SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

Syllabus of Final Year B. Pharmacy

2018 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 aninstitution 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/Decemberand 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 beput 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 semestercarries 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 atHSC 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	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements & Nutraceuticals			
BP813PW	Project Work	12/180	-	6
	Total	**24/360**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$^{\$}$/30$^{\#}$**
II	29
III	24
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co-curricular activities	**01***
Total credit points for the program	**207/209$^{\$}$/210$^{\#}$**

** 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.*

10. 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.

10.1 Duties of the Program Committee:

- Periodically reviewing the progress of the classes.
- Discussing the problems concerning curriculum, syllabus and the conduct of classes
- 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.
- Communicating its recommendation to the Head of the institution on academic matters.
- The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessional exam (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.

11.1 End semester examinations

The End Semester Examinations for each theory and practical course through semesters Ito 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

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 I – 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 RemedialMathematics (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 Pharmaceutics I –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 Hrs**	**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**	**8 Hrs**	**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 = 6Hrs	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	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812 ET	Dietary Supplements & Nutraceuticals - Theory							
BP813PW	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 beawarded 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 for10 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

Objective Type Questions (Answer 05 out of 7)	5 x 2 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Total	**30 marks**

For subjects having Non University Examination

Long Answers (Answer 1 out of 2)	1 x 10 = 10
Short Answers (Answer 4 out of 6)	4 x 5 = 20
Total	**30 marks**

Question paper pattern for practical sessional examinations

Synopsis	= 10
Experiments	= 25
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 examination of 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 examination shall be conducted as per the schedulegiven 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

Objective Type Questions (Answer 5 out of 7)	5x 3= 15
Long Answers (Answer 2 out of 4)	2 x 10 = 20
Short Answers (Answer 8 out of 10)	8 x 5 = 40
Total	**75 marks**

For 50 marks paper

Long Answers (Answer 2 out of 3)	2 x 10 = 20
Short Answers (Answer 6 out of 8)	6 x 5 = 30
Total	**50 marks**

For 35 marks paper

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

Question paper pattern for end semester practical examinations

Synopsis	5
Experiments	25
Viva voce	05
Total	**35 marks**

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 sem. 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 haveto 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

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

The learners who were admitted to S.Y B. Pharm. of 2015 pattern during the academicyear 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.

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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 C_1, C_2, C_3, C_4 and C_5 and the student's grade points in these courses are G_1, G_2, G_3, G_4 and G_5, respectively, and then students

SGPA is equal to:

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

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 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:

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

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 status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.

The CGPA is calculated as:

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

where C_1, C_2, C_3…. 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)**

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

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) onthe practice school he/she attended (not more than 25 pages). Along with the exams of semesterVII, 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 beawarded.

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 degreeduring 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.

FINAL YEAR B. PHARM

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. Upon completion of the course the student shall be able to
2. Illustrate the interaction of matter with electromagnetic radiations and justify its applications in drug analysis
3. Classify the chromatographic separation methods and choose appropriate technique for analysis of drugs.
4. Design methods for performing quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Introduction to 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**

FTIR 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, FTIR instrument, sample handling attachments –DRS and ATR and applications

Flame Photometry

Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy

Principle, interferences, instrumentation and Applications

Nepheloturbidimetry

Introduction

UNIT –III **10 Hours**

Introduction to chromatography -

Adsorption and partition column chromatography:

Methodology, advantages, disadvantages and applications.

Paper chromatography:

Introduction, methodology, development techniques, advantages, disadvantages and applications

Thin layer chromatography:

Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

HPTLC:

Introduction, Instrumentation and applications

UNIT –IV **08 Hours**

Theory of Chromatography

Plate theory, Rate theory, System suitability parameters

Gas chromatography

Introduction, theory, instrumentation, 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

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.

BP702T INDUSTRIAL PHARMACY -II (Theory) **45 Hours**

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

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, MoU's, 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 FDASubmissions, Management of Clinical Studies.

UNIT-IV **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.

UNIT-V **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

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 athttp://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs a Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc.available at http.//www.cgmp.com/ra.htm.

BP703T 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 counseling 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.

Course Content:

UNIT-I **10 Hours**

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.

Hospital pharmacy and its organization

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

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.

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**

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.

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.

Therapeutic drug monitoring

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

Medication adherence

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

Patient medication history interview

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

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT-III **10 Hours**

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.

Drug information services

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

Patient counseling

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

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.

Prescribed medication order and communication skills

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

UNIT-IV **08 Hours**

Budget preparation and implementation Budget preparation and implementation

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.

Over the counter (OTC) sales

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

UNIT-V **07 Hours**

Drug store management and inventory control

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

Investigational use of drugs

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

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)

BP704T NOVEL DRUG DELIVERY SYSTEM (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 implants and osmotic pump.

UNIT-III **10 Hours**

Transdermal Drug Delivery Systems:

Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.

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)

BP705P INSTRUMENTAL METHODS OF ANALYSIS (Practical) **04 Hours/ Week**

1. Weights and measures and pharmacopoeia in analysis
2. Determination of absorption maxima and effect of solvent on absorption maxima of organic compounds
3. Assay of Drug product as per IP (Assay of Paracetamol tablet by UV-Spectrophotometry)
4. Assay of Drug product by Calibration curve method
5. Assay of any drug/drug product by colorimetry.
6. Simultaneous estimation of multicomponent formulation by UV spectroscopy (SE/Q analysis)
7. Estimation of drug by fluorimetry
8. Study of quenching of fluorescence
9. Determination of sodium and potassium by flame photometry
10. Separation of amino acids by paper chromatography
11. Separation of sugars by thin layer chromatography
12. Separation of plant pigments by column chromatography
13. Demonstration of HPLC instrument
14. Demonstration of FTIR instrument
15. Interpretation of spectra of organic compounds by IR spectroscopy as per pharmacopoeia

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. HPLC by P.D.Sethi
11. HPTLC by P.D. Sethi
12. Spectrophotometric identification of Organic Compounds by Silverstein

BP706PS PRACTICE SCHOOL* **150 Hours**

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.

SEMESTER – VIII

BP801T BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory) 45 Hours

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

1. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of
2. Experiment)
3. Know the various statistical techniques to solve statistical problems
4. 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 **08 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 **07 Hours**

Design and Analysis of experiments:

Factorial Design:

Definition, 2^2, 2^3 design. Advantage of factorial design

Response Surface methodology:

Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP802T SOCIAL AND PREVENTIVE PHARMACY (Theory) 45 Hours

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health 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:

1. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
2. Develop a critical way of thinking based on current healthcare development.
3. Evaluate alternative ways of solving problems related to health 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.

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 PHARMACEUTICAL MARKETING (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.

Objective:

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

Course Content:

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 behaviour; industrial buying behaviour.

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 labelling 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 **08 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 **07 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

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

BP804ET PHARMACEUTICAL REGULATORY SCIENCE (Theory) 45 Hours

Scope:

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

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 **10 Hours**

New Drug Discovery and development

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

UNIT-II **10 Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). 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 **10 Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

UNIT-IV **08 Hours**

Clinical trials

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

UNIT-V **07 Hours**

Regulatory Concepts

Basic 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

BP805ET 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. Understand importance of drug safety monitoring.
2. Explain History, development, National and international scenario of pharmacovigilance & comprehend dictionaries, coding and terminologies used in pharmacovigilance
3. Understand detection and assessment of new adverse drug reactions, Adverse drug reaction reporting systems and communication in pharmacovigilance, Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning. CIOMS requirements for ADR reporting
4. Comprehend methods of safety data during pre-clinical, clinical and post approval phases of drugs' life cycle.
5. Write 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 Nonproprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

Basic drug information resources, Specialized resources for ADRs

Establishing pharmacovigilance programme

Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (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 **08 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 **07 Hours**

Pharmacogenomics of adverse drug reaction

Genetics related ADR with example focusing PK parameters.

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

BP806ET **QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)** **45 Hours**

Scope:

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

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

Course Content

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 edition):

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.

BP807ET 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

1. Understand the design and discovery of lead molecules
2. Classify the role of drug design tools for drug discovery process
3. Understand and analyse concepts of QSAR and docking
4. Analyse and apply various strategies to develop new drug like molecules.
5. Use various molecular modeling software to design new drug molecule

Course Content

UNIT-I **14 Hours**

Introduction to Drug Discovery and Development -

Stages of drug discovery and development,

Lead discovery approaches - 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.

Introduction to Ligand based and Structure Based DD

Analog Based Drug Design - Bioisosterism, Bioisosteric replacement

Case studies -

Ligand based (Design of inhibitors of tubulin polymerization eg. Colchicine), Structure based (Design of HMG-CoA reductase inhibitors. eg. Statins) and Analog based DD (Design of H2 histamine antagonist eg. Cimetidine)

UNIT- II **10 Hours**

Introduction to Computational tools

Molecular Modeling -

Introduction to molecular mechanics and quantum mechanics.

Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Molecular docking -

Rigid docking, flexible docking, manual docking, Docking based screening.

UNIT- III **14 Hours**

Quantitative Structure Activity Relationship (QSAR) and Pharmacophore modeling

Introduction -

SAR versus QSAR, History and development of QSAR, Types of physicochemical

parameters

2D QSAR -

Experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch's analysis, Free Wilson analysis

3D-QSAR approaches -

COMFA and COMSIA.

Pharmacophore modeling

Drug likeness screening, Concept of Pharmacophore mapping and Pharmacophore based screening

UNIT- IV **07 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemo informatics

Databases -

Chemical database, Natural compound database, Drug like compound database , Drug bank

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, NewYork.
3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, NewYork.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Korolkovas A, BurckhalterJH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, NewYork.
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" WrightBoston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
10. D. J. Triggle, John Bodenhan Taylor, Peter Kennewell,ComprehensiveMedicinal Chemistry, Volume I-VIII : Germany: Elsevier Science.

BP808ET CELL AND MOLECULAR BIOLOGY (Theory) **45 Hours**

Scope:

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

Objectives:

Upon completion of the subject student shall be able to:

1. Summarize cell and molecular biology history, cellular functioning and Composition & describe the chemical foundations of cell biology.
2. Describe cellular membrane structure and function properties and functions of DNA, Cell Cycle.
3. Describe basic molecular genetics mechanisms.
4. Understand the cell signaling pathways with their regulations and role in disease process.

Course contents

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

DNA and the Flow of Molecular Information, DNA Functioning, DNA and RNA,
Types of RNA, Transcription and Translation

UNIT-III **10 Hours**

Proteins: Defined and Amino Acids, Protein Structure, Regularities in Protein Pathways, Cellular Processes, Positive Control and significance of Protein Synthesis

UNIT-IV **08 Hours**

Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis,
Mitosis and Meiosis, Cellular Activities and Checkpoints Clinical phase, Post approval phase (PMS)

UNIT-V **07 Hours**

Cell Signals: Introduction, Receptors for Cell Signals, Signaling Pathways: Overview, Misregulation of Signaling Pathways, 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. Rose: Industrial Microbiology.
5. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
6. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution. Peppler: Microbial Technology.
7. Edward: Fundamentals of Microbiology.
8. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
9. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly Company
10. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and
11. Applications of Recombinant DNA: ASM Press Washington D.C. RA Goldshy et. al., : Kuby Immunology.

BP809ET COSMETIC SCIENCE (Theory) **45 Hours**

Scope:

This course is designed to impart fundamental knowledge of cosmetic and cosmeceutical products & their formulation studies.

Objectives:

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

1. Understand the concepts of cosmetics; anatomy of skin v/s hair, general excipients used in cosmetics.
2. Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals& cosmeceuticals agents
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course contents

UNIT-I **10 Hours**

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 cosmeceuticals.

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-IV **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.

BP810ET EXPERIMENTAL PHARMACOLOGY (Theory) **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,

1. Understand the applications of various commonly used laboratory animals.
2. Demonstrate the various screening methods used in preclinical research.
3. Comprehend and demonstrate the importance of biostatistics and research methodology.
4. Design and execute a research hypothesis independently.

Course contents

UNIT-I **10 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 **10 Hours**

Preclinical screening models:

for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

UNIT-IV **08 Hours**

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

UNIT-V **07 Hours**

Research methodology and Bio-statistics.

Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students‘t’ test and One-way ANOVA. Graphical representation of data

Recommended Books (latest edition):

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

BP811ET ADVANCED INSTRUMENTATION TECHNIQUES (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 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

1. Express the principle of the advanced instruments used and justify its applications in drug analysis
2. Understand the principles of analytical techniques and its application in analysis of drugs
3. Explain the importance and methods for the calibration of various analytical instruments
4. Formulate and justify techniques for the analysis of drugs using various analytical instruments.

Course contents

UNIT-I **14 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of ^{1}H-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

^{13}C-NMR- Introduction to ^{13}C-NMR spectroscopy

Mass Spectrometry

Principles, , Ionization techniques –Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, Fragmentation, applications

Simple structural elucidation problems

UNIT-II **07 Hours**

Thermal Methods of Analysis

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

UNIT-III **10 Hours**

Electrophoresis

Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel,

capillary electrophoresis, applications

X-Ray Diffraction Methods

Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, and applications.

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, HPLC.

UNIT-IV **06 Hours**

Radioimmuno assay

Principle, different methods, Importance, various components, Limitation and Applications of Radioimmuno assay

Extraction techniques

General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.

UNIT-V **08 Hours**

Hyphenated techniques

Introduction to hyphenated techniques and types of techniques

Details of LC-MS, GC-MS, HPTLC-MS, MS/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 spectroscopy by William Kemp
7. Quantitative Analysis of Drugs by D. C. Garrett
8. Spectrophotometric identification of Organic Compounds by Silverstein
9. Introduction to Spectroscopy by Donald Pavia
10. Spectroscopy of Organic compounds by P.S.Kalsi
11. Introduction to Spectroscopy by Donald Pavia
12. Spectroscopy of Organic compounds by P.S.Kalsi

BP812ET DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory) 45 Hours

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. Recognize the components in dietary supplements and the application.
4. Acquaint with the regulatory and commercial aspects of dietary supplements including health claims.

Course content:

UNIT-I **07 Hours**

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.

Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

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

Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin

Sulfides: Diallyl sulfides, Allyl trisulfide.

Polyphenolics: Reservetrol

Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans

Tocopherols

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**

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.

Dietary fibres and complex carbohydrates as functional food ingredients.

UNIT-IV **10 Hours**

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.

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

Functional foods for chronic disease prevention.

UNIT-IV **06 Hours**

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

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

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: BS Publication.
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

BP813PW 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.