cell ultra structure with special reference to plasma membrane, mitochondria and plastids. Cell inclusions. Cell division: Mitosis and Meiosis. Types of plant tissues, tissue systems, and their functions.

UNIT - II

Morphology and Histology: Root, Stem, Bark, Wood, Leaf, Flower, Fruit and Seed. Modifications of roots and stems.

UNIT -III

Taxonomy: Taxonomic hierarchy. Systematic position (Clasification) of the following families with special references to medicinal Magnoliophyta (Angiosperms): *Fabaceae(Leguminosae), Apiaceae(Umbelliferae), Apocynaceae, Solanaceae, Lamiaceae(Labiatae), Liliaceae and Zingiberaceae.*

Section – B (Zoology)

UNIT - IV

Animal cells and Tissues: Animal cell ultra structure with special reference to endoplasmic reticulum, golgi apparatus, and ribosome. Cell division. Types of cells and tissues, and their functions.

UNIT - V

Study of Anatomy of frog: A basic study of GI, nervous, cardiovascular, genito-urinary, musculo-skeletal and respiratory systems. A comparative study of gross anatomy of different organs of rabbit, mice, guinea pig and a primate.

UNIT - VI

Fundamentals of parasitology: Life cycles of some animal parasites that cause human disease : Amobeasis – *Entamoeba histolytica* (Protozoa); Malaria – *Plasmodium vivax* (Protozoa); Taeniasis and cysticercosis – *Taenia solium* (Cestoda); and Filaria – *Wuchereria bancrofti* (Nematoda).

I.P.4. REMEDIAL BIOLOGY

(For students from M.P.C stream)

(Practicals)[3Hrs/Week]

Experiments

1. Introduction of Microscopes and their handling.
2. Morphology of various Plant parts.
3. Histological study of (Transverse sections)
   a) Monocot Root b) Monocot stem
   c) Monocot Leaf d) Dicot Root
   e) Dicot Stem f) Dicot Leaf
4. Systematic study of representatives of the following families:
   a) *Apocynaceae* b) *Solanaceae*
   c) c, d, & e : Three sub-families of *Leguminosae*
5. Study of following systems of Frog (Dissections)
   a) Digestive system b) Respiratory system
   c) Venous system c) Arterial system

I.T.5. BIOCHEMISTRY

(Theory) [2 Hrs/Week]

UNIT – I

Carbohydrate Metabolism: Glycolysis, glycogenolysis, gluconeogenesis, Kreb's cycle, direct oxidative pathway (HMP), uronic acid pathway.

UNIT – II

Metabolism of Proteins and Amino Acids: Essential and non-essential amino acids, general metabolic reactions of amino acids like deamination, transamination, decarboxylation, urea cycle; metabolism of the following amino acids: glycine, phenylalanine, tyrosine, cystein, cystine, methionine, tryptophan, valine and lysine.

UNIT – III

Metabolism of Lipids: Essential fatty acids, β-oxidation of fatty acids, ketogenesis, biosynthesis of fatty acids and cholesterol.

Enzymes: Classification, structure, mechanism of enzyme action, properties, factors influencing enzyme action, activators and deactivators of enzymes, competitive and noncompetitive inhibition with respect to drug action, coenzymes.

UNIT – IV

The principles involved and the method used in the qualitative and quantitative analysis of blood for the following constituents: glucose, urea, cholesterol, bile salts, bile pigments, creatinine, calcium, phosphates, SGPT and SGOPT.

The principles involved and the method used in the qualitative and quantitative analysis of urine for the following constituents: glucose, ketone bodies, bile salts, bile pigments and albumin.

UNIT – V

Role of Minerals and Water in Biochemical Processes with emphasis on the following: calcium, sodium, potassium, magnesium, iron and phosphorous.

Nucleic acid metabolism: Structure of DNA and RNA, Biosynthesis of purines and pyrimidines, Biosynthesis of DNA and RNA.

Biological oxidation: Introduction, brief account on the role of oxidases, dehydrogenases, hydroperoxidases and oxygenases in biological oxidation.

I.P.5. BIOCHEMISTRY

(Practicals) [3 Hrs/Week]

Experiments:

1. Identification of Carbohydrates
2. Preparation of Osazones
3. Identification of Amino acids
4. Identification of Proteins
5. Colour reactions of Cholesterol
6. Analysis of urine.
7. Analysis of urine for abnormal constituents
8. Estimation of Chlorides in Urine
9. Estimation of Glucose in Urine
10. Estimation of Uric acid in Urine
11. Estimation of Creatinine in Urine
12. Estimation of Glucose in blood by Folin-Wu method.
13. Estimation of glucose in blood by glucose oxidase method
14. Estimation of serum cholesterol (Enzymatic method)
15. Estimation of Urea in Blood
16. Estimation of Creatinine in blood
17. Estimation of Serum protein
18. Estimation of Urobilinogen in Blood
19. Estimation of Bile pigments in Serum
20. Estimation of alkaline phosphatase in Serum

I.T.6. COMMUNICATIVE SKILLS IN ENGLISH

(Theory) [2hrs/Week]

UNIT-I

Role and importance of communication, Verbal and non-verbal communication, Group communication, effective communication, barriers to communication, communication media, participating in discussions, conduct of seminars, conferences etc., making presentations through collection, evaluation, organizing the information, interacting with learners and teachers, Role of wit and humor in communication.

UNIT-II

Spoken english Vs Written English, reading method, formal /informal English (one way /two way); British/American/Indian Englishes; how to introduce one self and others; how to tender apology; how to thank in different ways; greetings, some polite expressions; agreement and disagreements; how to use a dictionary; how to use a thesaurus; vocabulary development; synonyms and antonyms; one word substitutes; comprehension.

UNIT-III

Communication through letters; official and personal letters; letters of complaint; letters of enquiries; and responses; writing memos, circulars and notices; what to avoid while writing; paragraph writing; scientific/technical report writing; drafting and delivering a speech, resume writing and interview techniques.

UNIT-IV

Grammar: Sequence of tenses, voice, articles, direct and indirect speech; degrees of comparison; common errors in English made by Indian learners of English. Concepts of learning and listening: types and methods of learning and listening; learning and listening of knowledge, attitudes, skills, and practices.

UNIT-V

The following four essays from "*Selections from Modern English*" prose Edited by Haladhar Panda are prescribed:

1. **Our Own Civilization** **-C.E.M.Joad**
2. **Andrew Carnegie** **-E.H Carter**
3. **The Secret of work** **-Swami Vivekananda**
4. **The Generation Gap** **-Benjamin Spock**

B.PHARM II YEAR

2.1. Semester

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	Biostatistics & Computer Applications	4	20	80	100	3
2	Pharm. Engineering	4	20	80	100	3
3	Pharm. Org. Chemistry-II	3	20	80	100	3
4	Human Anatomy & Physiology - I	3	20	80	100	3
5	Pharm. Microbiology & Immunology-I	3	20	80	100	3
6	Tutorial	1				
	Total	18	100	400	500	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	Pharm Engineering	6	20	80	100	3
2	Biostatistics & computer Applications	6	20	80	100	3
3	Pharm. Microbiology & Immunology-I	6	20	80	100	4
	Total	18	60	240	300	

@ Two sessional examinations will be conducted and their average will be taken

2.1.T.1. BIO-STATISTICS AND COMPUTER APPLICATIONS

(Theory)[4/Week]

Section – A: Bio-statistics

UNIT – I

Data collection and treatment: Significant digits and rounding of numbers, data collection, random and non-random sampling methods, sample size, data organization, diagrammatic representation of data, bar, pie, 2-D and 3-D diagrams, standard deviation and standard error of means, co-efficient of variation, confidence (fiducial) limits, probability and events.

Probability and Distributions: Bayer's theorem, probability theorem, probability distribution, elements of binomial and poison distribution, normal distribution curve and properties, kurtosis and skewness.

UNIT-II

Regression: Correlation and regression analysis, method of least squares, non-linear regression.

Statistical inference: Common parametric and non-parametric tests employed in testing of significance in biological/pharmaceutical experiments and elements of ANOVA (One way and two way).

UNIT – III

Design of experiments: Basic concepts of CRD, RBD and Latin square designs.

Sampling and Quality Control: Concept of Random sampling, Statistical QC Charts. Applications of statistical concepts in pharmaceutical sciences.

Section – B: Computer Applications

UNIT – IV

Concept: History of computers, simple model of computer and working parts of the computer, CPU, memory, input/output devices, computer languages and their hierarchal machine language, assembly language, high level language, comparison of high level and low level languages especially C, C++, PASCAL etc.

Introduction to microcomputers and concepts of operating systems: Elements of DOS, UNIX, etc., introduction of computer networks.

UNIT – V

Database management: Spread sheets (like MS-EXCEL, ACCESS), concepts and objectives of database and database management system, advantages and disadvantages of the database management system and examples of DBMS packages (like DBASE III).

Flow chart and algorithm development: Definition and properties of the algorithm, Flow chart symbols and their uses, Examples of efficient algorithm and flow-chart, conversion of algorithm/flow-chart to high-level languages.

UNIT –VI

Introduction to computer programming: C language: Constant and string variables, expressions, functions, structures, repitition statements (loops), nested loop, definite and indefinite loop and arrays. Concepts of files. Sequential files and random access files, Simple program writing for bio-statistical methods.

Computer application in pharmaceutical and clinical studies.

2.1.P.1. BIO-STATISTICS AND COMPUTER APPLICATIONS

(Practicals)[6hrs/Week]

1. Solving of biostatistical problems related to inference, sampling, graphical representation of data etc., with the help of calculators and software programmes like Graph pad.

2. **Sample programs in C:** Program to calculate simple and complex arithmetic expressions, program using structures, program using loops and nested loops, program using functions and simple programs using arrays.

3. Operating systems like WINDOWS, UNIX, etc.

   Software packages like MS-WORD, EXCEL, ACCESS, POWER POINT.

2.1. T.2. PHARMACEUTICAL ENGINEERING

(Theory) [4 Hrs/week]

UNIT – I

Introduction: Fundamental concept of material and energy balances, Definitions of Unit-operation, unit process and chemical technology, stoichiometry, laboratory scale, pilot scale and industrial scale operations.

Flow of Fluids: Concepts of fluid statics and dynamics, construction of simple and differential manometers. Reynolds's number, Bernoulli's theorem, Study of orifice meter, venturimeter, pitot tube and rotameter.

Transportation of Solids: Construction details, advantages and disadvantages of belt conveyor, screw conveyor and pneumatic conveyor, bucket elevator.

Transportation of Fluids: Cocks, valves- gate valve, check valve, pump-centrifugal pump.

Humidity: Definitions of humidity relative humidity, percentage humidity, dew point, humidity chart, adiabatic saturation temperature. and method of determination of humidity.

UNIT - II

Mixing: Mixing of liquids and liquids, design of impellers, construction and application of dry mixer, v-type mixer, power consumption of mixer, impellers, kneading machine, and colloidal mill.

Size reduction and separation: Theory of size reduction, factors influencing size reduction, energy aspects in size reduction construction details, advantages

and disadvantages of hammer mill, ball mill, fluid energy mill. Principles of size separation, construction details of shaking and vibrating screens, cyclone separator, bag filter. Scrubber, sedimentation theory.

Flow of Heat: Concept of heat flow: Conduction fouriers law, Natural and forced convection, radiation, Stefan-Boltzmann law, temperature drop in parallel and counter current heat exchangers. construction, operation and applications of heat exchangers, interchangers and finned tubes

UNIT – III

Evaporation: Theory of evaporation, heat and material balances, construction detiails, advantages and disadvantages of steam jacketed kettle, horizontal vertical tube evaporator, forced circulation evaporator, falling film and climbing film evaporators. Capacity of multiple effect evaporator.

Distillation: Concept of distillation of binary miscible, immiscible mixtures. Rectification, azeotropic distillation, distillation under reduced pressure, steam distillation, simple distillation, extractive and fractional distillation, and molecular distillation,

UNIT – IV

Drying: Theory of drying, drying curves, shrinkage of materials, construction, operation and application of different dryers, atmospheric and vacuum compartment dryer, rotary dryer, spray dryer, freeze dryer and fluidized bed dryer.

Crystallization: Mier's theory, its limitations, crystal growth, nucleation, caking of crystals, material and energy balances in crystallization, construction, operation and application of batch crystallizer, agitated tank crystallizer, krystal crystallizer and vacuum crystallizer.

UNIT – V

Centrifugation: Theory, Classification of centrifuges, Principle, Construction and Working of the Centrifuges Viz., Perforated basket centrifuge, Horizontal continuous centrifuge, super centrifuge, and Conical disc centrifuge.

Filtration: Theory of filtration, filter media, construction and operation of filter press, metafilter, disc filter, rotary vacuum filter. Filteration of air- Mechanism and equipment.

Extraction: Theory of extraction, equipment, Podbielniak extractor, counter current extraction, leaching of solids.

2.1.P.2. PHARMACEUTICAL ENGINEERING

(Practicals) [6Hrs/week]

1. Determination of Reynold's number for a liquid flowing through a pipe.
2. Determination of Humidity - i. Dew point method
   ii. Psychrometric method
3. Ball mill / Effect of Ball charge (or) Effect of time of operation on size reduction.
4. Sieve analysis of given sample of granular powder.
5. Determination of Radiation constant for Iron.
6. Determination of Radiation constant for Brass
7. Determination of Radiation constant for Unpainted glass
8. Steam distillation
9. Identification of Azeotropic and Zeotropic mixture
10. Drying rate curve
11. Effect of Filter aid on rate of filteration
12. Factors effecting rate of filteration (pressure, slurry concentration, cake thickness)
13. Study of crystallization process
14. Verification of Stoke's law
15. Comparision of Extraction efficiencies of single and multiple stage extractions
16. Effect of nature of liquid on rate of evaporation.
17. Fluidised bed drier (demonstration)
18. Filter Press (demonstration)

2.1.T.3. PHARMACEUTICAL ORGANIC CHEMISTRY – II

(Theory) [3 Hrs/Week]

UNIT - I

Carbohydrates: Definition, Classification, Nomenclature, Relative Configuration of some important monosaccharides, Study of glucose/fructose structure , open chain structure of glucose, fructose, ribose, deoxy ribose, reactions of glucose/fructose, Oxidation-reduction reactions, Action of Barium hydroxide, Osazone formation, acetylations, Epimerization, , Lobry de Bruyn – van Ekenstein reaction, stereoisomerisims of glucose:nomenclature of aldose derivatives. Lengthening carbon chain of aldose, ruffdegradation, epimers: conversion of an aldose into its epimers: D and L configuaration:cyclic and ring structure of D(+) Glucose, Mutarotation, anomers and formation of glucosides/fructosides (structure elucidation excluded)

Unit-II

Structure of the disaccharides: sucrose and lactose, Glycosidic linkage, Non-reducing nature of sucrose, A brief account of starch and cellulose. A brief account on pharmaceutical importance of carbohydrates: starch, cellulose and derivatives, Glucose, lactose , sucrose, sorbitol, mannitol

Glycosides: Definition, and α, β – glycosidic linkages, chemical and Enzymatic hydrolysis, examples of c-glycosides, N-glycosides, S –glycosides, O –glycosides, ester glycosides and uses glycosides (physiological/ pharmaceutical importance.)

UNIT - III

Amino acids: Definition, Classification, Essential amino acids, configuration, Three important methods of preparation of amino acids, physical properties. Zwitter ionic nature, isoelectric point, peptide synthesis and important reactions of amino acids.

Unit -IV

Polypeptides and proteins: Definition, Classification of proteins, Denaturation of proteins, Isoelectric point, C-terminal and N-terminal concept end group analysis peptide syntheis, Brief account of primary, secondary and tertiary structure. A brief account of the Pharmaceutical importance of amino acids, polypeptides and proteins.

UNIT - V

Stereochemistry of Carbon compounds (with only one Chiral centre): Optical rotation, plane polarized light, optical activity, chirality, Notations (Assignment of Configuration), Relative Configuration (Fischer D, L configuration), Absolute configuration, Sequence rules (with examples), Enantiomers, Meso Compounds, Racemic Mixture.

Stereochemistry of Alkenes – cis-trnas isomerism,Concept of E & Z configurations. Importance of stereochemistry in biological activity/drug action

2.1 T.4.HUMAN ANATOMY AND PHYSIOLOGY-I (Theory: 3hrs/week)

UNIT – I

An introduction to human body, the tissue level organization of human body**,** Fundamentals of anatomy of different systems of human body – Skeletal system, Nervous system, Muscular system, Joints.

UNIT- II

Control system of the human body: The special senses-sense of smell and taste, vision, hearing and equilibrium, skin, Disorders of vision and hearing

UNIT-III

Haemopoietic system: Composition, functions and properties of blood, formation of blood cells-RBC, WBC and platelets, blood clotting mechanism ,factors effecting blood clottong,disorders of platelets and coagulation, blood groups and their significance

Lymphatic system: structure and functions of lymphatic system-lymph vessels and lymph circulation, lymph organs and tissue-thymus, lymph nodes, spleen, lymph nodules, disorders of lymph and lymphatic system

UNIT-IV

Respiratory system: Anatomy of respiratory system, mechanism and regulation of respiration-exchange and transport of oxygen and carbon di oxide, control of respiration; lung volumes and capacities, respiratory disorders

UNIT-V

Digestive system: Anatomy and functions of GIT-peritoneum, mouth, pharynx, esophagus, stomach, pancreas, liver&gall bladder, small intestine and large intestine, Mechanical ,chemical digestion and absorption of food in small intestine and large intestine, nerves innervation of GIT,different types of GI motility.
Knowledge on emesis, pyloric stenosis, peptic&duodenalulcers, dispepsis, constipation, diarrhea, piles, jaundice, cirrhosis.

2.1.T.5 **PHARMACEUTICAL MICROBIOLOGY AND IMMUNOLOGY - I**

(Theory) 3 hrs/ week]

UNIT – I

Scope and Introduction to Pharmaceutical Microbiology.

Study of morphology, broad classification of bacteria, yeasts, actinomycetes, protozoa, fungi and viruses.

Identification of Bacteria, theory of staining, simple, Gram`s, acid fast, negative, flagella and spore staining methods.

UNIT - II

Culture media, different types, Preparation, Media for bacterial, fungal & actinomycetes cultures.

Culture methods – aerobic and anaerobic cultures.

Pure culture, Different methods of isolating pure cultures, methods of preservation of microbial cultures.

UNIT - III

Study of bacterial growth. Effect of UV light, ultrasonic waves, temperature, pH, osmotic pressure, salt concentration and metal ions. An outline of theories of antimicrobial action of drugs and chemicals.

Dynamics of disinfection, merits and demerits of different disinfectants, commonly used disinfectants, their mechanism of action. Evaluation of disinfectants.

UNIT - IV

Study of sterilization by moist and dry heat, construction and operation of autoclave, sterilization by filtration, sterilization by radiation and gases. Sterilization monitors.

Concept of asepsis. Maintenance of aseptic conditions.

UNIT - V

Introduction to microbiology of air, water and milk. Methods of quantitative evaluation of microbial contamination.

Microbial limit tests official in I.P.

2.1. P.3. PHARMACEUTICAL MICROBIOLOGY AND IMMUNOLOGY-I

(Practicals) [6 Hrs/Week;]

1) Introduction to equipment and Glassware used in Microbiology Laboratory.
2) Simple Staining
3) Gram Staining
4) Negative Staining
5) Acid fast Staining
6) Aseptic Transfer
7) Enumeration of Bacteria by Pour Plate Technique.
8) Enumeration of Bacteria by Direct Microscopic Count
9) Isolation of pure Cultures by Streak Plate Method
10) Oligodynamic Action of Heavy Metals
11) Observation of Colony Characteristics
12) Microbiology of Air-Settling Plate Technique
13) Microbiology of Water – Presumptive, Confirmed & Completed tests
14) Biochemical Reactions:
    i) Indole test
    ii) Methyl Red Test
    iii) Voges Proskauer Test
    iv) Citrate Utilization Test

v) Starch Hydrolysis Test
vi) Gelatin Liquefaction Test
vii) Fermentation of Carbohydrates
viii) H_2S Production Test

15) Morphology of Molds
16) Morphology of Yeasts
17) Microbial Limit Tests – Viable Count
18) Microbial Limit Tests for *E. coli, Proteus, Pseudomonas*, etc.

Minimum no of experiments to be performed: At least 5 bio chemical tests, at least 14 other experiments.

Scheme for practical examinations- 3 experiments + spotting (minimum 5)

B.PHARM II YEAR

2.2. Semester

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	Pharm. Org. Chemistry-III	4	20	80	100	3
2	Human Anatomy & Physiology-II	4	20	80	100	3
3	Pharm. Microbiology & Immunology-II	4	20	80	100	3
4	Environmental sciences	4	20	80	100	3
5	PHARMACY MANAGEMENT	4	20	80	100	3
6.	tutorials	4				
	Total	24	100	400	500	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	Pharm. Org. Chemistry-II	6	20	80	100	4
2	Human Anatomy & Physiology	6	20	80	100	4
	Total	12	40	160	200	

@ Two sessional exams will be conducted and their average will be taken

2.2.T.1. PHARMACEUTICAL ORGANIC CHEMISTRY – III

(Theory) [4 Hrs/Week]

Unit-I

Lipids (oils and fats): Definition, fatty acids, characterization of lipids (Saponification value, Acid value and Iodine value), Hydrogenation and Rancidity of oils and fats.

Unit-II

A study of the mechanism and application in synthesis of the following named reactions:

A. Beckmann rearrangement
B. Fries rearrangement
C. Phillips condensation reaction
D. Mannich reaction
E. Michael addition reaction

Unit-III

Study of some reagents: Preparation and some synthetic applications of

A) n-Bromo succinamide
B) diazomethane
C) $LiAlH_4$
D) $NaBH_4$
E) Aluminium isopropoxide and potassium tertiary butaoxide
F) Witting reagent
G) DCC reagent (NN Diacylohexyl carbodiimide)

Unit-IV

A Study of Some Simple Heterocyclic Systems containg one heteroatom:

` **Five membered with one hetero atom:** Furan, Pyrrole, Thiophene and Pyridine. Structure, source, electrophilic substitution, reactivity and orientation, reduction

six membered ring systems with one hetero atoms:, Pyridine, Structure, source, electrophilic and nucleophillic substitution , basicity, reudction

Unit-V

Definition, Nomenclature, Structure, aromaticity, reactivity, acidity, basicity and characteristic reactions of some fused ring systems: Indole, benzimidazole, benzothiazole, quinoline, isoquinoline and phenothiazine

Structures names and numbering of the following compounds: pyrazole, imidazole, oxazole, isoxazole,thiazole, pyridazine pyrimidine, pyrazine, idole, benzimidazoel, benzothiazole, triazole, tetrazole

Structure of some drugs or compounds with biological activity containing these ring systems

2.2. P. 1. PHARMACEUTICAL ORGANIC CHEMISTRY-II

(Practicals) [6hrs/week]

I. Synthesis of some simple Heterocyclic Compounds.

i) 2,5-Dimethylpyrrole from Acetonylacetone.
ii) 2,5-Dimethylthiophene from Acetonylacetone.
iii) 2,5-Dimethylfuran from Acetonylacetone.
iv) 3,5-Dimethylpyrazole from Acetylacetone.
v) 3,5-Dimethylisooxazole from Acetylacetone.
vi) 4,5-Diphenylimidazole from Benzil.
vii) Benzoxazole from o-Aminophenol.
viii) 2,5-Dioxopiperazine from Glycine.
ix) Oxazolone from Benzoylglycine.

II. Molecular Rearrangements and Named Reactions

a) Mannich Base from Acetophenone (Mannich Reaction).
b) Benzimidazole from o-phenylene diamine (Phillip's Reaction).
c) O-hydroxyacetophenone from phenyl acetate (Fries migration)
d) Benzanilide from benzophenone oxime (Beckmann's rearrangement) (to be avoided from examination)

III. Systematic Analysis of Organic Binary Mixtures

a) Avoid the water-soluble compounds
b) Avoid the binary mixtures having a risk of chemical interaction.

IV. Analysis of Oils & Fats

a) Determination of Acid value of fixed oils.
b) Determination of Saponification value of a fixed oil.
c) Determination of Iodine value of a fixed oil.
d) Determination of Acetyl value of a fixed oil.

2.2.T.2 PHARMACEUTICAL MICROBIOLOGY AND IMMUNOLOGY -II

(Theory) [4 hrs/week]

UNIT - I

Genetic recombination- bacterial conjugation, transformation and transduction. Mutation, Mutagens, Mechanism of mutation, types of mutations, isolation of nutritional and antibiotic resistant mutants. Ames test for mutagenicity testing.

UNIT - II

Infection, classification of Infectious diseases, methods of transmission of communicable and infectious diseases, carriers, vectors and reservoirs.

Principles of Immunology, Immunity, Classification of Immunity, Natural and Acquired Immunity.

Non specific defenses of host Complement system, phagocytosis, Inflammatory response, Interferons, Natural Killer Cells.

UNIT - III

Specific defenses of host Immune system, anatomy and development, Immune response, Cells involved in Immune response, Antigens, Sources, Antibody, structure and function, Classification of Antibodies, Humoral Immunity, Recognition of bacterial components, Role of Antibody and Complement, Antibody diversity.

Cell Mediated Immunity, types and functions of T- Cells.

Hypersensitivity – types,

UNIT - IV

Immunity to Viruses: T- cell recognition of viral antigen role of interferon's, Viral defense mechanisms against host.

General methods of immunization against diseases.

Fundamentals of serology, the lattice theory, neutralization, agglutination, precipitation, opsonization and complement fixation.

UNIT - V

Study of etiology, diagnosis, sources of infection, mode of transmission, immunization methods, prevention and control of the following diseases:

Bacillary dysentery, diphtheria, tuberculosis, leprosy, cholera, typhoid, syphilis, gonerrhoea, tetanus, food poisoning, amoebiasis, infective hepatitis. AIDS (HIV).

II.2.2.T.3 ENVIRONMENTAL SCIENCES

(Theory) [2hrs/week]

UNIT-I

The Multidisciplinary nature of environmental studies:

Definition, scope and importance.

Natural Resources:

a) *Forest resources:* Use and over-exploitation, deforestation, case studies. Timber extraction, mining, dams and their effects on forests and tribal people.
b) *Water resources:* Use and over-utilization of surface and ground water, floods, drought, conflicts over water, dams-benefits and problems.
c) Mineral resources: Use and exploitation, environmental effects of extracting and using mineral resources, case studies.
d) *Food resources:* World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies
e) *Energy resources:* Growing energy needs, renewable and non-renewable energy sources use of alternate energy sources, case studies.
Land resources: Land as a resource, land degradation, man induced l andslides, soil erosion and desertification.

Role of an individual in conservation of natural resources.
Equitable use of resources for sustainable lifestyles.

UNIT-II

Ecosystems

Concept of an ecosystem. Structure and function of an ecosystem. Producers, Consumers and decomposers. Energy flow in the ecosystem. Ecological succession. Food chains, food webs and ecological pyramids. Introduction, types, characteristic features, structure and function of the following ecosystem:
a) Forest ecosystem b) Grassland ecosystem, c) Desert ecosystem, d) Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

UNIT-III

Biodiversity and its conservation

Introduction- Definition: genetic, species and ecosystem diversity.

Biogeographically, classification of India. Value of biodiversity: consumptive use, productive use, and social, ethical, aesthetic and option values, Biodiversity at global, National and local levels. India as a mega-diversity nation. Hot spots of biodiversity. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts. Endangered and endemic species of India. Conservation of biodiversity: In-situ conservation of biodiversity

UNIT-IV

Environmental Pollution

Definition, causes, effects and control measures of:

a) Air pollution, b) Water pollution, c) Soil pollution, d) Marine pollution, e) Noise pollution, f) Thermal pollution and g) Nuclear hazards solid waste Management: Causes, effects and control measures of urban and industrial wastes. Role of an individual in prevention of pollution. Pollution case studies. Disaster management: floods, earthquake, cyclone and landslides.

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UNIT-V

Social Issues and the Environment

From unsustainable to sustainable development. Urban problems related to energy. Water conservation, rain water harvesting, watershed management Resettlement and rehabilitation of people; its problems and concerns. Case studies. Environmental ethics: Issues and possible solutions. Climate change, global warming, acid rain, ozone layer depletion, nuclear Accidents and holocaust.

Case studies: Wasteland reclamation. Consumerism and waste products. Environment protection Act. Air (prevention and Control of pollution) Act. Water (prevention and control of pollution) Act, Wildlife protection Act, and Forest conservation Act, Issues involved in enforcement of environmental legislation. Public awareness.

Human population and the Environment

Population growth, variation among nations. Population explosion – Family welfare programme. Environment and human health, Human Rights. Value Education. HIV / AIDS Women and child welfare, Role of Information, Technology in Environment and human health. Case studies.

2.2 T.4.HUMAN ANATOMY AND PHYSIOLOGY-II (Theory: 4hrs/week)

UNIT-I

Central nervous system: Classification of nerves, their origin, innervation, transmission and functions – spinal nerves and cranial nerves, electrical signals in neurons, signal transmission at synapses, introduction to neurotransmittors, physiology of different parts of brain and spinal cord

Unit-II

Autonomous nervous system: ANS neurotransmittors, physiological effects of ANS neurotransmitters, autonomic reflexes

Unit-III

Cardio vascular system: Anatomy of heart, heart valves and circulation of blood, cardiac muscle tissue and cardiac conduction system, cardiac cycle, cardiac output, disorders of cardiac rhythm.

Knowledge on hypertension, myocardial ischemia and infarction and congestive heart failure.

Structure and functions of blood vessles, capillary exchange, factors effecting blood flow, control of B.P and blood flow.

UNIT-IV

Endocrine system: Principles of hormone activity and mechanism of hormone action control of hormone secretion, hypothalamus&pitutory gland, thyroid gland, parathyroid gland, adrenal gland, pancreatic islets.

Hormonal regulation of metabolism, growth development, testicular fuction, ovary, fertilization, pregnenecy and lactation.

UNIT – V

Body fluids and renal function: Anatomy of kidneys, nephron and their functions.

Fluid compartments and fluid balance, electrolyte in body fluid and their balance.

Acid-base balance.

II. 2.2.P.2. HUMAN ANATOMY ANDPHYSIOLOGY

(Practicals) [6Hrs/week]

1) Introduction to instruments used in physiology lab.
2) Study of compound microscope.
3) Study of different tissues.
4) Determination of blood groups.
5) Determination of Bleeding time and clotting time.
6) Estimation of Hemoglobin
7) Determination ESR
8) Estimation of RBC
9) Estimation of WBC
10) Determination of Differential Count
11) Recording of normal HR and Effect of Exercise on HR
12) Recording of BP and Effect of Exercise on BP
13) Recording of Vital capacity
14) Study of Reflexes (Knee Jerk and Light Reflexes)
15) Recording of Strength of Stimulus
16) Recording of Simple Muscle Curve
17) Recording of Beneficial Effect
18) Recording of Effect of Fatigue
19) Recording of Normal Cardiogram of Frog Heart
20) Recording of Effect f Temperature on Heart
21) Recording the Effect of Drugs on Heart.

II.2.2.T.5. PHARMACY MANAGEMENT

(Theory) [4hrs/Week]

UNIT –I

Pharmaceutical Industrial administration:

Principles of Pharmaceutical Industrial Management in relation to the Introduction to forms of Business Organization.

Manufacturing Management: Plant location, factory building lay-out, production management goals and organization, operating problems, production policy, initiation of production, purchasing and inventory control, works lay-out and plant management.

UNIT -II

Workman Safety: measures to health hazards and prevention of environmental pollution.

Organization of Distribution and Marketing: Factors in distributions, Sales organization and sales promotions. General principles of medical detailing. Export and Import trade. GATT,WTO- New product development.

UNIT -III

Indian pharmaceutical industry:

Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health.
Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector.
Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT -IV

Export and import of drugs and pharmaceuticals –knowledge of PHRMEXIL.
Various types of insurances including marine insurance.
Pharmaceutical associations and societies, statutory councils governing the profession.

Principle of Drug store and community pharmacy administration:

Drug store management: Drug store planning and lay – out, sales promotion and salesmanship in drug store. Accounting records in drug stores.

UNIT -V

Elements of industrial accounting accountancy: Elements of double entry, books of accounts, journal, ledger and cashbook. The balance sheet, profit and loss account. Principles of costing and estimating.

B.PHARM III YEAR

3.1. Semester

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL INSTRUMENTAL ANALYSIS	6	20	80	100	3
2	PHYSICAL PHARMACY	6	20	80	100	3
3	COSMETIC TECHNOLOGY	4	20	80	100	3
4	Tutorials	2				
		18	100	400	500	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL INSTRUMENTAL ANALYSIS	6	20	80	100	4
2	PHYSICAL PHARMACY	6	20	80	100	4
3	COSMETIC TECHNOLOGY	6	20	80	100	4
	Total	18	60	240	300	

3.1. Semester B.PHARM – THIRD YEAR

3.1. T.1. PHARMACEUTICAL INSTRUMENTAL ANALYSIS

(Theory) [6 hrs/week]

UNIT-I

A Detailed account of the theory, instrumentation and pharmaceutical applications of:

Visible, UV & I.R. Spectrophotometry

UNIT-II

A Detailed account of the theory, instrumentation and pharmaceutical applications of:

Fluorimetry
Flame photometry
Refractometry
Polarimetry and Spectropolarimetry

UNIT-III

A brief account of the theory, instrumentation and applications of the following techniques:

1. Nephelometry & turbidometry
2. Potentiometry & pH metry (include specific ion electrons)
3. Conductometry
4. Polarography

UNIT-IV

A brief account of the theory, instrumentation and applications of the following techniques:

5. Differential thermal analysis
6. Paper, thin layer and column chromatographies, GC & HPLC
7. Electrophoresis
8. RIA & ELISA

UNIT-V

Analysis of the following drugs/compounds by different techniques:

Vitamins:

Vitamin A – Colorimetric methods (Carr-Price method and glycerol-1,3-dichlorohydrin method).
Vitamin B1 – Thiochrome flurometric method and silicotungstic acid – gravimetric methods.
Vitamin B2 – Fluorimetric method, colorimetric and polarographic methods.
Vitamin B6 – Colorimetric and spectrophotometric methods.
Vitamin B12 – Spectrophotometric and counter current distribution methods.
Vitamin D – Colorimetric (antimony trichloride) method.

Antibiotics:

Pencillins – Colorimetric (hydroxamic acid) method and U.V. methods.
Streptomycin – Fluorimetric and polarographic methods.
Tetracyclines – Spectrophotometric and fluorimetric methods.
Erythromycin – I.R. method.

Steroids:

Progesterone – Colorimetric (2,4 DNP) method.
Estrogens – UV, IR and polarographic methods.

Alkaloids:

Quinine – Fluorimetric and nephelometric methods.
Codeine – I.R. method.
Reserpine – Paper chromatographic method.
Ergometrine – Column chromatographic method.

Synthetic drugs:

Sulpha drugs – Colorimetric and polarographic methods.
Barbiturates – Spectrophotometric and paper chromatographic methods.
Xanthines – Theophylline – Spectrophotometric and gravimetric methods.
Aspirin and its combinations – Spectrophotometric and I.R. methods.

3.1.P.1. PHARMACEUTICAL INSTRUMENTAL ANALYSIS

(Practical) [36hrs/week]

Practical experiments

1. Ascending paper chromatography.
2. Radial paper chromatography.
3. Thin layer chromatography.
4. Column chromatography * (demonstration only).
5. Conductometric titration.
6. Potentiometric titration.
7. Determination of λ- max of a drug*
8. Determination of concentration of glycerine by Abbe's refractometer.
9. Assay of ibuprofen - UV-spectro photometry.
10. Assay of paracetomol - UV-spectro photometry.
11. Assay of riboflavin - Colorimetric method.
12. Assay of rifampicin - Colorimetric method.
13. Flame photometric determination of sodium.
14. Nephelometric determination of sulfate.
15. Fluorimetric estimation of quinine.
16. Paper electrophoresis of amino acids.
17. Gel electrophoresis* (demonstration only).
18. HPLC*(demonstration only).
19. PAGE* (demonstration only).
20. Kinematic viscosity*.
21. IR- Analysis* - related problems (demonstration only).

Note. *Not for examinations

3.1. T.2. PHYSICAL PHARMACY

(Theory)[6hrs/week]

UNIT – I

Buffers and Isotonic Solutions: Buffer equation, buffer capacity, buffers in pharmacy and biological systems, buffered isotonic solutions and methods of adjusting tonicity and pH.

Solubility: Solutions of solids/liquids, rate of solution. Energetics of solubility concept. Factors influencing solubility of solids/liquids, liquids/liquids and gases/liquids. Mechanism of solute-solvent interactions. Distribution phenomena, True and apparent distribution and application.

UNIT – II

Interfacial Phenomena: Concept of adhesive and cohesive forces, and their influence on surface and interfacial tensions. Spreading coefficient and its applications. Adsorption isotherms: Mathematical concept of adsorption at solid/gas, solid/liquid and liquid/liquid interfaces. Biological and pharmaceutical applications of adsorption phenomenon. Electrokinetics of interfaces, knowledge of HLB scales to aid the dispersion stabilization. Methods to determine HLB & CMC and their applications in Pharmacy.

UNIT – III

Colloids: Study of their optical, kinetic and electrical properties by giving special emphasis of their applications towards pharmaceutical product formulation. Stability of colloids: Electro kinetic stabilization, sensitization, protection and solubilization mechanisms.

Suspensions: Basic concept of particle-particle interactions, sedimentation of suspension, derived sedimentation parameters. Control of suspension stability through zeta-potential and structured vehicles.

Emulsions: Concept of free energy of surfaces and its effects on emulsion stability. Theories of emulsification and emulsion stability, concept of critical HLB. Mechanisms of emulsion stability. Factors influencing emulsion stability. Non-aqueous emulsions and micro-emulsions and their formation mechanisms.

UNIT – IV

Rheology: Hagen-Poiseulli's equation, Newtonian and non-Newtonian systems, Mathematical concept of viscosity coefficient. Factors influencing viscosity and measurement of viscosity. Thixotropy and its applicants. Factors influencing viscosity and measurement of viscocity. Thixotropy and its application towards formulation design of pharmaceutical systems.

Micromeritics: Particle size measurement. Statistical approach towards the particle size measurement in heterogenous pharmaceutical systems. Porosity, density and packing arrangements of particles. Flow properties of powders and their effect on solid dosage form processing.

UNIT – V

Chemical kinetics : Introduction to the concept of kinetics and their application towards Pharmacy. Mathematical concept of zero order, first order and pseudo first order reactions. Determination of reaction order. Half-life, period 90% and their usefulness. Influence of temperature on reaction rate, Arrhenius theory. Accelerated stability testing of drug compounds and determination of shelf life period.

Complexation and protein binding: Classification of complexes, mechanism of complex formation, advantages of complexations, stoichiometry of complexations, detection methods and protein binding.

3.1. P.2. PHYSICAL PHARMACY

(Practicals)[6hrs/Week]

Minimum 15 experiments to be completed

1. Determination of bulk density, true density and percentage porosity.
2. Effect of particle size and effect of glidant on angle of repose.
3. Microscopic size analysis.
4. Phase diagram - Phenol – Water, Effect of Impurities.
5. Ternary phase diagram.
6. Cloud point – nonionic surfactant-water system.
7. Surface and Interfacial tension using Stalagmometer.
8. Viscosity – by Ostwald Viscomete.
9. Determination of CMC of a surfactant.
10. Adsorption Isotherm.
11. Partition coefficient – Effect of Additives.
12. Determination of sedimentation volume and degree of flocculation.
13. Determination of Order of reaction – First order.
14. Second order Reaction.
15. Determination of Spreading Coefficient.
16. Buffers (Preparation and testing buffer capacity).
17. Effect of co-solvent on solubility.
18. Effect of temperature on solubility of solid in liquid.
19. Preparation of Multiple emulsion - Demonstration.
20. Preparation of Micro emulsion - Demonstration.
21. Determination of Zeta potential - Demonstration.

3.1. T.3. COSMETIC TECHNOLOGY

(Theory) [4Hrs/Week]

UNIT – I

Introduction: Definition of cosmetic. Basic knowledge of the skin, classification of cosmetics.

General aspects of cosmetic preparations: Coloring agents in cosmetics, preservatives, antioxidants and perfumes used in cosmetics.

UNIT – II

Ideal requirement, raw materials, formulation, manufacture and evaluation of following classes of cosmetic products.

Preparations for the face: Foundation and moisturizing creams, cleansing creams, face powders, lipsticks, sunscreen products.

UNIT – III

Preparation for hands: Hand creams and lotions, nail lacquers and nail polish removers.

Body cosmetics: Deodorants and antiperspirants, talcum and dusting powders, and bleaching preparations.

UNIT – IV

Preparations for the hair: Shampoos, hair creams, hair tonics, hair dyes and depilatories (hair removers).

Dental Preparations: Tooth powders and pastes, mouth washes.

UNIT – V

Shaving preparations: Pre-shave and after shave lotions shaving creams and shaving soaps.

Baby specialities: Baby powder, baby oils and lotions.

3.1. P.3. COSMETIC TECHNOLOGY

(Practical) [6Hrs/Weel]

Preparations of following cosmetic Products and their Possible evaluation.

The Preparations of the following are compulsory:

1. Vanishing / Foundation Cream
2. Cold Cream
3. Moisturizing Cream
4. Hand Cream
5. Talcum Powder
6. Face Powder
7. Lotion Shampoo
8. Antidandruff shampoo
9. Hair Cream
10. Depilatory Paste / Cream
11. Tooth Paste
12. Tooth Powder
13. Mouth Wash / Liquid dentifrice
14. Nail Lacquer Remover
15. Baby Powder
16. Lather Shaving Cream
17. After Shave Lotion
18. Antiperspirant Lotion

The Preparation of the following cosmetic products are optional

1. Barrier Cream
2. Hair dye (Metallic/Vegetable)
3. Deodorant Powder
4. Baby Lotion
5. Makeup Powder
6. Brush less Shaving Cream
7. Coconut Oil Shampoo
8. Conditioner Shampoo
9. After Shave Powder

Demonstration of preparation of the following products

1. Nail Lacquer
2. Lipstick
3. Depilatory Wax
4. Styptic

3.2. Semester B.PHARM III YEAR

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	MEDICINAL CHEMISTRY – I (Natural Products)	5	20	80	100	3
2	PHARMACOGNOSY – I	5	20	80	100	3
3	PHARMACOLOGY – I	4	20	80	100	3
4.	Pharmaceutical Jurisprudence	4	20	80	100	3
		18	100	400	500	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	MEDICINAL CHEMISTRY – I (Natural Products)	6	20	80	100	4
2	PHARMACOGNOSY – I	6	20	80	100	4
3	Pharmacology -I	6	20	80	100	4
	Total	18	60	240	300	

3.2. T.1. MEDICINAL CHEMISTRY – I

(Natural Products)

(Theory) [5Hrs/week]

UNIT – I

Antibiotics: Brief historical background, definition, requirements for a substance to be considered as an antibiotic and classification of antibiotics.

Penicillins: Historical background and biological sources. Structures of different penicillins.

Nomenclature: Numbering and naming according to the CA and USP systems, as derivatives of penam, penicillanic acid and as penicillins (trivial system).

Reactions: Hydrolysis of penicillin by cold and hot dilute mineral acid, alkali, enzymatic hydrolysis with Pencillinase, amidase and methanolysis followed by aqueous mercuric chloride.

Based on the route of administration- **Classification:** Oral and parenteral, based on spectrum of activity and resistance to β-lactamase, as natural, biosynthetic and semi-synthetic.

General method of synthesis of pencillins from 6-APA, SAR, mechanism of action, therapeutic uses, toxicity. A note on β-lactamase inhibitors.

Cephalosporins: Historical background and biological sources. Structures of some important Cephalosporins and Cephamycins. Acid hydrolysis of Cephalosporin C. Comparison of 6-APA and 7-ACA, penam and cepham.

Classification: Generations of cephalosporins Oral and parenteral, SAR and Advantages over penicillins, therapeutic uses and toxicity.

Tetracyclins: Biological sources, structures of the important tetracyclines, important structural units and the three acidity constants in the tetracycline

molecule, Amphoteric nature, epimerisation, chelation with metals, mechanism of action, spectrum of activity, SAR, therapeutic uses and toxicity.

Aminoglycosides: Structure of streptomycin, acid hydrolysis, mechanism of action, therapeutic uses and toxicity. Dihydrostreptomycin and its importance. A mention of other aminoglycoside antibiotics.

A brief account of **chloramphenicol, macrolide** and **polypeptide** antibiotics and **Rifampicin** (Structures not included).

UNIT – II

Vitamins: Introduction and Classification.

Fat-soluble vitamins: Vitamins A1 and A2 – Structures, Physiological role and uses, Tretinoin (Retinoic acid), Isotretinoin.

Vit D – Structures – Physiological role and uses, preparation of ergocalciferol from ergosterol, and cholecalciferol from 7-dehydrocholesterol.

Vit E – Structures of α, β and γ - tocopherols – Physiological role and uses.

Vitamin Ks – Vit K_1, K_2, K_3 and K_4 – Structures – Physiological role and uses.

Water soluble vitamins: Structures, physiological role and uses of Vit B_1, B_2, B_6, B_{12} , Nicotinic acid and amide, Cyanocobalamine, folic acid and Ascorbic acid.

Some important reactions of water soluble vitamins like: The oxidation of thiamine to thiochrome, the oxidation of nicotine to nicotinic acid, the amidation of nicotinic acid to nicotinamide, the degradation of riboflavine to lumiflavine and lumichrome, the reduction of folic acid to dihydro and tetrahydro folic acids in the biological system, the oxidation of Ascorbic acid to dehydroascorbic acid and related compounds

UNIT – III

Steroids:

Introduction: Brief history of development of steroid industry. Sources of steroidal drugs – diosgenin, cholesterol, stigmasterol and ergosterol – their structures. Marker's synthesis of progesterone. Nomenclature of steroids, stereochemistry and numbering the ring system. Colour reactions of steroids. Selenium distillation of steroids.

Steroidal Anti-Inflammatory drugs: Classification, structures, SAR, uses & toxicity.

Cardiac glycosides: structures of glycosides from Digitalis, Strophanthus, Squill and Bufa. Enzymatic and acid hydrolytic reactions of the glycosides. Mechanism of action, SAR, therapeutic uses and toxicity.

Bile acids: Names, structures and functions.

Hormones:

Sex Hormones: Male and female sex hormones.

Estrogens – estradiol, estrone, estriol. Structures and their interconversion.

Structures of synthetic estrogens. Therapeutic uses and side effects.

Progesterone and selected progestins – structures, uses and side-effects.

Preparation of progesterone from diosgenin. A note on Steroid contraceptive agents and regimens.

Androgens – Testosterone and derivatives. Structure and biological activities & uses

Adrenal Cortex Hormones:

Mineralocorticoids: Aldosterone, Deoxycorticosterone, Fludrocortisone – structures, biological activity and uses. Aldosterone antagonist Spiranolactone.

Glucocorticoids: Cortisone & Hydrocortisone – Structure, biological actions, uses.

Hormones of Pancreas:

Insulin – introduction, structural features – some sequence differences in insulins of some species like humans, pork, beef. Metabolic effects of insulin. A note on insulin preparations. Glucagon – Structure and Physiological role.

Hormones of Thyroid: Thyroxine and triiodothyronine – structure and functions.

UNIT – IV

Alkaloids:

Definition of alkaloids, pseudoalkaloids and protoalkaloids. General methods of extraction and isolation. Properties of alkaloids. Tests for alkaloids.

Opium alkaloids: Structural features of Morphine molecule – Peripheral groups. Modification of structure and effect on analgesic activity – SAR of morphine and morphine-like analgesics. Narcotic antagonists: Nalorphine, Levallorphan, nalaxone, nalthrixose. Anti-tussive agents: Dextromethorphan. Smooth muscle relaxants: Papaverine and related compounds like ethaverine, Dioxyline. Structures and uses of these compounds.

Tropane alkaloids: Structures of Atropine/hyoscyamine, Hyoscine, Hydrolytic products of these – Tropine and Scopine. Relationship between tropine & pseudotropine. Bioligical actions and uses of tropane alkaloids. Homatropine.

Rauwolfia alkaloids: Structures and uses of Reserpine, Rescinnamine,. Hydrolysis of reserpine and rescinnamine. Mechanism of action of reserpine.

Ergot alkaloids: Classification, structures, hydrolytic products, pharmacological actions, therapeutic uses and toxicity. Synthetic derivatives: Methylergonovine (Methylergometrine), L S D, Methysergide.

UNIT – V

Terpenoids:

Volatile oils: Definition of terpenoids, Classification, isoprene, special isoprene and gem-dialkyl rules.

Citrals: Sources and structures, isomerism in citral, citral-a (Geranial), citral-b (Neral). Reduction of citral to citronellal, citronellol, geraniol and nerol. Oxidation of citral to geranic acid. Cyclodehydration of citral to p-cymene. Conversion of citrals – a and b into alfa-terpeneol and ionones.

Alfa – Terpeniol: Sources and structure. Conversion into p-cymene, 1,8 – terpin, terpinolene, dipentene, dipentene dihydrochloride. Preparation of alfa-terpeneol from limonene/dipentene, 1,8-Terpin and pinene.

Carvone: Sources and structure. Conversion into Carvacrol. Reduction of Carvone with different reagents. Synthesis from Limonene/Dipentene and alfa – Terpeneol.

Menthol and menthone: Sources, structures and uses. Oxidation of menthol to menthone. Conversion of menthol into thymol.

1,8-cineole: Sources and structure. Preparation from Cis-terpin. Mention of 1,4-cineole.

Camphor: Source, properties, commercial method of preparation from α-pinene and uses. Oxidation to camphoric acid and camphoronic acids, conversion into p-cymene. Reduction of camphor to Borneol & isoborneol. Source, structures, uses of borneol. Oxidation of borneols to camphor.

NOTE:

1. Structure elucidation of compounds is not included in the syllabus.
2. Structural features like the basic nucleus, presence of substituent groups shall be discussed.
3. Simple reactions like hydrolysis, selenium dehydrogenation, oxidation, reduction etc., shall be taught wherever applicable.

3.2. P.1. MEDICINAL CHEMISTRY – I

(Natural Products)

(Practical) [6 Hrs/week]

1. Preparation of different Alkaloid testing reagents like Dragendroff, Mayer's Wagner's, etc. and testing some alkaloids and Plant extracts using these reagents.
2. Identification of Alkaloids by specific colour tests.
3. Tests for steroids, steroidal glycosides and cardiac glycosides. Liberman-Burchard test, Salkowski reaction, Kedde reaction, etc.
4. Tests for flavanoids and their glycosides. Shinoda Test (Mg /Hcl test), $Fecl_3$ test.
5. TLC Examination of Alkaloids, Steroids, Steroidal Glycosides and Cardiac Glycosides.
6. Identification of natural products.
7. Isolation of phytochemicals:
    a. Diosgenin - from Fenugreek or Dioscorea Yams.
    b. Strychnine & Brucine - from Nux-vomica seeds.
8. Estimations of the following.
9. Ascorbic acid(Raw materila, tablets and injections)
10. Vitamin B1(Gravimetry).
11. Penicillin(alkalimetry).
12. Alkaloid (by gravimetry).
13. Eugenol content in Clove oil.
14. Citral by Hydroxylamine hydrochloride.
15. Assay of camphor by gravimetry (hydroxylamine method)
16. organoleptic testing of terpenoids and terpenoid containing materials

3.2. T.2. PHARMACOGNOSY – I

(Theory)[5 hrs/week]

UNIT – I

A) Definition, History, and Scope of Pharmacognosy.

Crude drugs: Organized and unorganized crude drugs, Classification of crude drugs.

Scheme for pharmacognostic study of crude drugs.

Cultivation, Collection, Processing of Crude drugs:

Merits and demerits of cultivation of crude drugs. Exogenous factors affecting cultivation. A brief account of pests and methods of pest control. A brief introduction to plant growth regulators. Collection and processing of crude drugs.

Quality Control of Crude Drugs: Crude drug adultration; Types of adultrants, evaluation of a crude drug and methods of evaluation.

UNIT – II

Biogenesis of natural products:

A) A brief introduction to biosynthesis.

B) A brief account of primary and secondary metabolite's production from carbon metabolism in plants.

C) Production of amino acid by shikimic acid pathway.

D) Biogenesis of Atropine, Morphine, Isoprenoid compounds and cardiac glycosides.

UNIT – III

A) A brief introduction to Ayurveda and to its preparation like Arishtas, Asavas, Gutickas, Tailas, Churnas, Lehyas and Bhasmas.

B) A brief account phytopharmaceuticals of commercial significance.

UNIT – IV

A) General introduction to carbohydrates, lipids, enzymes and proteins and tannins.
B) Systematic pharmacognostic study of agar and isapgol.
C) Biological source, collection, preparation, chemical constituents, tests for identification and uses of following.
Guargum, Gum acacia, Honey, Pectin, Starch, Sterculia and Tragacanth, Almond oil, Bees wax, Castor oil, Cocoa butter, Cod-liver, Hydnocarpus oil, Kokum butter, Lard, Linseed oil, Olive oil, Shark liver oil and Wool fat, Diastase, Papain, Pepsin, Trypsin, Pancreatin and Gelatin, Pale catechu, Black catechu, Gall and Myrobalan.

UNIT – V

1. Study of mineral dugs; Bentonite, Kaolin, Kieselguhr and Talc.

2. Study of fibers used in pharmacy; Asbestos, Cotton, Glass-wool, Nylon, Polyester, Silk and Wool.
3. A brief introduction to plant bitters and sweeteners.
4. A brief introduction to natural colors and dyes.
5. An introduction to potential cardio-vascular, anticancer/cytotoxic and antibiotic drugs from marine sources.

3.2. P. 2. PHARMACOGNOSY –I

(Practical)[6hrs/week]

List of experiments:

1. Measurement of Starch grains in powdered crude drug.
2. Measurement of Phloem fibers in powdered crude drug.
3. Identification of Cinnamon by Linear measurement technique (by measuring the diameter of starch grains and width of Phloem fibers).
4. Measurement of Calcium oxalate crystals in powdered crude drug.
5&6. Determination of Stomatal number and Stomatal index of two dicot leaf drugs.
7&8. Determination of Vein islet number and Vein-let termination number of two dicot leaf drugs.
9&10. Determination of Palisade ratio of two dicot leaf drugs.
11. Detection of carbohydrates in crude drug by chemical tests.
12. Detection of proteins in crude drugs.
13. Detection of lipids in crude drugs.
14. Detection of tannins in crude drugs.
15. Identification of fibers by chemical tests.
16. Determination of ash values of vegetable crude drugs.
17. Determination of extractive values of vegetable crude drugs.
18. Determination of swelling factors.
19. Determination of foreign organic matter.
20. Spotting of Crude drugs: Minimum 20 Crude drugs belonging to Carbohydrates, Proteins, Lipids and Tannins.

3.2. T.3. PHARMACOLOGY – I

(Theory)[6hrs/week]

UNIT – I

General Pharmacology: Definitions, scope and branches of pharmacology. Concept of pharmacokinetics, pharmacodynamics and their interrelationship. Molecular mechanisms and factors affecting the drug action. Concept of receptors, ion-channels, enzymes and carrier systems. Dose effect relationship. Brief description of cellular signaling systems.

UNIT – II

Pharmacology of drugs acting on autonomic nervous system: Organization and functions of ANS. ANS (cholinergic & adrenergic) transmission and co-transmission. Pharmacology of parasympathomimetic, anti-cholinesterase, anti-cholinergic drugs. Pharmacology of adrenergic drugs, alpha, beta adrenoceptor blockers, adrenergic neuron blockers. Drugs acting on autonomic ganglia: stimulants and blockers. Neuromuscular blocking agents.

UNIT –III

Drugs acting on cardiovascular system: Cardiac rate and rhythm, disturbances in rhythm. Mechanism of action and therapeutic uses of antiarrhythmic, cardiotonic and anti-anginal drugs. Vascular smooth muscle and role of endothelium in controlling it. Vasoconstrictor and dilator drugs. Pharmacology of drugs used in hypertension.

Pharmacology of drugs affecting blood formation, coagulation, thrombolysis and platelet aggregation.

Pharmacology of drugs acting on kidney: Water and electrolyte balances, diuretics and urinary pH modifying agents.

UNIT – IV

Pharmacology of drugs acting on gastrointestinal tract: Laxatives-antidiarrhoeals, emetics-anti-emetics, prokinetic agents, antiulcer drugs.

Hormones and related drugs: Study of hormones of different endocrine glands (adrenal, thyroid, pituitary and gonadal), antithyroid drugs, corticosteroids, antiestrogens, antiprogestogens, oral contraceptives and drugs regulating calcium homoeostasis. Pancreatic hormones and their actions, Role of insulin and oral hypoglycaemic agents in deabetes mellitus.

UNIT – V

Basics of cell and molecular biology: Structural organization of life. Surface architecture, cell memberane: Structure and functions, nucleus and cytoplasmic matrix, cell growth and division, Molecular organization and Genome, DNA Replication and Transcription. Mechanism of protein sysnthesis, Genetic recombination, Molecular basis of protein syntheis. Genetic recombination, Molecular basis of mutation and variations, types of mutations.

3.2.P.3 PHARMACOLOGY – I
(6 per week)

1. Common laboratory animals and anesthetics used in animal studies. Some common and standard techniques of bleeding, intravenous injection, intra-gastric administration, procedures for rendering animal unconscious and chemical euthanasia, separation of plasma and serum.

2. Study of different routes of administration of drugs in mice/rats. To study the effect of

hepatic microsomal enzyme inhibitors and inducers on the phenobarbitone sleeping time in mice.

3. **Experiments on isolated preparations:**

- Study of different physiological salt solutions used in experimental Pharmacology

- Study on basic concept of *in vitro* experimental pharmacology. Commonly used instruments in experimental pharmacology- organ bath, levers, balancing, mounting procedures to be followed in *in vitro* measurements.

- Study on different tissues, agonists, antagonists and receptors employed in *in vitro* evaluation.

- Dose response curve (cumulative and non-cumulative) and ED 50 measurement of agonist in different tissues like skeletal muscles and smooth muscles (rat fundus, rat colon, rat seminal vesicle, rat uterus, rat vas deference, rat anococcygeus muscle, guinea pig ileum, rabbit jejunum)

- Study on isolated heart preparation with different agonist and antagonist.

- Blocking of agonist response using appropriate antagonist in isolated tissue preparation

- Study of potentiating response of different drugs in isolated tissue preparation

4. Effect of autonomic drugs on rabbit's eye.

5. Statistical calculations in Pharmacology

a. Student's - t test
b. ANOVA
C.Chi-square test

6. Experiments based on computer models like Ex Pharm.

3.2. T.4. PHARMACEUTICAL JURISPRUDENCE

(Theory) [4Hrs\week]

UNIT - I

Development of Pharmaceutical and drug legislation in India.

Legislation to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Drugs and Cosmetic Act, 1940 and Drugs and Cosmetics Rules, 1945, as corrected up to-date.

Legislation to regulate the profession of pharmacy. The Pharmacy Act, 1948.

UNIT - II

Legislation to control the advertisements, excise duties and prices of drugs.

a) The Drugs and Magic Remedies (Objectionable Advertisement) Act.
b) The Medicinal and Toilet Preparations (Excise duties) Act, and Rule of 1956.
c) Drugs (Prices Control) Order, as corrected up to –date.

UNIT – III

Legislations to control the operations regulating the Dangerous Drugs, Poisons and Opium, the Narcotic Drugs and Psychotropic Substances Act, 1985.

UNIT – IV

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Legislations affecting Pharmaceutical and Food Industry.

Industries (Development and Regulations) Act, 1951.

UNIT – V

a) The India Patents and Design Act, 1970 with reference to the Drugs and Pharmaceutical, only.
b) Prevention of Food Adulteration Act.
c) The factories act 1948 and the amendments
d) Consumer protection act 1986
e) Intellectual property rights – a brief introduction to various IPRs.
f) Case histories involving different Acts.

Note: The Students are expected to be acquainted with amendments to the above Acts.

4.1. Semester B.PHARM IV YEAR

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL TECHNOLOGY-I (Dosage forms)	6	20	80	100	3
2	PHARMACOGNOSY – II	6	20	80	100	3
3	PHARMACOLOGY – II AND TOXICOLOGY	6	20	80	100	3
		18	60	240	300	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL TECHNOLOGY-I (Dosage forms)	6	20	80	100	4
2	PHARMACOGNOSY – II	6	20	80	100	4
3	Pharmacology –II and TOXICOLOGY	6	20	80	100	4
	Total	18	60	240	300	

4.1. T.1. PHARMACEUTICAL TECHNOLOGY
(Dosage forms)

(Theory)[6Hrs/Week]

UNIT – I

Preformulation: Objectives, Brief study of solubility, Pka, Partition- coefficient, Dissolution and Solid-state properties.

Packing: Materials of packing (plastic, glass, Tin, Aluminum), Packaging of all formulations, package testing.

Liquid orals:

Formulation technology and evaluation of:

(a) Solutions, (b) Suspensions (c) Emulsions and d) Dry syrups.

UNIT – II

Parenteral preparations: Definitions, classification, formulation, vehicles, containers, filling, sealing and testing, design of aseptic filling area, quality control of parenterals.

UNIT - III

Solid dosage forms:

a) Compressed Tablets: Additives: diluents, binders, disintegrating agents, lubricants, colours, flavors and sweeteners. Formulation and manufacture of tablets, quality control of tablets. Coating – sugar, film, press and enteric coating methods.
b) Capsules-Hard and Soft: Formulation and manufacture and their quality control.

UNIT – IV

Concept of sustained action dosage forms: Dosage calculations, methods adopted in release controlling, micro encapsulation techniques. Quality control.

Control release: Concept, Definitions, and types of targeting. Applications of control release in Gastro retentive drug delivery systems and Transdermal drug delivery systems.

Semi-solid dosage forms: Classification of bases, formulation, preparation, packaging, storage and quality control of ophthalmic ointments, creams and suppositories.

UNIT – V

Aerosols: Classification, propellants, advantages and disadvantages, formulation and manufacture. Pressurized packaging and applications. Quality control of aerosols.

Radiopharmaceuticals: Definition, Radioactivity, A short list of radiopharmaceuticals, production of Tc99m injection, quality control and applications.

Basic concepts of GMP, validation and types of validation.

IV.P.1. PHARMACEUTICAL TECHNOLOGY
(Dosage forms)

(Practicals)[3 Hrs/Week]

A) Compulsory (fifteen)

Formulation and evaluation of the following:

1. Solution
2. Dry syrup
3. Suspension
4. Solid dispersion
5. Effervescent granules
6. Emulsion

Preparation and evaluation of the following:

1. Paracetamol tablets (wet granulation procedure).
2. Diclofenac sodium tablets.
3. Chewable tablets.
4. Aspirin tablets.
5. Capsule filling.
6. Micro encapsulation.
7. Dip coating.
8. Ampoule sealing – Parenteral injection.
9. Drug release from different ointment bases.

B) Optional (seven)

Preparation and evaluation of the following

1. Enteric coating of tablets
2. Drug loading on to pellets
3. Preparation of films for Transdermal delivery
4. Suppository
5. Soluble tablets
6. Effervescent tablets

7. Matrix sustained release tablets

4.1. T.2. PHARMACOGNOSY-II

(Theory) [6hrs/week]

UNIT – I

General introduction to Volatile Oils and Resins.

Systematic pharmacognostic study of following: Cardamom, Cinnamon, Cassia, Clove and Nutmeg, Capsicum, Ginger and Turmeric.

Biological source, collection and preparation, chemical constituents and tests for identification, uses, Substitutes and adulterants of following:

Chenopodium, Eucalyptus oil, Gaultheria, Lemon peel, Lemon grass oil, Oil of citronella, Orange peel, Mentha oil, Musk, palmarosa and Sandalwood.

Asafoetida, Balsam of Tolu, Balsam of Peru, Benzoin, Guggul, Myrrh, Podophyllum and Storax.

General pharmacognostic features of Umbelliferous fruit (Fennel, Dill, Coriander, Caraway) and their biological sources, chemical constituents, uses and adulterants / substituents (if any).

UNIT – II

General introduction to Alkaloids.

Systematic pharmacognostic study of following:

Cinchona, Ergot, Ephedra, Ipecac, Kurchi, Rauwolfia and Vasaka.

Biological source, diagnostic features, chemical constituents and Tests for identification, uses, adulterants and substituents of following:

Belladonna, Catharanthus, Coca, Cola, Coffee, Colchicum, Datura, Duboisia, Hyosyamus, Lobelia, Opium, Nux-vomoca, Pilocarpus, Solanum, Tobacco, Tea and Withania.

UNIT – III

General introduction to Glycosides.

Systematic pharmacognostic study of following:

Aloe, Ammi majus, Digitalis, Liquorice, Senna and Saffron.

Biological source, diagnostic features, chemical constituents and tests for identification, uses, adulterants and substitutes of following:

Ammi visnaga, Cascara, Chirata, Dioscoria, Gentian, Ginseng, Squill, Strophanthus and Quassia.

UNIT – IV

Historical development of plant tissue culture: Types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in production of pharmaceutically important secondary metabolites.

UNIT – V

Source, structure, commercial significance and uses of novel biochemcals – Artemesinin, Asiaticosides, Bacoposides, Camptothecin, Gymnemic acid, Neem derivatives and taxol.

4.1.P.2. PHARMACOGNOSY – II

(Practicals) [6hrs/week]

List of experiments

1. Isolation of starch from potatoes.
2. Preparation of cetyl alcohol from Spermaceti.
3. Isolation of Piperine from black pepper.
4. Isolation of Bixin.
5. Isolation of Curcuminoids.
6. TLC profile of nux vomica / cinchona alkaloids.
7. TLC of glycosides
8. TLC profile of peppermint oil.
9. Detection of alkaloids by chemical tests.
10. Detection of glycosides.
11. Detection of steroidal compounds.
12. Detection of flavonoids.
13. Identification of following powdered crude drugs and their combinations with the help of organoleptic, microscopic,micro chemical nadf chemical methods (if any).

    a. Senna b.Vasaka. c. Cinchona. d. Consia.
    e. Kurchi. f. Quassia. G. Ipecac. h. Rauwolfia.
    i. Squill. J. Ginger k. Fennel/ Coriander
    l. Nux Vomica. m. Clove.

    And some exercises on powdered crude drug mixtures

14. Anatomy of following crude drugs.

    a. Senna. b. Cassia/ Cinnamon c. Clove.
    d. Ephedra. E. Fennel. f.Linseed/nux vomica.
    g. Ipecac. h. Quassia I. Ginger.

15. Spotting of crude drugs mentioned in theory (minimum 30 crude drugs).

4.2. T.3. PHARMACOLOGY – II AND TOXICOLOGY

(Theory) [6 Hrs./Week]

UNIT - I

Pharmacology of drugs acting on central nervous system: Organization and functions of CNS. CNS transmission and study of distribution and functions of different neurotransmitters.

Pharmacology of drugs used in Parkinson's disease, Schizophrenia, Mental Depression, Epilepsy, and Dementia & Alzheimer disease, Anxiety, Insomnia.

Pharmacology of drugs used in pain: Opiods and related drugs.
Pharmacology of agents used in general and local anesthesia. Pharmacology of cortical and medullary stimulants.

UNIT – II

Bioethics and bioassay of some selective drugs
Principles of Bioethics, Bioethics of Animals used in Bioassay studies: Designs of bioassays, Principles of Bioassays, Official Bioassays of Insulin, Vasopressin, Oxytocin, Acetyl Choline, Adrenaline, d-Tubocurarine, coticotrophin, Digitalis, Histamine, Heparin, Gonado tropins, Cholera vaccine, Polio vaccine.

UNIT – III

Drugs acting on respiratory system: Drugs affecting respiration and drugs used in disorders of respiratory function.
Drugs acting in atherosclerosis. Lipid lowering drugs.

Local hormones, inflammation and allergy: Acute inflammatory reaction, unwanted immune responses and mediators of inflammation and allergy. Antiallergic drugs and Non-steroidal analgesic, antipyretic and anti-inflammatory drugs.
Peptides and proteins as mediators: Regulation of peptides and peptide antagonists, proteins and peptides as drugs.
Peripheral mediators: 5-Hydroxytryptamine and purines.

UNIT – IV

Chemotherapy of infections and malignant disease: basic principles, study of antibacterial, antifungal, antiviral, antihelminthic, antimalarial, antiamebic and anticancer drugs.
Pharmacology of immunosuppressants and stimulants. Drug dependance and drug abuse: Nicotine, Ethonal and cannabis.

UNIT – V

Principles of Toxicology

Acute, Sub acute and Chronic toxicities.
General principles of treatment of acute toxicity and poisoning-Signs, symptoms and treatment of poisoning due to:
OP and non OP pesticides (Organophosphorus and Non Organophosphorus)
Barbiturates, Benzodiazepines and opioids.
Neuroleptics and antidepressants.
Heavy metals like lead, Iron, mercury, Arsenic.
Alcohol
Snake and Scorpion venoms.

IV.P.4. PHARMACOLOGY – II

(Practicals) [3hrs/week]

1. Introduction to different equipment used in Pharmacology lab.
2. Introduction to different Physiological Solutions used in Pharmacology lab.
2. Effect of Routes of Administration on the Action of Drugs.
3. Determination of ED_{50} using isolated tissue preparations.
4. Effect of Drugs on Rabbit eye.
5. Effect of drugs on Ciliary Movements in frog's oesophagus.
6. Recording of Dose response curve of Acetylcholine on Frog Rectus Abdominis Muscle.
7. Recording of Dose response curve of Acetylcholine in presence of Physostigmine on Rectus Adbominis Muscle.
8. Recording of Dose response curve of Acetylcholine in presence of d-tubocurarine on Rectus Adbominis Muscle.
9. Effect of different Electrolytes / Drugs on Isolated frog's Heart by Syme's technique.
10. Recording of the effect of Venous Pressure on Isolated frogs Heart by Syme's technique.
11. To demonstrate to presence of Cholinesterase in Blood.
12. To record the Cumulative Dose Response of ACh on frog and the influence of Physostigmine and dtc.
13. To demonstrate the effect of Drugs on frog rectum.
    i. Effect of Ach, Adr, Isoprenaline and Nicotine.
    ii. Effect of Atropine in presence of Ach.
    iii. Effect of Adrenaline in presence of Propranolol.
14. Demonstration of Local Anaesthetic Activity on Rabbit eye.
15. Demonstration of Local Anaesthetic Activity on Frog's Hind-limb Withdrawal.

16. Bio-assay of Acetylcholine on Frog Rectus Abdominus Muscle by different Methods.
17. Recording of DRC of Histamine on Guinea-pig ileum.
18. Bioassay of Histamine on Guinea pig ileum.
19. Demonstration of difference between Cardiac Stimulants and Cardiotonic Agents (DEMONSTRATION).
20. Drug Interaction studies ACh X SCh, ACh X Pilocarpine.
21. Study of Different types of Antagonism in from rectus abdominis / Rat Colon.
22. Demonstration of Effect of local Anaesthetics on Isolated preparation like rectus abdominus or rat intestine or frog rectum. Demonstration of type of antagonism by local anaestheics.
23. Demonstration of effect of drugs on coronary blood vessels (DEMONSTRATION).

4.2. Semester B.PHARM IV YEAR

THEORY PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL BIOTECHNOLOGY	6	20	80	100	3
2	BIOPHARMACEUTICS AND PHARMACOKINETICS	4	20	80	100	3
3	MEDICINAL CHEMISTRY – II (Synthetic)	6	20	80	100	3
4	Hospital and clinical Pharmacy	4	60	240	300	

PRATICAL PAPERS:

S.No	Subjects	Hours/ Week	Sessional Marks	Annual Marks	Total Marks	Exam Duration (hrs)
1	PHARMACEUTICAL BIOTECHNOLOGY	6	20	80	100	4
2	BIOPHARMACEUTICS AND PHARMACOKINETICS	6	20	80	100	4
3	MEDICINAL CHEMISTRY – II (Synthetic)	6	20	80	100	4
	Total	18	60	240	300	

4.2. T.1. PHARMACEUTICAL BIOTECHNOLOGY

(Theory) [6hrs/Week]

UNIT – I

Fermentation Technology:

1) Screening Methods for bioactive metabolites.
2) Introduction to fermenter and its accessories.
3) Anaerobic and aerobic fermentations; Surface, submerged and solid-state fermentations.
4) Manufacture of the following: Study of culture, media, production conditions, extraction and purifications of:
    i) Antibiotics-Penicillin and Streptomycin.
    ii) Acids-lactic acid.
    iii) Enzymes-Fungal diastase.
    iv) Vitamins- Vitamin B12.
    v) Polysccharides-Dextran.

UNIT - II

Animal, blood and immunological products.

Animal Products:

i) Insulin-extraction, purification and types of formulations.

ii) Pepsin (iii) Heparin I.P

Blood products: Whole human blood, Plasma, dried plasma, fibrin, thrombin, Normal human immunoglobulin injection, Ideal characters of plasma substitutes, Dextran formulations (Preparations, uses and storage).

Immunological preparations: Definition and classification of immunoloical preparations. Manufacture and standardization of:

Bacterial	-	Cholera, BCG Vaccine.
Viral	-	Polio and Rabies.
Toxoids	-	Diphtheria.
Antitoxins	-	Tetanus antitoxin
Diagnostic agents	-	Purified protein derivatives for Tuberculin test.

UNIT – III

Testing methods:

Test for sterility: Sterility testing, media, sampling, neutralization of various antimicrobial substances in dosage forms. Conducting these tests for injections, surgical sutures (cat gut) & cotton.

Principles of microbiological assays and detailed assays for Vitamin. B12 and Penicillin.

UNIT – IV

Enzymes and animal cell biotechnology:

Enzymes: Sources. Applications in pharmaceutical industry, therapeutics and clinical analysis.

Immobilization of enzymes, advantages and limitations of immobilization and brief study of gel entrapment, adsorption methods of immobilization.

Microbial transformation of steroids: Introduction, types of transformation and uses.

Brief account of animal cell culture and its applications.

Monoclonal antibodies: Preparation and applications.

UNIT – V

r-DNA (recombinant DNA) technology and applications.

Fundamentals of genetic engineering: Definition of **rDNA** technology, Brief knowledge of **RNA** and **DNA** structures, prokaryotic and eukaryotic gene organization, basic techniques like agarose-gel electrophoresis, Southern blotting and Northern blotting.

Plasmids as cloning vehicles: Basic properties of plasmids, purification of plasmid **DNA.** Desirable properties of plasmid cloning vectors & **PBR** 322.

Cutting and joining of DNA molecules: Cutting of **DNA** molecules, restriction endonucleases and their nomenclature, target sites and joining of **DNA** molecules, **cDNA, DNA** manipulations with the help of enzymes like Alkaline phosphatase, S1 nuclease, exonuclease, **DNA** polymerase and reverse transcriptase. **DNA** ligase, double linkers, adapters and homopolymer tailing.

Introduction in to host cell: Transfection with recombinant phage DNA, E.coli transformation with plasmid **DNA**. Recombinant selection by genetic, immunochemical, and nucleic acid hybridization methods and Expression of cloned genes.

Applications of genetic engineering: Simple steps to constrct the rDNA for production of Human insulin, interferon, somatostatin, hepatitis B vaccine (no process details). A short list of products obtained through genetic engineering.

IV.P.2. PHARMACEUTICAL BIOTECHNOLOGY

(Practicals) [4 Hrs\week]

(3hr on the same day and 1hr in the next day morning)

1. Preparation of killed bacterial vaccine
2. Sterility testing of injections, powders
3. Preparation of antiserum from rabbit (demo)
4. Estimation of lactic acid produced by *Lactobacillus sporogenes.*
5. Production of alcohol and estimation of alcohol (Anaerobic fermentation).
6. Microbiological assay of antibiotics by agar diffusion method.
7. Microbiological assay of antibiotics by turbidimetry method.
8. Production of an antibiotic (Aerobic fermentation).
9. Estimation of diastase activity.
10. Gel electrophoresis of nucleic acid (demo).
11. Isolation of plasmid **DNA** from bacterial cells.
12. Transformation of *E. coli* (Demonstration).
13. Detection of antibiotics by Bioautography technique.
14. Determination of **MIC** of antibacterial substances (phenol).
15. Heparin bio-assay (demo).
16. Immobilization of enzymes (Gel entrapment).

17. Determination of Additive/synergistic effect of combination of drugs.
18. Pyrogen testing – **LAL** test (demo)
19. Antigen – Antibody reaction diffusion method.
20. RIA/ESLISA test. (Demo).

4.2.T.2. BIOPHARMACEUTICS AND PHARMACOKINETICS

(Theory) [4 Hrs/Week]

UNIT – I

INTRODUCTION TO BIOPHARMACEUTICS:

Introduction
The Concept of Biopharmaceutics

ABSORPTION OF DRUGS:

ABSORPTION OF DRUGS FROM GASTROINTESTINAL TRACT

Introduction, Rate Limiting Step in Bioavailability, Anatomical and Physiological Considerations of the Gastrointestinal Tract (GIT), Mechanisms of Drug Absorption, Factors Governing Gastrointestinal Drug Absorption:
Physiological Factors, Physicochemical Factors, Oil/Water Partition Coefficient (Lipid solubility), Drug Dissociation Constant and Gastrointestinal pH, pH-Partition Hypothesis, Metabolic Factors, and Formulation Factors.
Advantages and disadvantages of various routes of administration.

UNIT – II

DISSOLUTION:

Mechanisms of Dissolution, Factors Affecting the Rate of Dissolution, Measurement of Dissolution Rates, Official Methods of Dissolution, Unofficial Methods of Dissolution, Control of Variables in Dissolution Testing, In-vitro and In-vivo correlation's, Limitations of Dissolution Test.

Sink condition in dissolution. Methods used to achieve sink condition.

Bioavailability and Bio equivalence studies: Designing of bioavailability studies, and interpretation of results.

UNIT – III

DRUG DISTRIBUTION:

Physicochemical Properties of the Drug, Organ/Tissue Size, Blood Flow to the Organ, Physiological Barriers to the Diffusion of Drugs, Drug Binding in Blood, Drug Binding to Tissue and Other Macromolecules and Apparent Volume of distribution.

DRUG ELEMINATION:

Renal Excretion, Renal Blood Flow, Renal Clearance, Hepatic Elimination of Drugs, Drug Metabolism, Phase-I Reactions, Phase-II Reactions, Induction and Inhibition of Drug Metabolizing Enzymes, Hepatic Clearance, Pharmacological Activity of Metabolites, Disposition of Metabolites, First Pass Effect, Biliary Excretion, Enterohepatic Circulation, Extrahepatic Metabolism and Minor Pathways of Drug Excretion

UNIT – IV

INTRODUCTION TO PHARMACOKINETICS:

Mathematical Model, Drug levels in blood, Introduction to Pharmacokinetic Models, Pharmacokinetic Study,

ONE COMPARTMENT OPEN MODEL
INTRAVENOUS INJECTION (BOLUS)

I.V. Bolus-Unchanged Drug in Blood Plasma, Apparent volume of distribution, Elimination Rate Constant, Biological Half-life, Area under the curve (AUC) and Clearance.

I.V. Bolus-Unchanged Drug in Urine, Calculation of Pharmacokenetic Parameters, Excretion rate Method, Sigma-Minus Method and Comparison of the two methods.

UNIT – V

Concept of Nonlinear pharmacokinetics.
Basic concepts of Non compartment models.
Tests of significance: T-Test, Paired T-Test, ANOVA, multiple ANOVA, Practical applications of these in solving bioavailability and bioequivalence problems.

IV.P.3. BIOPHARMACEUTICS AND PHARMACOKINETICS

(Practicals) [3 Hrs/Week]

I. Determination of disintegration time of tablets

II. *In-vitro* dissolution studies:

1. a) Construction of standard graph of a drug.
   b) Dissolution of uncoated tablets of the drug.
2. a) Construction of diclofenac sodium standard graph by spectroscopic method.
   b) Dissolution of enteric coated tablets. (Diclofenac sodium)
3. Dissolution of sustained release tablets –diclofenac sodium
4. *In-vitro* ointment release studies

III. Protein binding studies

1) Equilibrium dialysis method-demonstration of protein binding.
2) Equilibrium dialysis method –demonstration of drug- drug interaction at protein bind sites.

PHARMACOKINETICS

IV. Theoretical problems

1. One compartment open model-I.V.(bolus)
   a) Unchanged drug in blood
   b) Unchanged drug in urine
      i) Rate excretion method
      ii) Sigma minus method
2. One compartment open model-extra vascular administration.
   b) Unchanged drug in blood
   c) Unchanged drug in urine
      i) Rate excretion method
      ii) Sigma minus method.

4.2.T.3. MEDICINAL CHEMISTRY – II (Synthetic)

(Theory) [6 Hrs/Week]

UNIT – I

Basic considerations of Drug activity:

Introduction, Factors affecting bioactivity,

a) Physicochemical Properties such as solubility, partition coefficients, and ionization.
b) Chemical structure parameters such as Resonance, Inductive effect, Types of bonding and Isosterism.
c) Spatial considerations: Molecular d mensions, Interactomic distances and Sterochemistry.

Theories of drug activity,

Occupancy Theory, Rate Theory, Induced fit Theory, Macromolecular perturbation Theory.

A brief account of quantitative aspects of drug action and Receptor concept of drug action mechanism.

Mechanisms of Drug action: Introduction, Enzyme stimulation, Enzyme inhibition, Sulfonamides and Membrane – active drugs

Drug metabolism and inactivation: Introduction, Biotransformations, Metabolic reactions, Conjugation reactions

UNIT – II

A study of the following classes of drugs including introduction, classification, structures, general method of synthesis (if any), mechanism of action and SAR. Synthesis of compounds specified against each class is to be studied.

Drugs acting on CNS:
A brief study of the chemistry of **neurotransmitters.**
Hypnotics and Anxiolytics – Phenobarbital, Diazepam, Alprazolam.
Antipsychotics – Chlorpromazine, Haloperidol
Antiepileptics – Phenytoin, Valproic acid
Antidepressants – Imipramine Fluoxetien (No synthesis)
General and Local anesthetic agents:

Definition, Introduction, chemical classification, SAR, mechanism of action and synthesis of Benzocaine and Lidocaine, Halothane and Ketamine.

UNIT – III

A study of the following classes of drugs including introduction, classification, structures, mechanism of action and SAR. Synthesis of compounds specified against each class is to be studied.

Drugs affecting adrenergic mechanism:

Introduction,
Adrenergic receptors, catabolism
Direct acting sympathomimetics Phenylephrine, Xylometazoline
Indirect acting sympathomimetics: Amphetamine

Drugs affecting cholinergic mechanism:

Introduction – some aspects of cholinergic system
Cholinergics – Carbacol
Anticholinesterase – Neostigmine
Antidotes for Ach Inhibitors:- PAM (Pralidoxime)
Cholinergic blockers: Propantheline
Neuromuscular blockers: Galamine

UNIT – IV

A study of the following classes of drugs including introduction, classification with examples structures, mechanism of action and SAR. Synthesis of compounds specified against each class is to be studied.

Drugs and Cardio-vascular diseases:

General account of cardiovascular diseases
Antihypertensives – Methyl Dopa, Amlodipine, Captopril, Losartan (No Synthesis)
Anti-arrhythmics – Procainamide
Diuretics – Acetazolamide, Hydrochlorthiazide, Furosemide
Anticoagulants, anti-anginals, and coronary vasodilators – Isosorbide dinitrate, Verapamil, Diltiazem,
Antihyperlipidemics (Hypocholesteremic drugs): Clofibrate, Atorvastatin, (No Synthesis) simvastatin (No Synthesis).
General account on panereatic and thyroid hormonal malfunctions. A brief account on statins
Antidiabetics – Metformin, Glipizide including a brief account on PPAR r inhibitors
Drugs affecting Thyroid Function: Methimazole, Propylthiouracil

UNIT – V

Analgesics and NSAIDS (Non-steroidal anti-inflamatory agents):

a) Introduction and types of pain and inflammation, b) classification and systematic development of analgesics of morphine, mild analgesics and strong analgesics : meperidine and methadone, c) NSAIDS – aspirin, paracetamol, ibuprofen diclofenac d) A brief account on co-x-2 inhibitors and nimesulide.

Chemotherapeutic Agents:

Definition Chemical Classification, SAR and mechanism of action and synthesis of the specified drugs in the following:

Sulpha drugs	**:**	Sulphamethoxazole, Sulphameter
Anti tuberculars	**:**	Isonicotinic acid hydrazide and ethambutol
Anti leprotics	**:**	Dapsone
Antiamoebics	**:**	Metronidazole, Diloxanide furoate
Anthelmintics	**:**	Diethylcarbamazine citrate, pyrantel pamoate, mebendazole.
Antimalarial Drugs	**:**	Chloroquine, Primaquine and pyrimethamine
Anticancer Drugs	**:**	Chlorambucil, Busulphan, Procarbazine, Carmustine, 5-Flurourasil, 5-Mercaptopurine and Methotrexate.
Anti viral Drugs	**:**	Aciclovir, Zidovudine
Antifungal Agents	**:**	Clotrimazole and Ketoconazole.

4.2. T.4. HOSPITAL AND CLINICAL PHARMACY

(Theory) [4Hrs/Week]

SECTION – A: Hospital Pharmacy

UNIT – I

Introduction to hospitals and hospital pharmacy

Hospital pharmacy: Objectives and functions, organization, planning and administration of modern hospital pharmacy services, location, layout, personal, qualifications, requirements, abilities and evaluation of hospital pharmacist, workload and remuneration of hospital pharmacist.

Pharmacy and therapeutic committee – Purpose, organization and functions.

Hospital formulary – Organization, formulary content, preparation and distribution. Pharmacy procedural manual preparation and publication.

Hospital committees – Infection control committee, Antibiotic committee and Research and ethics committee.

Role of hospital pharmacist in hospital committees and practice of Rational Drug Therapy . Drug exchange program.

UNIT – II

Hospital manufacturing: Economical considerations and estimation of demands lay out, raw materials, production, planning, requirements, manpower requirements and quality assurance, manufacturing of (including repacking and

prepacking) sterile products (small and large volume Parenteral), non sterile products, total parenteral nutrition and intravenous additives.

Drug distribution: Outpatient and Inpatient services, unit dose drug distribution systems, floor ward stock systems, satellite pharmacy services, central sterile services and bedside pharmacy.

Radiopharmaceuticals: Radioisotope committee, role of hospital pharmacist in isotope and non-isotope pharmacy.

SECTION – B: Clinical Pharmacy

UNIT - III

Definition, scope, history and development of clinical pharmacy.

Professional activities of the clinical pharmacist: Drug therapy monitoring (medication chart review, clinical review, TDM and pharmacist interventions), drug interactions, adverse drug reaction management, medication history review and patient counseling.

Patient data analysis: Clinical laboratory tests used in the evaluation of common disease states, interpretation of test results of liver function tests, pulmonary function tests, haemogram and renal function tests.

Drug and poison information services: Introduction of drug information, resources available, design of literature searches, critical evaluation of drug information and literature, preparation of written and verbal reports, development of a drug information data base and emergency treatment of poisoning.

UNIT – IV

Pathophysiology, drug therapy and critical analysis of rational use of drugs in the following disorders:

Cardiovascular disorders: Hypertension, congestive cardiac failure, ischemic heart disease.

Respiratory disorders: Asthma and chronic obstructive airways disease.

Renal disorders: Acute and chronic renal failure.

Hematological disorders: Anemia.

Endocrine disorders: Diabetes mellitus.

Bone & Joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout.

Ophthalmic disorders: Glaucoma.

UNIT – V

Pathophysiology, drug therapy and critical analysis of rational use of drugs in the following disorders:

Nervous diseases: Epilepsy and Parkinson's disease.

Psychiatric disorders: Schizophrenia, depression and anxiety.

Gastrointestinal disorders: Peptic ulcer disease, inflammatory bowel diseases and hepatitis.

Infectious disease: Respiratory tract infections, Typhoid, Urinary tract infections, tuberculosis, leprosy and AIDS.

Oncological disorders: Leukaemia, Hodgkin's disease.