SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

Syllabus of Third Year B. Pharmacy

2019 PATTERN (Revised)

(EFFECTIVE FROM ACADEMIC YEAR 2021-2022)

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 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 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 semester shall consist of not less than 90 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.

7.1. Credit assignment

7.1.1. 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.

7.2. 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 Project over 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 per week/Total no of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3/45	1	4
BP102T	Pharmaceutical Analysis I – Theory	3/45	1	4
BP103T	Pharmaceutics I – Theory	3/45	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3/45	1	4
BP105T	Communication skills – Theory *	2/30	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2/30	-	D
BP107P	Human Anatomy and Physiology – Practical	4/60	-	2
BP108P	Pharmaceutical Analysis I – Practical	4/60	-	2
BP109P	Pharmaceutics I – Practical	4/60	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4/60	-	2
BP111P	Communication skills – Practical*	2/30	-	1
BP112RBP	Remedial Biology – Practical*	2/30	-	D
Total		**32/34$/36#/480 /510$/540#**	**4**	**27**

Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course. However for Remedial biology and Mathematics no credits to be allotted only 50 % passing i.e D grade will be prerequisite.

$ 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 per week/Total no of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3/45	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3/45	1	4
BP203T	Biochemistry – Theory	3/45	1	4
BP204T	Pathophysiology – Theory	3/45	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3/45	-	3
BP206T	Environmental sciences – Theory *	3/45	-	3
BP207P	Human Anatomy and Physiology II –Practical	4/60	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4/60	-	2
BP209P	Biochemistry – Practical	4/60	-	2
BP210P	Computer Applications in Pharmacy – Practical*	4/60	-	1
Total		**32/480**	**4**	**29**

*****Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3/45	1	4
BP302T	Physical Pharmaceutics I – Theory	3/45	1	4
BP303T	Pharmaceutical Microbiology – Theory	3/45	1	4
BP304T	Pharmaceutical Engineering – Theory	3/45	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4/60	-	2
BP306P	Physical Pharmaceutics I – Practical	4/60	-	2
BP307P	Pharmaceutical Microbiology – Practical	4/60	-	2
BP 308P	Pharmaceutical Engineering –Practical	4/60	-	2
Total		**28/420**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit Points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3/45	1	4
BP402T	Medicinal Chemistry I – Theory	3/45	1	4
BP403T	Physical Pharmaceutics II – Theory	3/45	1	4
BP404T	Pharmacology I – Theory	3/45	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3/45	1	4
BP406P	Medicinal Chemistry I – Practical	4/60	-	2
BP407P	Physical Pharmaceutics II – Practical	4/60		2
BP408P	Pharmacology I – Practical	4/60	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4/60	-	2
Total		**31/465**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3/45	1	4
BP502T	Industrial Pharmacy-I– Theory	3/45	1	4
BP503T	Pharmacology II – Theory	3/45	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3/45	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3/45	1	4
BP506P	Industrial Pharmacy-I - Practical	4/60	-	2
BP507P	Pharmacology II – Practical	4/60	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4/60	-	2
Total		**27/405**	**5**	**26**

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3/45	1	4
BP602T	Pharmacology III – Theory	3/45	1	4
BP603T	Herbal Drug Technology – Theory	3/45	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3/45	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3/45	1	4
BP606T	Quality Assurance –Theory	3/45	1	4
BP607P	Medicinal chemistry III – Practical	4/60	-	2
BP608P	Pharmacology III – Practical	4/60	-	2
BP609P	Herbal Drug Technology – Practical	4/60	-	2
Total		**30/450**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy-II – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		**28/420**	**5**	**24**

***** Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3/45	1	4
BP802T	Social and Preventive Pharmacy	3/45	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6/90	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	**Pharmacological Screening Methods**			
BP811ET	Advanced Instrumentation Techniques			
BP812PW	Project Work	12/180	-	6
Total		**24/360**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27**
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	**01***
Total credit points for the program	**209**

* 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 colleges 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**.**

1. Program Committee

- 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.
- 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.

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.

2. Examinations/Assessments

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

2.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted 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

Cource 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$^{\#}$**	**31.5/35$^{\$}$/ 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	Physical PharmaceuticsI –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 Pharmacy–I- 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 Pharmacy–I – 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 -II– 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 Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			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
BP803ET	Pharma. Marketing Management–Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardizations of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Pharmacological Screening Methods-Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150
Total		**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

11.2 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 2 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	4	03
Student – Teacher interaction	2	
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

11.2.1. 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. The duration for the conduct of the exam is as below

Exam Type	**Marks allotted**	**Duration**
Theory	30	1.5 Hr
Practical	40	04 Hr

Question paper pattern for theory Sessional

For subjects having University exams

I. Objective Type Questions (Answer 05 out of 7)	=5 x 2 = 10
II. Long Answers (Answer 1 out of 2)	=1 x 10 = 10
III. 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**

12 . Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in 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 student fails 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 Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in 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 of end 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. Objective Type Questions (Answer 5 out of 7)	=5x 3= 15
II. Long Answers (Answer 2 out of 4)	= 2 x 10 = 20
III. Short Answers (Answer 8 out of 10)	= 8 x 5 = 40
Total	**= 75marks**

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 1out of 2)	= 1 x 10 = 10
II. Short Answers (Answer 5 out of 7)	= 5 x 5 = 25
Total	**= 25 marks**

Question paper pattern for end semester practical examinations

I. Synopsis	= 5
II. Experiments	= 25
III. Viva voce	= 05
Total	**= 35marks**

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 has given 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 AB should 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 any semester.

Rules for Carry Forward:

The curriculum (including regulations, structure and syllabi) is in force from academic year 2018-19 and onwards for First Year B. Pharm, for academic year 2019- 20 onwards for Second Year B. Pharm., for academic year 2020-21 and onwards for Third Year B. Pharm., and for academic year 2021-22 and onwards for Final Year B. Pharm.

The learners who were admitted to First Year B. Pharm. of 2015 pattern during the academic year 2017-18 or before & failed in the First Year B.Pharm. of 2015 pattern examination will have to take admission to Semester-III of Second Year B. Pharm. of 2018 pattern in academic

year 2019-20 or onwards, provided that

Sr. No	**Remedial courses for admission to S.Y.B.Pharm in Academic Year 2019-20 (Cleared F.Y. B. Pharm as per 2015 Pattern)**		
	(Non University Examination)	**Semester**	**Passing Criteria**
1.	Biochemistry – Theory/Practicals	Semester III	Minimum 50% marks with D grade
2.	Pathophysiology- Theory		Minimum 50% marks with D grade
3.	Computer Applications in Pharmacy – Theory/Practicals	Semester IV	Minimum 50% marks with D grade
4.	Environmental sciences – Theory		Minimum 50% marks with D grade

a) Their result of F. Y. B. Pharm of 2015 pattern is either pass or fails with A. T. K. T. The said students will have to take up additional remedial courses as follows.

b) The learners who were admitted to S.Y B. Pharm. of 2015 pattern during the academic year 2018-19 or before and fail in the S.Y B.Pharm. of 2015 pattern examination will have to take admission to Semester-V of Third Year B. Pharm. of 2018 pattern in academic year 2020-21 or onwards, provided that Their result of S. Y. B. Pharm of 2015 pattern is either pass or fails with A. T. K. T. The said students will have to take up additional remedial course as follows.

Sr. No	Remedial courses for admission to T.Y. B.Pharm in Academic Year 2020-21 (Cleared S. Y.B. Pharm as per 2015 Pattern)		
	(Non University Examination with 50% passing.)	**Semester**	**Passing Criteria**
1.	Medicinal Chemistry I – Theory/ Practical	Semester V	Minimum 50% marks with D grade

17. Grading of performances

17.1. 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 AB and 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 obtained in 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 points in these courses are G1, G2, G3, G4 and G5, respectively, and then students‟ SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C1 + C2 + C3 + C4 + C5}$$

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 ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO + C5G5}{C1 + C2 + C3 + C4 + C5}$$

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:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4 + C5S5 + C6S6 + C7S7 + C8S8}{C1 + C2 + C3 + C4 + C5 + C6 + C7 + C8}$$

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,....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 project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed for evaluation of the project shall be approved teachers of SPPU /Industrial Experts appointed by Principal of the respective institute. 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.

AND/OR

Every candidate shall be required to undergo any one of the Skill development modules mentioned below**(Duration – Min. 04 weeks)**

a) Hands on Training (Central instrumentation lab/Machine room etc)

b) UGC/AICTE recognized online courses (SWAYAM/NPTEL etc)

After the successful completion of the module the candidate shall submit satisfactory report and certificate duly signed by the authority of training organization/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 level and 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.

T.Y.B.PHARM 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 mentioned in bracket []only to be covered.

UNIT- I 10 Hours

Antihistaminic agents and autacoids

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

b) H1-antagonists: Diphenhydramine hydrochloride, Dimenhydrinate, Doxylamine ssuccinate, Clemastine fumarate, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride, Phenindamine tartarate, Promethazine hydrochloride, Trimeprazine tartrate, Fexofenadine, Astemizole, Loratadine, Cetirizine, Cromolyn sodium

c) H_2-antagonists: Cimetidine, Famotidine, Ranitidine

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

e) **Autacoids:** Prostaglandins, Prostanoids, Leucotriene antagonists

[Diphenhydramine hydrochloride, Cetirizine, Promethazine hydrochloride, Ranitidine]

UNIT – II **10 Hours**

Drugs acting on Cardiovascular system

a) **Anti-anginals**:

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

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

b) **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

c) **Anti-hypertensive Agents**:

α blockers- Prazosin, Terazosin

β blockers- Propanolol, Timolol, Atenolol

ACE inhibitors- Captopril, Lisinopril, Enalapril, Quinapril hydrochloride

Angiotensin II receptor antagonists- Losartan, Telmisartan, Valsartan

Misc.class- Methyldopate hydrochloride, Clonidine hydrochloride, Guanethidine monosulphate, Reserpine, Hydralazine hydrochloride.

[Isosorbide dinitrite, Nifedipine, Chlorthiazide, Furosemide, Lisinopril, Atenolol]

UNIT-III **10 Hours**

Drugs acting on cardiovascular system (Continued)

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

b) **Anti-hyperlipidemic agents**

HMG Co-A reductase inhibitors: Lovastatin, Simvastatin, Atorvastatin

Misc. class-Ezetimibe, Clofibrate

c) **Coagulant & Anticoagulants**: Menadione, Warfarin, Clopidogrel

d) **Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan

[Amiodarone, Atorvastatin]

UNIT-IV **08 Hours**

Drugs acting on Endocrine system

a) **Chemistry, Nomenclature, Stereochemistry and metabolism of steroids**

b) **Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

c) **Drugs for erectile dysfunction:** Sildenafil, Tadalafil.

d) **Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol

e) **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone,Dexamethasone

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

UNIT – V **07 Hours**

Antidiabetic agents and Local anaesthetics

a) **Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

DPP IV inhibitors -Sitagliptin, Teneligliptin

SGLT2 inhibitors – Empagliflozin, Canagliflozin

b) Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Meprylcaine, Cyclomethycaine, Piperocaine.

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

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

Miscellaneous: Phenacaine

[Tolbutamide, Benzocaine]

Recommended Books (Latest Editions)

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

BP 502 T. Industrial Pharmacy I (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

1. illustrate various pharmaceutical dosage forms and their manufacturing techniques.
2. describe various factors to be considered 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 **03 Hours**

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

UNIT-II **14 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, preformulation and 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: Preformulation, 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; preformulation, formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

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

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz

2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman

3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman

4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

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, 5thedition, 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 **10hr**

Pharmacology of drugs acting on cardiovascular system

a. Introduction to hemodynamic and electrophysiology of heart.

b. Drugs used in congestive heart failure

c. Anti-hypertensive drugs.

d. Anti-anginal drugs.

e. Anti-arrhythmic drugs.

f. Anti-hyperlipidemic drugs.

UNIT-II

Pharmacology of drugs acting on cardiovascular system **10hr**

a. Drug used in the therapy of shock.

b. Hematinics, coagulants and anticoagulants.

c. Fibrinolytics and anti-platelet drugs

d. Plasma volume expanders

Pharmacology of drugs acting on urinary system

a. Diuretics

b. Anti-diuretics.

UNIT-III

Autocoids and related drugs **10hr**

a. Introduction to autacoids and classification

b. Histamine, 5-HT and their antagonists.

c. Prostaglandins, Thromboxanes and Leucotrienes

d. Angiotensin, Bradykinin and Substance P.

e. Non-steroidal anti-inflammatory agents

f. Anti-gout drugs

g. Antirheumatic drugs

UNIT-IV

Pharmacology of drugs acting on endocrine system **08hr**

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

Pharmacology of drugs acting on endocrine system **07hr**

a. Androgens and Anabolic steroids.

b. Estrogens, progesterone and oral contraceptives.

c. Drugs acting on the uterus.

Bioassay

a. Principles, applications and types of bioassay.

b. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

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 McGraw-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,

BP504 T PHARMACOGNOSY AND PHYTOCHEMISTRY-II (Theory) 45 Hours

Scope:

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

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 production of of Phytoconstituents /herbal formulation.
3. To understand the metabolic pathways in formation of secondary metabolites and application of biogenetic studies.
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 of Biogenetic studies.

UNIT-II 14 Hours

General introduction, composition, chemistry & chemical classes, bio sources, **methods of extraction**, 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 **06 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

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

UNIT V **12 Hours**

Basics of Phytochemistry

Methods of extraction (Soxhlet, Maceration, Percolation , Supercritical fluid extraction, Microwave assisted extraction, Ultrasound assisted extraction , Solid Phase Extraction)

Application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs

Non-chromatographic separation techniques: Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth floatation technique.

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 122 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 Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist‟s oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-byM.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) 124

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, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition,Marcel Dekker Series, Vol 107.

BP 507 P. PHARMACOLOGY-II (Practical) 4Hrs/Week

Sr. No	Experiment
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. Dose calculation in pharmacological experiments
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 using hotplate method
16. Antiallergic activity by mast cell stabilization assay
17. Clinical Case study

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

Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
3. Goyal RK. Practicals in Pharmacology, BS Shaha Prakashan.
4. Kasture SB. A handbook of experiments in pre-clinical pharmacology, Career Publications.
5. Bikas Medhi, Ajay Prakash. Practical Manual of Experimental and Clinical Pharmacology. Jaypee Publications.

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.

T.Y.B.PHARM 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 also discusses the concept of quantitative structure activity relationship (QSAR) in drug design. 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 mentioned in bracket []only to be covered

UNIT - I 10 Hours

Antibiotics

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

a) **β-Lactam antibiotics:** Penicillins, Cepholosporins, β-Lactamase inhibitors, Monobactams
b) **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

c) **Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **07 Hours**

a) **Antibiotics**

Macrolide: Erythromycin, Clarithromycin, Azithromycin.

Polypeptide antibiotics-Vancomycin, Bacitracin

Miscellaneous: Chloramphenicol, Clindamycin, Linzolide

b) **Antimalarials:** Etiology of malaria.

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

Biguanides and dihydrotriazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone, Halofantrine, Lumefantrine.

[Chloramphenicol, Chloroquine]

UNIT – III **08 Hours**

Antimycobacterial and Antiviral agents

a) **Anti-tubercular Agents**

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

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

b) **Antileprosy agents:** Clofazimine, Dapsone, Rifamycin

c) **Antiviral agents:**

DNA virus inhibitors-Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoridine, Acyclovir, Gancyclovir.

RNA virus inhibitors

Anti-HIV agents- Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine , Ribavirin, Saquinavir, Indinavir, Ritonavir.

[Isoniazid, Ethambutol, Acyclovir]

UNIT – IV **10 Hours**

a) **Antifungal agents**

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Oxiconazole,Tioconozole, Miconazole, Ketoconazole, Itraconazole, Fluconazole, Tolnaftate.

b) **Anti-protozoal Agents:** Metronidazole, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Atovaquone, Eflornithine.

c) **Anthelmintics:** Diethylcarbamazine citrate, Thiabendazole, Mebendazole, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

d) **Synthetic anti-infective agents :**

Sulphonamides: Historical development, chemistry and drug resistance

Sulfacetamide, Sulphapyridine, Sulfamethoxazole, Sulphadiazine, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim

Quinolones: Nalidixic Acid, Norfloxacin, Ciprofloxacin, Ofloxacin, Lomefloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin, Methanamine.

[Fluconazole, Metronidazole, Mebendazole, Sulfamethoxazole, Trimethoprim , Ciprofloxacin]

UNIT – V **07 Hours**

Anti-neoplastic agents:

Alkylating agents: Meclorethamine, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Kinase inhibitors: Gefitinib, Imatinib, Erlotinib

Monoclonal antibodies-Bedvacizumab, Cetuximab

Miscellaneous: Cisplatin, Mitotane.

[Chlorambucil, Mercaptopurine, Methotrexate)

UNIT – VI **03 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, Ferguson principle.

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.
11. An Introduction to Medicinal Chemistry by Graham Patrick

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 poisonings and appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hr**

Pharmacology of drugs acting on Respiratory system

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

Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT-II

Chemotherapy **10hr**

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

UNIT-III

Chemotherapy **10hr**

a. Antitubercular agents
b. Antileprotic agents

c. Antifungal agents
d. Antiviral drugs
a. Anthelmintics
e. Antimalarial drugs
f. Antiamoebic agents

UNIT-IV

Chemotherapy **08hr**

a. Urinary tract infections and sexually transmitted diseases.

b. Chemotherapy of malignancy.

Immunopharmacology

a. Immunostimulants
b. Immunosuppressant

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

UNIT-V

Principles of toxicology **07hr**

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.

Chronopharmacology

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

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale‟s Pharmacology, Churchil Livingstone Elsevier

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-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 LippincottWilliams &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 MedicalPublishers (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. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

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.

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.

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

Study of Omega-3-polyunsaturated fatty acids, Dietary fibers, Carotenoids, proanthocyanidins, and Resveratrol

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

Market overview, ,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:

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

Herbal formulations :

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

UNIT- IV **12 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.

Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)

UNIT-V **05Hours**

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.

S**chedule T – GoodManufacturing 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 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 dosage form development.

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand the concept of dissolution and application of in vitro in vivo correlation in drug product development.

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, 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, factors affecting drug metabolism, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus, dissolution models, *in-vitro-in-vivo* correlations

UNIT- III **10 Hours**

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, bioequivalence studies and study designs, Review of regulatory requirements for conducting bioequivalence study, bio-waivers, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- IV **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, $t_{1/2}$, Vd, AUC, Ka, CL_T and CL_R- definitions methods of eliminations, understanding of their significance and application. Introduction to multi-compartment model.

UNIT- V **05 Hours**

Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-menten equation, Determination of V_{max} and K_m. Significance of nonlinear pharmacokinetics, 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 Rowland M, Tozer T, Ed 4, WolterKluwers – Lippincott,Williams and Wilkins.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
Remington‟s Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia.

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY(Theory) 45 Hours

- 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 technologymakes the subjectinteresting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceuticaldrugs.
- Biotechnology has already produced transgenic crops and animals and thefuture promises lot more.
- It is basically a research-basedsubject.

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 inIndustries
4. Appreciate the use of microorganisms in fermentationtechnology

Unit I 10 Hours

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

Brief introduction to Protein Engineering.

Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

Basic principles of genetic engineering.

Unit II **10 Hours**

Study of cloning vectors, restriction endonucleases and DNAligase.

Recombinant DNA technology. Application of genetic engineering inmedicine.

Application of r DNA technology and genetic engineering in the productionof:

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

Brief introduction toPCR139

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

Structure of Immunoglobulins

Structure and Function of MHC

Hypersensitivity reactions, Immune stimulation and Immune suppressions.

General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

Storage conditions and stability of official vaccines

Hybridoma technology- Production, Purification and Applications

Unit IV **08Hours**

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

Microbial genetics including transformation, transduction, conjugation, plasmidsand transposons.

Introduction to Microbial biotransformation andapplications.

Mutation: Types of mutation/mutants.

Unit V **07 Hours**

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process,stirring.

Large scale production fermenter design and its variouscontrols.

Study of the production of - penicillins, Vitamin B12, Glutamicacid,

Blood Products: Collection, Processing and Storage of whole human blood,dried human plasma, plasmaSubstituties.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles andApplications of Recombinant DNA: ASM Press WashingtonD.C.
2. RA Goldshyet. al., :KubyImmunology.
3. J.W. Goding: MonoclonalAntibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology byRoyal Society ofChemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland,Ohio.

6. S.B. Primrose: Molecular Biotechnology (Second Edition) BlackwellScientific Publication.

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentationtechnology, 2nd edition, Aditya books Ltd., NewDelhi.

BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

Scope:

This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries. It deals with the important aspects likecGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives:

Upon completion of the course student shall be able to:

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. 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, Introduction to Regulatory agencies like CDSCO, USFDA, WHO, PIC/S.

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

ICH Guidelines: Brief overview of QSEM, ICH stability testing guidelines

Quality by design (QbD): Definition, Overview, Elements of QbD program

ISO 9000 & ISO14000: Overview, Benefits and Elements

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 of Packaging material: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices &Role of CPCSEA

UNIT – IV **08 Hours**

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

Document maintenance in pharmaceutical industry in brief: Batch Formula Record, Master Formula Record, SOP, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, type of validation.

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, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Relatedmaterials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP‟s – P P Sharma.
6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysisand Quality specification for Pharmaceutical Substances, Excipients and Dosageforms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines142
10. Pharmaceutical Quality Assurance – Sohan Chitlange, Sanjeevani Deshkar, Rupali Kale and Bhupesh Patil

BP607P. MEDICINAL CHEMISTRY-III (Practical) 4 Hours / week

I Preparation of drugs and intermediates (Any six) 10 turns

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol
4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine
7 Paracetamol
8. Methyl salicylate
9. Caprolactum

II Preparation of medicinally important compounds or intermediates by Microwave synthesis (any two) **02 turns**

III Drawing structures and reactions using Chem draw® **01 turn**

IV Determination of physicochemical properties such as logP, clogP, MR, Molecular weight **01 turn**

V Hydrogen bond donors and acceptors for class of drugs using drug design software Drug likeliness screening (Lipinskies RO5) **01 turn**

Recommended Books (Latest Editions)

1. Martindale‟s extra pharmacopoeia.
2. Organic Chemistry by I. L. Finar Vol II

3. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
4. Indian Pharmacopoeia.
5. Text book of practical organic chemistry-A.I.Vogel.
6. Medicinal Chemistry By Ashutosh Kar
7. Practical Pharmaceutical Chemistry: Part II Fourth Edition, A. H. Beckett, J. B. Stenlake.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

Sr. No	**Experiment**
1.	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
2.	Study of effect of drugs on gastrointestinal motility
3.	Effect of agonist and antagonists on guinea pig ileum
4.	Estimation of serum biochemical parameters by using semi- autoanalyser
5.	Effect of saline purgative on frog intestine
6.	Hypoglycemic effect of insulin in rabbit
7.	Test for pyrogens (rabbit method)
8.	Determination of acute oral toxicity (LD50) of a drug from a given data
9.	Determination of acute skin irritation / corrosion of a test substance
10.	Determination of acute eye irritation / corrosion of a test substance
11.	Calculation of pharmacokinetic parameters from a given data
12.	Biostatistics methods in experimental pharmacology(student‟s t test, ANOVA)
13.	Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)
14.	Bioassay of serotonin using rat fundus strip by three point bioassay.
15.	Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
16.	Study of mydriatic and miotic effects on rabbit eye.

*Experiments are demonstrated by simulated experiments/videos

Recommended Books (Latest Editions)

1. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.
3. Goyal RK. Practicals in Pharmacology, BS Shaha Prakashan.
4. Kasture SB. A handbook of experiments in pre-clinical pharmacology, Career Publications.
5. Bikas Medhi, Ajay Prakash. Practical Manual of Experimental and Clinical Pharmacology. Jaypee Publications.

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.
8. B.A.Baviskar, S.L.Deore, Dr.S.S.Khadbadi : Experimental Phytopharmacognosy, Nirali Publication