Sanjay Ghodawat University

Kolhapur

Established under section 2(f) of UGC act 1956
Sanjay Ghodawat University Act XL of 2017 of Govt. of Maharashtra
Approved by PCI, COA & AICTE

Empowering Lives Globally!

School of Pharmaceutical Science

T. Y. B. Pharm.

Curriculum

Academic Year 2022-23

Revised Ordinance Governing Bachelor of Pharmacy (B.Pharm.) Degree Course Pharmacy Council of India.

Rules & Syllabus for the Bachelor of Pharmacy (T. Y. B. Pharm) Course

Index

SANJAY GHODAWAT UNIVERSITY KOLHAPUR

Sanjay Ghodawat University (SGU) is established in the Academic Year 2017-18, as a State Private University under Govt. of Maharashtra Act No. XL of 2017 dated 3rd May 2017, with the approval of the UGC and the State Government. "For the true measure of giving is giving without measure." Spread across 150 Acres, Sou. Sushila Danchand Ghodawat Charitable Trust's Sanjay Ghodawat University (SGU) is situated in a serene atmosphere amidst idyllic hills and lush green meadows to study in harmony with Nature. The Institution aspires to run along the lines of best-in-the-world education and become a world-class institution where the teaching-learning process gets a far deeper meaning. SGUalways stands as the guiding star of brilliance, quality, and deliverance beyond expectations. Innovativeness and Creativity are the hallmarks of a genius enterprise and SGU stands to be a stage where these qualities would be nurtured, encouraged, andblossomed. The genius is incomplete without the sense of social responsibility and SGU's ultimate goal remains the development of an attitude of gratitude that freely gives back without expectations. The Sanjay Ghodawat University stands as a beacon of light to guidethe younger generation of the day on the right path to fulfillment in career and life. The USP of the University is its research-based curriculum and academically-oriented teaching staff. The world-class ambiance and infrastructure help the students to easily accommodate themselves in an environment that is conducive to the teaching-learning process. Hands-on experience, challenge-based case studies, maximum participation of students in the classroom, use of modern digital technology, smart classrooms, solution-oriented thinking promotion, stress on research and innovation, international tie-ups, choice-based credit system for flexibility in choosing areas of interest, etc. are some of the features of the University. The university will help students develop as unique individual-to be educated as a whole person, intellectually, emotionally, socially, ethically, and spiritually. The educational program designs are worked out meticulously in line with best in class universities with a special focus on:

- Flexible Choice Based Credit System
- OBE-Outcome Based Education System
- Experiential Learning
- Project-Based Learning
- Case-Based Learning
- Training need analysis based on Performance Appraisal System
- Active Learning tools for effective delivery
- Mentoring / Proctorship
- Online learning /Self-learning platforms
- Flipped Classroom concept
- Effective Student Feedback Mechanism

SCHOOL OF PHARMACEUTICAL SCIENCES

Vision

To be recognized as the to pharmaceutical education provider in the region by imparting high level of academic and research outcomes which are aligned with better regional and global needs.

Mission

- **M 1 – Outcomes based quality education:**

  To provide outcomes based quality education to produce competent and ethical pharmacy professionals to face emerging challenges of the globalized pharmaceutical industry.

- **M2-Research and lifelong learning:**

  To establish the strong industry connections, develop research profile and lifelong learning to optimize adequate care and healthcare delivery.

- **M3-Inculcating values and ethics:**

  To inculcate the professional ethics and human values in pharmacy professionals and developing them to serve the healthcare needs of society.

- **M4- Fostering leadership qualities:**

  To provide conducive environment to boost the practical skills, entrepreneur traits and leadership qualities in budding pharmacists to stay ahead in the competitive world.

CORE VALUES

- Integrity
- Transparency
- Accountability
- Equality
- Empathy
- Stewardship

QUALITY POLICY

Sanjay Ghodawat University is committed to establish high standards in value-basedquality education to enhance and nurture young minds to excel in their chosen profession and develop into socially responsible citizens through resourceful collaboration, innovationand research

OUTCOME BASED EDUCATION (OBE) MODEL

Sanjay Ghodawat University (SGU) has implemented the OBE model of education, which is a learner cantered approach. SGU has witnessed a sea change in the entire academic system with the implementation of all three components of OBE – Design, Delivery, and Assessment. The SGU model of autonomy focuses on experiential learning which beliefs in learning by doing. This is achieved through hands-on experience, industrial assignments, mini-projects, and live problem solving and collaboration with industries.

SGU is set into dynamics of transformation and witnessing a shift in focus from teaching to learning and the entire academic system of SGU is designed to provide multiple learning opportunities for students to acquire and demonstrate the Knowledge, Skills, and Attitudes (KSA) for rewarding career. The Vision and Mission of the Management, the contribution from eminent BOG members and knowledgeable members of Academic Council and Board of Studies, the motivation and drive of the Director, the relentless efforts of the fellow Deans and Head of Departments and all teaching and non-teaching staff along witha commitment to the learning of students made it possible to successfully transform the institute and stand out to carve a niche for itself as an Institute of repute.

OBE is an approach to curriculum design and teaching that focuses on what students should be able to do (attained) at the end of the course/ program. Outcome-based education (OBE) is a student-centered instruction model that focuses on measuring student performance through outcomes. Outcomes include knowledge, skills, and attitudes (KSA). Its focus remains on the evaluation of outcomes of the program by stating the knowledge, skill and behavior a graduate is expected to attain upon completion of a program and after 4 – 5 years of graduation. In the OBE model, the required knowledge and skill sets for a particular degree are predetermined and the students are evaluated for all the required parameters (Outcomes) during the course of the program.

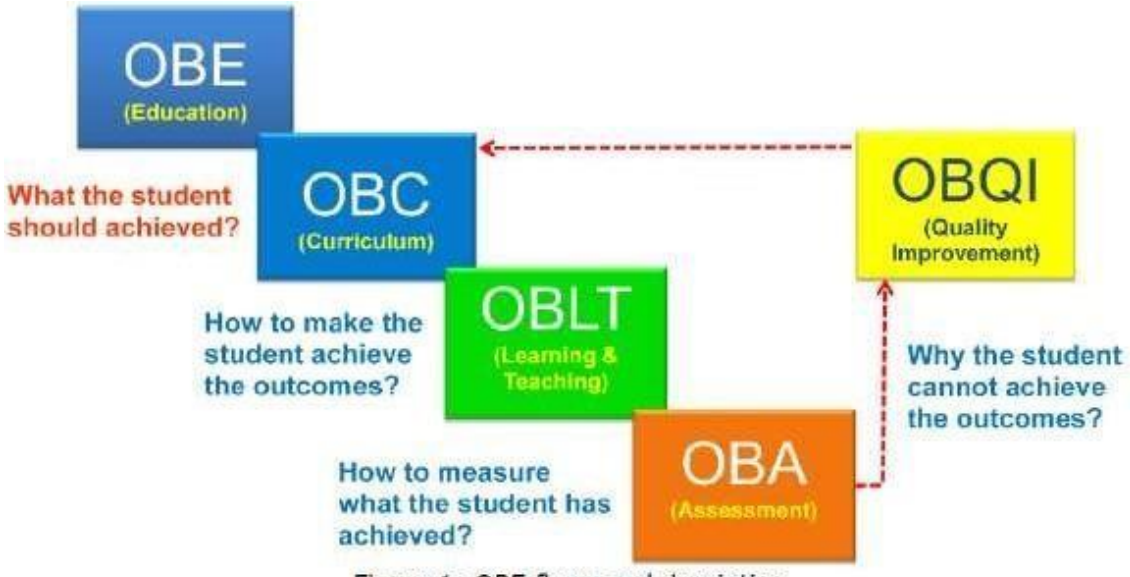
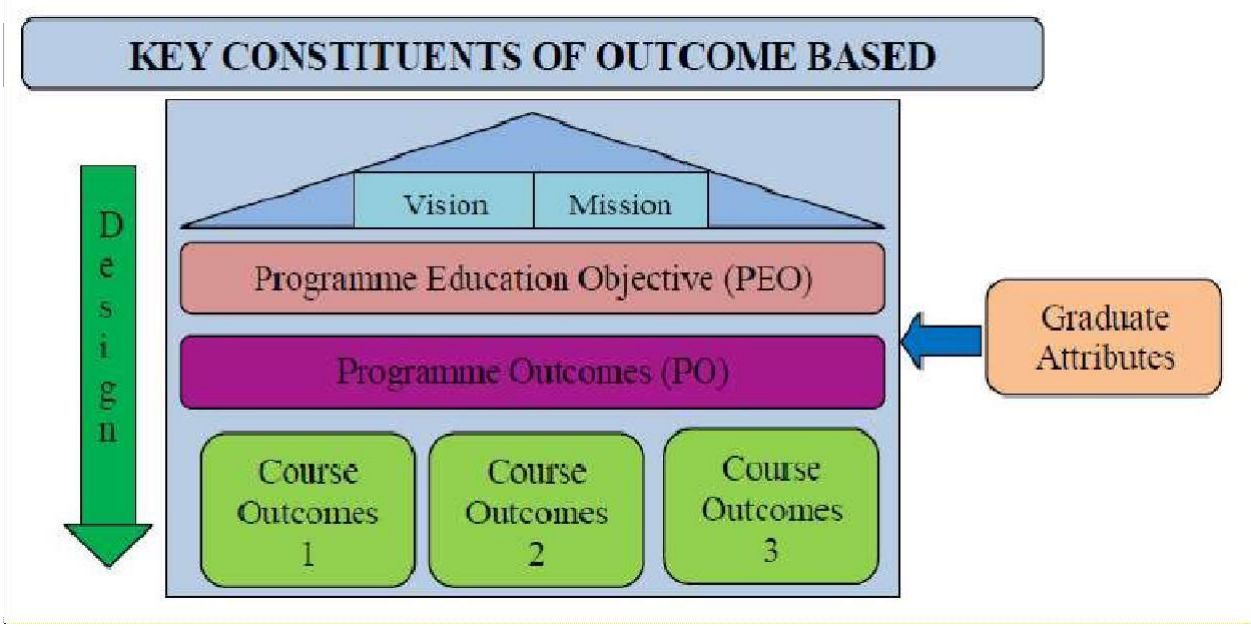


Figure 1: OBE flows and desciption

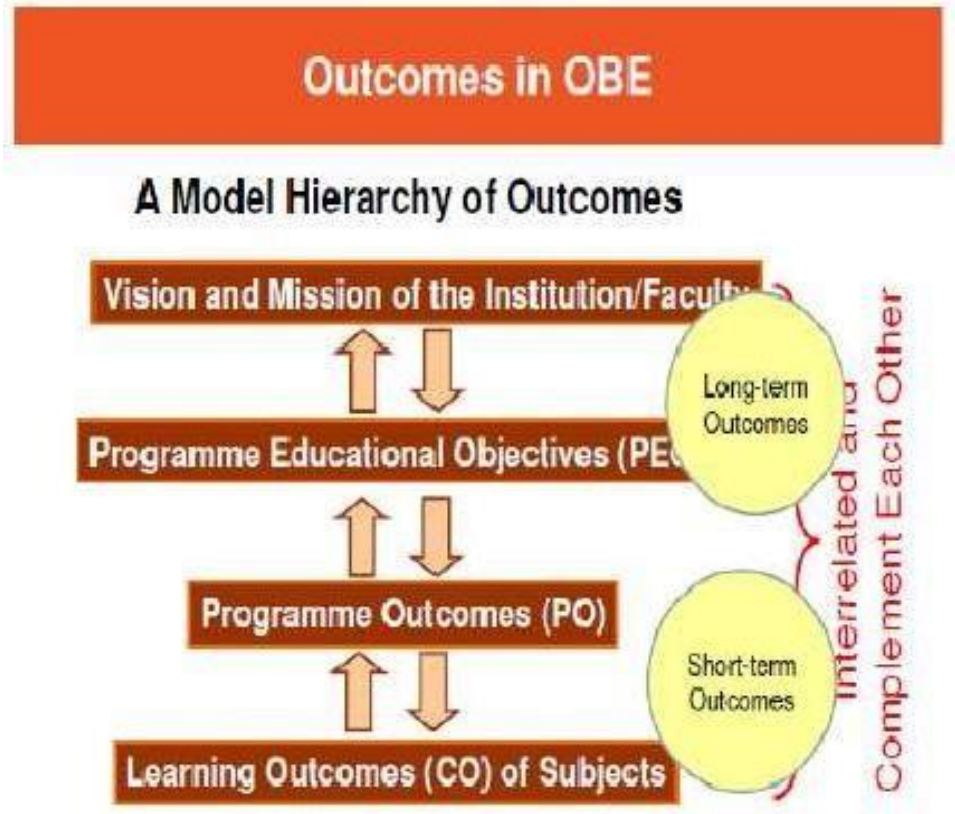


The OBE model measures the progress of the graduate in three parameters, which are

- Program Educational Objectives (PEO)
- Program Outcomes (PO)
- Course Outcomes (CO)

Program Educational Objectives (PEO) are broad statements that describe the career and professional accomplishments that the program is preparing the graduates to achieve.PEO's are measured 4-5 years after graduation. Program outcomes are narrower statementsthat describe what students are expected to know and be able to do by the time ofgraduation. They must reflect the Graduate attributes. Course outcomes are the measurable parameters that evaluate each student's performance for each course that the student undertakes every semester.

The various assessment tools for measuring Course Outcomes include Tests and End Semester Examinations, Tutorials, Assignments, Project work, Labs, Presentations, Employer/Alumni Feedback, etc, These course outcomes are mapped to Graduate attributes and Program outcomes based on relevance. This evaluation pattern helps Institutions to measure the Program Outcome. The Program Educational Objective ismeasure through Employer satisfaction survey (Yearly), Alumni survey (Yearly), Placement records, and higher education records.



Special Features of OBE

- OBE is an educational process that focuses on what students can do or the qualities they should develop after they are taught.
- OBE involves the restructuring of curriculum, assessment, and reporting practices in education to reflect the achievement of high order learning and mastery rather than accumulation of course credits.
- Both structures and curricula are designed to achieve those capabilities or qualities.
- Discourages traditional education approaches based on direct instruction of facts and standard methods.
- It requires that the students demonstrate that they have learned the required skills and content.

CHAPTER-I:

REGULATIONS

1. Short Title and Commencement

These regulations shall be called "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 the Pharmacy Council of India.

2. Minimum qualification for admission

First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Associationof 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.

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

The medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout the semester carries a credit of2.

Sr. No	Component	Hours	Credit
	B. Pharm (Direct)		
1	Theory	1hr	1
2	Tutorial	1hr	1
3	Practical	Hr	½ per Hr
	Lateral Entry		
	D. Pharm		52
	Remedial Course Communication Skills(Theory and Practical) and 'Computer Applications in Pharmacy)		7

Minimum credit requirements

The minimum credit points required for the award of 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. Pharmprogram. Such students shall take up additional remedial courses of 'CommunicationSkills' (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, andpractical course in any semester shall not be less than that shown in Table – I to VIII.

Table I: Course of study for Semester-I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology-I (Theory)	3	1	**4**
BP102T	Pharmaceutical Analysis-I (Theory)	3	1	**4**
BP103T	Pharmaceutics-I (Theory)	3	1	**4**
BP104T	Pharmaceutical Inorganic Chemistry (Theory)	3	1	**4**
BP105T	Communication skills (Theory) *	2	-	**2**
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics (Theory)*	2	-	**2**
BP107P	Human Anatomy and Physiology (Practical)	4	-	**2**
BP108P	Pharmaceutical Analysis-I (Practical)	4	-	**2**
BP109P	Pharmaceutics-I (Practical)	4	-	**2**
BP110P	Pharmaceutical Inorganic Chemistry (Practical)	4	-	**2**
BP111P	Communication skills (Practical)*	2	-	**1**
BP112RBP	Remedial Biology (Practical)*	2	-	**1**
	Total	32/34$^{\$}$/36$^{\#}$	4	27/29$^{\$}$/30$^{\#}$

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

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

* Non-University Examination (NUE)

Table II: Course of study for Semester-II

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

***** Non-University Examination (NUE)

Table III: Course of study for Semester-III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry-II (Theory)	3	1	**4**
BP302T	Physical Pharmaceutics-I (Theory)	3	1	**4**
BP303T	Pharmaceutical Microbiology (Theory)	3	1	**4**
BP304T	Pharmaceutical Engineering (Theory)	3	1	**4**
BP305P	Pharmaceutical Organic Chemistry-II (Practical)	4	-	**2**
BP306P	Physical Pharmaceutics-I (Practical)	4	-	**2**
BP307P	Pharmaceutical Microbiology (Practical)	4	-	**2**
BP308P	Pharmaceutical Engineering (Practical)	4	-	**2**
	Total	28	4	24

Table IV: Course of study for Semester-IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry-III (Theory)	3	1	4
BP402T	Medicinal Chemistry-I (Theory)	3	1	4
BP403T	Physical Pharmaceutics-II (Theory)	3	1	4
BP404T	Pharmacology-I (Theory)	3	1	4
BP405T	Pharmacognosy and Phytochemistry-I (Theory)	3	1	4
BP406P	Medicinal Chemistry-I (Practical)	4	-	2
BP407P	Physical Pharmaceutics-II (Practical)	4		2
BP408P	Pharmacology-I (Practical)	4	-	2
BP409P	Pharmacognosy and Phytochemistry-I (Practical)	4	-	2
BP410T	Constitution of India and Professional Ethics- (T)			
	Total	31	5	28

Table V: Course of study for Semester-V

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

Table VI: Course of study for Semester-VI

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

Table VII: Course of study for Semester-VII

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

***** Non-University Examination (NUE)

Table VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	**4**
BP802T	Social and Preventive Pharmacy	3	1	**4**
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	**4 + 4 = 8**
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization 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 and Nutraceuticals			
BP813PW	Project Work	12	-	**6**
	Total	24	4	22

Table IX: Semester wise credits distribution

Semester	Credit Points
I	27/29[$]/30[#]
II	29
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	210/212[$]/213[#]+ (01*)

***** 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

1. The B. Pharm program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B. Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.
3. Duties of the program committee:
   - i. Periodically reviewing the progress of the classes.
   - ii. Discussing the problems concerning curriculum, syllabus, and the conduct of classes.
   - iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   - iv. Communicating its recommendation to the Head of the institution on academic matters.
   - v. The Program Committee shall meet at least thrice in a semester preferably at the end of each 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.

End semester examinations

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

Table X: - SEMESTER – V

Course Code	Course Title	L	T	P	C	Component (Marks)	Exam	WT		Passing Min. (%)
BP501T	Medicinal Chemistry-II (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP502T	Industrial Pharmacy-I (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP503T	Pharmacology-II (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP504T	Pharmacognosy and Phytochemistry-II (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP505T	Pharmaceutical Jurisprudence (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP506P	Industrial Pharmacy-I (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	
BP507P	Pharmacology-II (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	
BP508P	Pharmacognosy and Phytochemistry-II (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	
Total		**15**	**5**	**12**	**26**				**650**	
		32								

Table X: SEMESTER-VI

Course Code	Course Title	L	T	P	C	Component (Marks)	Exam	WT		Passing Min (%)
BP601T	Medicinal Chemistry-III (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP602T	Pharmacology-III (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP603T	Herbal Drug Technology (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP604T	Biopharmaceutics and Pharmacokinetics (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP605T	Pharmaceutical Biotechnology (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP606T	Pharmaceutical Quality Assurance (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP607P	Medicinal Chemistry-III (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-I	10	10	
							Sessional-II	10		
							ESE		35	
BP608P	Pharmacology-III (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-I	10	10	
							Sessional-II	10		
							ESE		35	
BP609P	Herbal Drug Technology (Practical)	-	-	4	2	Practical (50)	CA	05	05	50
							Sessional-I	10	10	
							Sessional-II	10		
							ESE		35	
Total		**18**	**6**	**12**	**30**				**750**	
		36								

Internal assessment: Continuous mode

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

Table XI: Scheme for awarding internal assessment: Continuous mode

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

Table XII: Guidelines for the allotment of marks for attendance

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

Sessional Exams

Two sessional exams shall be conducted for each theory/practical course as per the schedule fixed by the college(s). The scheme of the 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.

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

Question paper pattern for theory Sessional examinations

For subjects having University examination

I	Multiple Choice Questions (MCQs) (10 x 1) OR Objective Type Questions (5 x 2) (Answer all questions)	10 x 1 = 10 05 x 2 = 10
II	Long Answer Questions (Answer 1 out of 2)	01 x 10 = 10
III	Short Answers (Answer 2 out of 3)	02 x 05 = 10
	Total	**30 marks**

For subjects having Non University Examination

I	Long Answers (Answer 1 out of 2)	1 x 10 = 10
II	Short Answers (Answer 4 outof6)	4 x 5 = 20
	Total	**30 marks**

Question paper pattern for practical sessional examinations

I	Synopsis	10
II	Experiments Major experiment Minor experiment	 15 10
III	Viva voce	05
	Total	**40 marks**

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting a 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 the 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 marksfor 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 to the 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 the next end semester theoryexaminations.

15. Re-examination of end semester examinations

Reexamination of the end semester examination shall be conducted as per the schedule given in Table XIII. The exact dates of examinations shall be notified from time to time.

Table XIII: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations

For 75 marks paper		
I	Multiple Choice Questions (MCQs) OR Objective Type Questions (10 x 2) (Answer all the questions)	20 x 1= 20 OR 10 x 2= 20
II	Long Answers (Answer 2 out of 3)	2 x 10 = 20
III	Short Answers (Answer 7 out of 9)	7 x 5 = 35
	Total	**75 marks**
For 50 marks paper		
I.	Long Answers (Answer 2 out of 3)	2 x 10 = 20
II.	Short Answers (Answer 6 out of 8)	6 x 05 = 30
	Total	**50 marks**
For 35 marks paper		
I.	Long Answers (Answer 1 out of 2)	1 x 10 =10
II.	Short Answers (Answer 5 out of 7)	5 x 5 =25
	Total	**35 marks**
Question paper pattern for end semester practical examinations		
I.	Synopsis	5
	Experiments	25
	Viva voce	5
	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 the V semester until all the courses of I and II semesters are successfully completed.

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

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

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

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

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

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in26.

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.

17. Grading of performances

Letter grades and grade points allocations:

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

Table XIV: Letter grades and grade points equivalent to Percentage of marks and performances.

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

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

18. The Semester grade point average (SGPA)

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

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

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

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in the 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 passing grade on subsequent examination(s) the GPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

where $C_1, C_2, C_3, \ldots$ is the total number of credits for the semester I, II, III,…. and $S_1, S_2, S_3, \ldots$is the SGPA of the 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 to any one of the elective subjects opted by the student in Semester-VIII. The project shall be carried out in a group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluatedin 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		15Marks
Methodology adopted		20Marks
Results and Discussions		20Marks
Conclusions and Outcomes		20Marks
	Total	**75Marks**

Evaluation of Presentation:

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

Explanation: The 75 marks assigned to the dissertation book shall be the same for all the students in a group. However, the 75 marks assigned for the 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 the 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 the satisfactory report of such work and certificate duly

signed by the authority of training organization to the head of the institute.

23. Practice School

In the semester-VII, every candidate shall undergo practice school for a **period of 150 hours evenly distributed throughout the semester**. The student shall opt for 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 the college level and grade point shall be awarded.

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of the final CGPA. However, candidates who fail in one or more courses during the B. Pharm program shall not be eligible for the award of ranks. Moreover, the candidates should have completed the B. Pharm program in the 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 the award of degree during the ensuing convocation.

26. Duration for completion of the program of study

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

27. Re-admission after a break of study

The candidate who seeks re-admission to the program after a break of study has to get 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.

28. Audit Course:

A student may have to register for an audit course in a D. Pharm Part-I or Part-II which could be an institute requirement or department requirement.

An audit course may include either a) a regular course required to be done as perstructure or required as a pre-requisite of any higher-level course or b) the programs like practical training, industry visits, societal activities, etc

Audit course shall not carry any credits but shall be reflected in Grade Card as "PP"/"NP" depending upon the satisfactory performance in the semester evaluation as per the course curriculum structure.

29. Facilitation to Students:

Faculty Advisor:

On joining the institute, a student or a group of students shall be assigned to a faculty advisor who shall be a mentor for a student throughout his/her tenure in the institute. A student shall be expected to consult the faculty advisor on any matter relating to his/her academic performance and the courses he/she may take in various semesters/summer terms. A faculty advisor shall be the person to whom the parents/guardians should contact for performance-related issues of their ward.

The role of the Faculty Adviser is outlined below:

a) Guide the students about the rules and regulations governing the courses of study for a particular degree.

b) Advise the students for registering courses as per the curriculum given. For this purpose, the Faculty Adviser has to discuss with the student his/her academic performance during the previous semester and then decide the number and nature of the courses for which He / She can register during the semester as per the curriculum.

c) Approve the registration of the students.

d) Advice students to overload/drop one or more courses/activities based on her/his academic performance as per the prescribed rules.

e) At the end of the first semester/year, the Faculty Adviser may even advise a reduced load program for a poorly performing student.

f) Pay special attention to weak students and carefully monitor the performance of students recommended for the slow track option.

g) Advice students for Course Adjustment/Dropping of courses during the Semester within the stipulated time frame given in the Academic calendar.

h) Advice students seeking semester drop either during the ongoing semester or before the commencement of the semester. FA has to ensure strict compliance of rules and regulations laid down for this purpose. Recommend the cases to the appropriate authorities for consideration.

i) Make a revised plan of study for weak/bright students based on their semester-wise performance.

j) Suggest modalities for course/credit requirements for the students recommended for the exchange program.

k) Guidance and liaison with parents of students for their performance.

l) To ensure that students are not permitted to reregister for courses, which they have already passed.

m) Inform students that any academic activity (course/Lab/seminar/project/non credit requirement etc.) undergone without proper registration will not be counted towards the requirements of his/her degree.

n) Strictly warn students that if she/he fails to register during any semester without prior approval, his/her studentship is liable to be canceled.

o) Keep the students updated about the Academic Administration of the University.

29. 2. Helping Weaker Students:

A student with backlog/s should continuously seek help from his/her faculty advisor, Head of the Department and the Dean of respective schools. Additionally, he/she must also be in constant touch with his/her parents/local guardians for keeping them informed about academic performance. The university also shall communicate to the parents/guardians of such students at least once during each semester regarding his/her performance in various tests and examinations and also about his/her attendance. It shall be expected that the parents/guardians to keep constant touch with the concerned faculty advisor or Head of the Department, and if necessary - the Dean of the respective school.

30. Discipline and Conduct:

- Every student shall be required to observe discipline and decorous behavior both inside and outside the campus and not to indulge in any activity, which shall tend to bring down the prestige of the university.
- Any act of indiscipline of a student reported to the Dean, Student Development, shall be discussed in a Disciplinary Action Committee of the institute. The Committee shall enquire into the charges and recommend suitable punishment ifthe charges are substantiated.
- If a student while studying in the university is found indulging in anti-national activities contrary to the provisions of acts and laws enforced by the Government, he/she shall be liable to be expelled from the institute without any notice.
- If a student is involved in any kind of ragging, the student shall be liable for strict action as per provisions in the Maharashtra anti-ragging act.
- If any statement/information supplied by the student in connection with his/her admission is found to be false/ incorrect at any time, his/ her admission shall be cancelled and he/she shall be expelled from the university, and fees paid shall be forfeited.
- If a student is found guilty of malpractice in examinations, then he/she shall be punished as per the recommendations of the Grievance Redressal Committee (CRC) constituted by the Board of Examinations.
- Every admitted student shall be issued a photo identification (ID) card which must be retained by the student while he/she is registered at Sanjay Ghodawat University Kolhapur. The student must have a valid ID card with him/her while in the University Campus.
- Any student who alters or intentionally mutilates an ID card or who uses the ID card of another student or allows his/her ID card to be used by another, a student shall be subjected to disciplinary action.
- The valid ID card must be presented for identification purposes as and when demanded by authorities. Any student refusing to provide an ID card shall be

subjected to disciplinary action.

- Students should switch off the Mobiles during the Instructional hours and in the academic areas of the university Building, Library, Reading room etc. Strict action will be taken if students do not adhere to this.
- During the conduct of any Tests and Examinations, students must not bring their mobiles. A student in possession of the mobile whether in use or switched off condition will face disciplinary action and will be debarred from appearing for the Test / Examination.

31. Academic Calendar

The academic activities of the institute are regulated by Academic Calendar and are made available to the student's/ faculty members and all other concerned in electronic form or hard copy. It shall be mandatory for students/faculty to strictly adhere to the academic calendar for thecompletion of academic activities.

CHAPTER - II:

SYLLABUS

Semester V

Course code	Name of the course	No. of Hr/wk	Tutorial	Credit points	Internal		ESE
					CA	SE	
BP501T	Medicinal Chemistry-II (T)	3	1	4	10	15	75
BP502T	Industrial Pharmacy-I (T)	3	1	4	10	15	75
BP503T	Pharmacology-II (T)	3	1	4	10	15	75
BP504T	Pharmacognosy and Phytochemistry-II (T)	3	1	4	10	15	75
BP505T	Pharmaceutical Jurisprudence (T)	3	1	4	10	15	75
BP506P	Industrial Pharmacy-I (P)	4	-	2	5	10	35
BP507P	Pharmacology-II (P)	4	-	2	5	10	35
BP508P	Pharmacognosy and Phytochemistry-II (P)	4	-	2	5	10	35
	Total	**27**	**5**	**26**	65	105	480
					= 650		

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min.(%)
BP501T	Medicinal Chemistry – II (Theory)	3	1	-	4	Theory (100 marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Define[1] drug categories along with examples and structures

CLO2. Classify[2] drugs on the basis of their chemical structure (chemical classification)/receptor affinity (pharmacological classification)

CLO3. Illustrate[3] the mode of action, therapeutic value, and adverse effect of the drugs

CLO4. Justify[6] Structure-Activity Relationship (SAR) with respect to their pharmacological activity

CLO5. Give[2] the chemical synthesis of drugs

Course Content:

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

UNIT	Description	Hours
I	**Antihistaminic agents:** Histamine, receptors and their distribution in the human body **H1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium. **H2-antagonists:** Cimetidine*, Famotidine, Ranitidin. **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole,	10

	Rabeprazole, Pantoprazole **Anti-neoplastic agents:** Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate Miscellaneous: Cisplatin, Mitotane	
II	**Anti-anginal:** Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole. Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. **Diuretics:** Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol **Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.	10
III	**Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol. **Anti-hyperlipidemic agents:** Clofibrate, Lovastatin, Cholesteramine and Cholestipol **Coagulant & Anticoagulants:** Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel **Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.	10
IV	**Drugs acting on Endocrine system:** Nomenclature, Stereochemistry and metabolism of steroids **Sex hormones:** Testosterone, Nandralone, Progestrones, Oestriol,	08

	Oestradiol, Oestrione, Diethyl stilbestrol. **Drugs for erectile dysfunction:** Sildenafil, Tadalafil. **Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone **Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	
V	**Antidiabetic agents:** Insulin and its preparations Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acarbose, Voglibose. **Local Anesthetics:** SAR of Local anesthetics **Benzoic Acid derivatives:** Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. **Amino Benzoic acid derivatives**: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate. **Lidocaine/Anilide derivatives:** Lignocaine, Mepivacaine, Prilocaine, Etidocaine. **Miscellaneous:** Phenacaine, Diperodon, Dibucaine.*	07

Recommended Books (Latest Editions)

1. Beale JM. Block J. **Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry**. Lippincott Williams and Wilkins.
2. Williams A.D (Editor). **Foye's Principles of Medicinal Chemistry.** Lippincott Williams and Wilkins.
3. Abraham DJ, Rotella DP. (Editor). **Burger′s Medicinal Chemistry, Drug Discovery, and Development**. Wiley-Blackwell.
4. Smith JH, Williams H. **Smith and Williams' Introduction to the Principles of Drug Design and Action.** CRC Press.
5. Finar IL. **Organic Chemistry, Volume 2: Stereochemistry and the Chemistry Natural Products**. Pearson Education India.
6. Lednicer D**. The Organic Chemistry of Drug Synthesis Vol 1-5.** Wiley-Blackwell**.**
7. Martindale W, Westcott W**. Martindale: The Extra Pharmacopoeia.** Pharmaceutical Press
8. Adejare A**. (Ed) Remington:** The Science and Practice of Pharmacy. Academic Press.
9. Anonymus. **Indian pharmacopoeia.** Ghaziabad: Indian Pharmacopoeia Commission Ministry of Health & Family Welfare, Govt. of India.
10. Furniss BS, Hannaford AJ, Smith Peter WG, Tatchell AR. **Vogel's textbook of Practical Organic Chemistry.** Noida: Pearson Education

BP502T. Industrial Pharmacy-I (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP502T	Industrial Pharmacy-I (Theory)	3	1	-	4	Theory (100 marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, student shall be able to

CLO1. State[1] the meaning of various terminologies, types of dosage forms, and factors affecting the stability of dosage forms.

CLO2. Illustrate[3] the pre-formulation concept, their evaluation parameters, effect on stability and applications in the development of pharmaceutical dosage forms.

CLO3. Discribe[2] the formulation, characteristics, types, manufacturing, quality control and stability of solid dosage forms

CLO4. Illustrate[2] the pharmaceutical aspects of liquid oral, parenteral and ophthalmic preparations.

CLO5. Summarize[2] formulation, manufacturing and evaluation of cosmetic preparations, pharmaceutical aerosols and packaging materials

Course Content

UNIT	Description	Hours
I	**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on the stability of dosage forms	07
II	**Tablets:** a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. **Tablet coating:** Types of coating, coating materials, formulation of	10

	coating composition, methods of coating, equipment employed and defects in coating. c. **Quality control tests:** In process and finished product tests **Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia	
III	**Capsules:** a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules. b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. **Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets.	08
IV	**Parenteral Products:** a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity b. Production procedure, production facilities and controls, aseptic processing c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations.	10
V	**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. **Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. **Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.	10

Recommended Books: (Latest Editions)

1. Liberman HA, Lachman C. **Pharmaceutical Dosage forms: Tablets.** Volume-1, 2, 3, New York: Marcel Dekker
2. Kenneth E. Avis, Leon Lachman, and Herbert A. Lieberman (Ed). **Pharmaceutical dosage forms: Parenteral medications**, vol. 1 and 2. Marcel Dekker, 270 Madison Avenue, New York, NY
3. Liberman HA, Lachman C. **Pharmaceutical Dosage forms**: **Disperse systems**. volume 1, 2, 3. New York: Marcel Dekker.
4. Gilbert S. Banker, Christopher T. Rhodes (Ed). **Modern Pharmaceutics** 3rd Edition. CRC Press
5. Adejare A**. (Ed) Remington: The Science and Practice of Pharmacy**. Academic Press.
6. Khar **RK,** Vyas, SP, **Ahmad FJ, Jain GK.** Lachman Lieberman's The Theory And Practice Of Industrial Pharmacy. **Delhi: CBS Publication.**
7. Aulton ME, Taylor Kevin MG (Editor), **Pharmaceutics: The Science of Dosage Form Design**. Churchill Livingstone.
8. Ansel HC Lea and Febiger. **Introduction to pharmaceutical dosage forms** 5th ed. Philadelphia.
9. Carstensen JT. and Rhodes CT. **Drug Stability: Principles and Practices.** 3rd Edition, Vol. 107, Marcel Dekker Inc, New York, ISBN: 0-8247-0376-6.

BP506P. Industrial Pharmacy-I (Practical)

4 Hours / Week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP506P	Industrial Pharmacy-I (Practical)	-	-	4	2	Practical (50 marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

Upon completion of the course, students shall be able to

CLO1. Interpret[5] the preformulation studies on drugs.

CLO2. Prepare[6] and **evaluate[5]** various oral solid and liquid dosage forms.

CLO3. Prepare[6] and **evaluate[5]** parenteral dosage forms.

CLO4. Prepare[6] and **evaluate[5]** external preparations.

CLO5. Illustrate[2] the evaluation of glass containers as per pharmacopeial specifications**.**

Sr. No.	Description
1.	Preformulation studies on paracetamol/aspirin/or any other drug
2.	Preparation and evaluation of Paracetamol tablets
3.	Preparation and evaluation of Aspirin tablets/Dispersible tablets*
4.	Coating of tablets- film coating of tables/granules
5.	Preparation and evaluation of suspension*(oral antacid)
6.	Preparation and evaluation of Tetracycline capsules
7.	Preparation of Calcium Gluconate injection
8.	Preparation of Ascorbic Acid injection
9.	Quality control test of (as per IP) marketed tablets and capsules
10.	Preparation of Eye drops/ and Eye ointments
11.	Preparation of Creams (cold / vanishing cream)/Gels*
12.	Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Parrott EL. Saski W. **Experimental pharmaceutics.** Burgess Publication.
2. Stoklosa MJ, Ansel HC. **Pharmaceutical Calculations**. Lea &Febiger, Washington Square, Philadelphia.
3. Anonymus. **Indian pharmacopoeia.** Ghaziabad: Indian Pharmacopoeia Commission Ministry of Health & Family Welfare, Govt. of India

BP503T. PHARMACOLOGY-II (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP503T	Pharmacology-II (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional -2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Classify[2] drugs on the basis of therapeutic use, acting on various organ disorders.

CLO2. Illustrate[3] the haemodynamic physiology, electrophysiology, and pharmacology of drugs acting on cardiovascular system along with their adverse effects and interactions.

CLO3. Describe[2] the pharmacology of drugs acting on the urinary system along with their therapeutic value, adverse effects and interactions.

CLO4. Explain[2] the physiology, pharmacology of autocoids, hormones and drugs used in endocrine and inflammatory diseases including their therapeutic value and adverse effects.

CLO5. Illustrate[2] the principles, types and applications of bioassays.

Course Content:

UNIT	Description	Hours
I	**Pharmacology of drugs acting on cardio vascular system** a) Introduction to hemodynamic and electrophysiology of the heart. b) Anti-hypertensive drugs. c) Anti-arrhythmic drugs. d) Anti-anginal drugs. e) Drugs used in congestive heart failure f) Anti-hyperlipidemic drugs	10
II	**1. Pharmacology of drugs acting on cardiovascular system** a) Drug used in the therapy of shock. b) Hematinics, coagulants and anticoagulants. c) Fibrinolytics and anti-platelet drugs d) Plasma volume expanders **2. Pharmacology of drugs acting on urinary system** a) Diuretics b) Anti-diuretics	10

III	**Autocoids and related drugs** a) Introduction to autacoids and classification b) Histamine, 5-HT and their antagonists. c) Prostaglandins, Thromboxanes and Leukotrienes. d) Angiotensin, Bradykinin and Substance P. e) Non-steroidal anti-inflammatory agents f) Anti-gout drugs g) Antirheumatic drugs	10
IV	**Pharmacology of drugs acting on endocrine system** a) Basic concepts in endocrine pharmacology. b) Anterior Pituitary hormones- analogues and their inhibitors. c) Thyroid hormones- analogues and their inhibitors. d) Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. e) Insulin, Oral Hypoglycemic agents and glucagon. f) ACTH and corticosteroids	08
V	**1. Pharmacology of drugs acting on endocrine system** a) Androgens and Anabolic steroids. b) Estrogens, progesterone, and oral contraceptives. c) Drugs acting on the uterus. **2. Bioassay** a) Principles and applications of bioassay. b) Types of bioassay c) Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine, digitalis, histamine and 5-HT	07

Recommended Books: (Latest Editions)

1. Rang HP, Dale MM, Ritter JM, Flower RJ. **Rang and Dale's Pharmacology.** Churchil Livingstone Elsevier
2. Katzung BG, Masters SB, Trevor AJ. **Basic and clinical pharmacology.** Tata McGraw-Hill
3. Marry Anne KK, Lloyd Yee Y, Brian KA, Robbin LC, Joseph G B, Wayne AK, Bradley RW. **Applied Therapeutics, The Clinical use of Drugs.** Lippincott Williams &Wilkins
4. Brunton L, Chabner BA, Knollman B. Goodman and Gilman's, The Pharmacological Basis of Therapeutics. McGraw Hill Education
5. Mycek MJ, Gelnet SB, Perper MM. **Lippincott's Illustrated Reviews- Pharmacology**. Lippincott Williams and Wilkins
6. K.D.Tripathi. **Essentials of Medical Pharmacology.** JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma HL, Sharma KK. **Principles of Pharmacology**. Paras medical publisher.
8. Craig CR, Stitzel RE. **Modern Pharmacology with clinical Applications**. Lippincott Williams and Wilkins

BP507P. PHARMACOLOGY-II (Practical)

4 Hours / week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP507P	Pharmacology-II (Practical)	-	-	4	2	Practical (50 Marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

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

CLO1. Prepare[6] physiological salt solutions for various isolated tissue preparations.

CLO2. Demonstrate[3] isolation of different organs/tissues from the laboratory animals by simulated experiments with DRC*.

CLO3. Evaluate[6] drugs using *in-vitro* bioassay and *in-vivo* pharmacological screening methods.

CLO4. Determine[3] PA2 and PD2 value of drugs.

No.	Description
1.	Introduction to in-vitro pharmacology and physiological salt solutions.
2.	Effect of drugs on isolated frog heart.
3.	Effect of drugs on blood pressure and heart rate of dog.
4.	Study of diuretic activity of drugs using rats/mice.
5.	DRC of acetylcholine using frog rectus abdominis muscle.
6.	Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7.	Bioassay of histamine using guinea pig ileum by matching method.
8.	Bioassay of oxytocin using rat uterine horn by interpolation method.
9.	Bioassay of serotonin using rat fundus strip by three point bioassay.
10.	Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11.	Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12.	Determination of PD2 value using guinea pig ileum.
13.	Effect of spasmogens and spasmolytics using rabbit jejunum.
14.	Anti-inflammatory activity of drugs using carrageenan induced paw-edema
15.	Analgesic activity of drug using central and peripheral methods
	Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books: (Latest Editions)

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

1. Kulkarni SK. **Handbook of experimental pharmacology.** Vallabh Prakashan

BP504T. PHARMACOGNOSY AND PHYTOCHEMISTRY -II (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP504T	Pharmacognosy and Phytochemistry- II (Theory)	3	1	-	4	Theory (100 marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, students shall be able to

CLO1. Describe[2] Basic Metabolic Pathway in higher plants

CLO2. Illustrate[3] pharmacognostic charachterstics and therapeutic uses of Various Secondary Metabolite based upon their biosources, Chemistry and therapeutic uses.

CLO3. Illustrate[3] pharmacognostic evaluation, extraction and isolation of terpenoids, alkaloids, glycosides, resins and tannins*.

CLO4. Describe[2] Industrial and Commercial production of important phytoconstituents

CLO5. Describe[2] Modern methods of extraction for isolation and purification*, and analytical techniques for identification of crude drugs

Course Content:

UNIT	Description	Hours
I	**Metabolic pathways in higher plants and their determination** **a)** A brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. **b)** Study of the utilization of radioactive isotopes in the investigation of Biogenetic studies	07
II	General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of the following secondary metabolites: **a) Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium, **b) Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta **c) Steroids, Cardiac Glycosides & Triterpenoids:** Liquorice, Dioscorea, Digitalis **d) Volatile oils:** Mentha, Clove, Cinnamon, Fennel, Coriander, **e) Tannins:** Catechu, Pterocarpus f) **Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony	14

	g) **Glycosides:** Senna, Aloes, Bitter Almond h) **Iridoids, Other terpenoids &Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids	
III	**Isolation, Identification and Analysis of Phytoconstituents** **a) Terpenoids:** Menthol, Citral, Artemisin **b) Glycosides:** Glycyrhetinic acid &Rutin **c) Alkaloids:** Atropine, Quinine, Reserpine, Caffeine **d) Resins:** Podophyllotoxin, Curcumin **e) Tannins***	06
IV	**Industrial production, estimation and utilization of the following phytoconstituents:** Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine	10
V	**Basics of Phytochemistry** Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.	08

Recommended Books: (Latest Editions)

1. Evans WC. **Trease and Evans Pharmacognosy**. W.B. Sounders & Co., London, 2009**.**
2. Mohammad Ali. **Pharmacognosy and Phytochemistry**. New Delhi: CBS Publishers & Distribution.
3. Kokate CK, Purohit AP, Gokhlae SB. **Text book of Pharmacognosy**. New Delhi: Nirali Prakashan
4. Choudhary RD, Chopra RD. **Herbal drug industry: A Practical Approach to Industrial Pharmacognosy**. New Delhi: Eastern Publisher
5. Ansari SH. **Essentials of Pharmacognosy.** 2nd edition, Birla publications, New Delhi.
6. Pande H. **Herbal Cosmetics.** Asia Pacific Business Press, Inc, New Delhi.
7. Kalia AN. **Textbook of Industrial Pharmacognosy.** CBS Publishers & Distributors Pvt. Ltd.
8. Rudolf E. **Plant Cell Biotechnology.** Springer-Verlag Berlin Heidelberg. 1994.
9. Robbers JE. Speedie M. Tyler VE. **Pharmacognosy and Pharmacobiotechnology** Lippincott Williams and Wilkins, 1996.
10. Appell L. **The Formulation and Preparation of Cosmetics, Fragrances and Flavors**. Micelle Press, 1994
11. Vyas SP, Dixit V. **Pharmaceutical Biotechnology**. CBS Publishers & Distributors Pvt Ltd, India. 2009.
12. Dubey RC. **A Textbook of Biotechnology.** 4th Rev. Edn, S Chand Publications 2006.

BP508P. PHARMACOGNOSY AND PHYTOCHEMISTRY-II (Practical)

4 Hours/Week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP508P	Pharmacognosy and Phytochemistry- II (Practical)	-	-	4	2	Practical (50 Makrs)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

Upon completion of the course, students shall be able to

CLO1. Prepare[5] (Extract*) and **Analyze[4]** crude drugs by qualitative parameters.

CLO2. Determine[6] the microscopic and morphological characteristics of crude drugs.

CLO3. Identify[2] crude drugs based upon pharmacognostic characters including powder characteristics*.

CLO4. Describe[2] Analytical techniques for the identification of herbal drugs.

No.	Description
1.	Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2.	Exercise involving isolation & detection of active principles a. Caffeine - from tea dust. b. Diosgenin from Dioscorea c. Atropine from Belladonna d. Sennosides from Senna
3.	Separation of sugars by Paper chromatography
4.	TLC of herbal extract
5.	Distillation of volatile oils and detection of phytoconstitutents by TLC
6.	Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books (Latest Editions)

1. Gokhale SB, Kokate CK. **Practical Pharmacognosy**.Nirali Prakashan
2. Iyengar MA. **Anatomy of Crude Drugs.** PharmaMed Press
3. Khandelwal KR. **Practical Pharmacognosy**. Nirali Prakashan.

BP505T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP505T	Pharmaceutical Jurisprudence (Theory)	3	-	1	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. State[1] the objectives, terminologies, offenses, and penalties of various laws relatedto drugs.

CLO2. Expalin[2] the history of pharmaceutical legislations, pharmacy ethics, pharmacy act, administration and controlling of acts and rules.

CLO3. Describe[2] the Drug and cosmetic act and rules and Medicinal and Toilet Preparation Act

CLO4. Explain[2] the acts and rules to control drug price, Narcotic Drugs and Psychotropic substances, magic remedies.

CO5. Illustrate[3] the act for prevention of cruelty to animals, medical termination of pregnancy, and rights to information and intellectual property right.

Course content:

UNIT	Description	Hours
I	**Drugs and Cosmetics Act, 1940 and its rules 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs: Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offenses and penalties. Manufacture of drugs: Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of the new drug, loan license and repacking license.	10
II	**Drugs and Cosmetics Act, 1940 and its rules 1945.** Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs: Wholesale, Retail sale and Restricted license. offense and penalties	10

	Labeling & Packing of drugs: General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offenses and penalties. **Administration of the Act and Rules**: Drugs Technical Advisory Board, Central drugs laboratory, Drugs Consultative Committee, Government drug analysts, licensing authorities, controlling authorities, Drugs Inspectors	
III	**Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offenses and Penalties. **Narcotic Drugs and Psychotropic substances** Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	10
IV	**Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of exempted advertisements, Offences, and Penalties **Prevention of Cruelty to Animals Act- 1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for the experiment, Records, Power to suspend or revoke registration, Offences and Penalties. **National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013:** Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of essential medicines (NLEM).	08
V	**Pharmaceutical Legislations: –** A brief review, Introduction, Study of drugs inquiry committee, Health survey and development committee, Hathi committee, and Mudaliar committee **Code of Pharmaceutical ethics:** Definition, Pharmacist in relation to his job, trade, the medical profession and his profession, Pharmacist's oath **Medical Termination of Pregnancy Act** **Right to Information Act** **Introduction to Intellectual Property Rights (IPR)**	07

Recommended Books: (Latest Edition)

1. Suresh B. **A Textbook of Forensic Pharmacy.** Birla Publication. Pvt Ltd. Delhi
2. Mittal BM. **A Textbook of Forensic Pharmacy**. Vallabh Prakashan. Delhi.
3. Mehra ML. **Handbook of drug law** Universal Book Traders, Delhi
4. Jain NK. **A Textbook of Forensic Pharmacy**.Vallabh Prakashan. Delhi.
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government.

Semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points	Internal		ESE
					CA	SE	
BP601T	Medicinal Chemistry-III (T)	3	1	4	10	15	75
BP602T	Pharmacology-III (T)	3	1	4	10	15	75
BP603T	Herbal Drug Technology (T)	3	1	4	10	15	75
BP604T	Biopharmaceutics and Pharmacokinetics (T)	3	1	4	10	15	75
BP605T	Pharmaceutical Biotechnology (T)	3	1	4	10	15	75
BP606T	Pharmaceutical Quality Assurance (T)	3	1	4	10	15	75
BP607P	Medicinal Chemistry-III (P)	4	-	2	05	10	35
BP608P	Pharmacology-III (P)	4	-	2	05	10	35
BP609P	Herbal Drug Technology (P)	4	-	2	05	10	35
	Total	**30**	**6**	**30**	75	120	555
					750		

BP601T. MEDICINAL CHEMISTRY –III (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP601T	Medicinal Chemistry – III (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Define[1] drug categories/classifications* along with examples and structures.

CLO2. Describe[2] the historical background and different classes of the drug along withtheir chemistry and synthesis.

CLO3. Illustrate[3] the mode of action, therapeutic value and adverse effect of the drugs

CLO4. Justify[6] the Structure Activity Relationship (SAR) with respect to their pharmacological activity.

CLO5. Summarize[5] various approaches in drug design, different techniques of drug designand combinatorial chemistry

Course Content:

UNIT	Description	Hours
	Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)	
I	**Antibiotics:** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes. a) **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams b) **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin c) **Tetracyclines**: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	10
II	**1. Antibiotics** Historical background, Nomenclature, Stereochemistry, Structure	10

	activity relationship, Chemical degradation classification and important products of the following classes a) **Macrolide:** Erythromycin Clarithromycin, Azithromycin. b) **Miscellaneous:** Chloramphenicol*, Clindamycin. 2. **Prodrugs:** Basic concepts and application of prodrugs design. 3. **Antimalarials:** Etiology of malaria. a) **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. b) **Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil. c) **Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone	
III	**Anti-tubercular Agents** Synthetic antitubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para aminosalicylic acid.* Antitubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulfate. **Urinary tract anti-infective agents** Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine. **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridinetrifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	10
IV	**Antifungal agents:** Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin. Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoal Agents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone,Eflornithine. **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin**.** **Sulphonamides and Sulfones:** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.	08

	Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole. **Sulfones:** Dapsone*.	
V	**Introduction to Drug Design** Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis. **Pharmacophore modeling and docking techniques.** **Combinatorial Chemistry:** Concept and applications chemistry: solid phase and solution phase synthesis of combinatorial	07

Recommended Books (Latest Editions)

1. Beale JM. Block J. **Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry**. Lippincott Williams and Wilkins
2. Williams A.D (Editor). **Foye's Principles of Medicinal Chemistry.** Lippincott Williams and Wilkins.
3. Abraham DJ, Rotella DP. (Editor). **Burger′s Medicinal Chemistry, Drug Discovery, and Development**. Wiley-Blackwell.
4. Smith JH, Williams H. **Smith and Williams' Introduction to the Principles of Drug Design and Action.** CRC Press.
5. Adejare A**. (Ed) Remington: The Science and Practice of Pharmacy**. Academic Press
6. Martindale W, Westcott W**. Martindale: The Extra Pharmacopoeia.** Pharmaceutical Press
7. Finar IL. **Organic Chemistry, Volume 2: Stereochemistry and the Chemistry Natural Products**. Pearson Education India
8. Lednicer D**. The Organic Chemistry of Drug Synthesis** Vol 1-5. Wiley-Blackwell.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours/week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP607P	Medicinal Chemistry- III (Practical)	-	-	4	2	Practical (50 Marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

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

CLO1. Synthesise[5] the intermediates and drugs using conventional and microwave synthesis methods.

CLO2. Evaluate[6] the drugs using chemical assays.

CLO3. Draw[5] chemical structure using chem. Draw/any freeware* software.

CLO4. Determine[3] the physiochemical properties and establishing a correlation with pharmacological property* of drug using software.

No.	Description
1.	**Preparation of drugs/ intermediates** 1) Sulphanilamide 2) 7-Hydroxy, 4-methyl coumarin 3) Chlorobutanol 4) Triphenyl imidazole 5) Tolbutamide 6) Hexamine
2.	**Assay of drugs** 1) Isonicotinic acid hydrazide 2) Chloroquine 3) Metronidazole 1) Dapsone 2) Chlorpheniramine maleate 3) Benzyl penicillin
3.	Preparation of medicinally important compounds or intermediates byMicrowave irradiation technique.
4.	Drawing structures and reactions using chem draw®/ any freeware*
5.	Determination of physicochemical properties (logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors) and establishing correlation with pharmacological property* for the class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Adejare A**. (Ed)** Remington: The Science and Practice of Pharmacy. Academic Press**.**
2. Anonymous. **Indian pharmacopoeia.** Ghaziabad: Indian Pharmacopoeia Commission Ministry of Health & Family Welfare, Govt. of India**.**
3. Furniss BS, Hannaford AJ, Smith Peter WG, Tatchell AR. **Vogel's textbook of practical organic chemistry.** Noida: Pearson Education
4. Lednice**. The Organic Chemistry of Drug Synthesis** Vol 1-5. Wiley-Blackwell**.**
5. Martindale W, Westcott W**.** Martindale: The Extra Pharmacopoeia**.** PharmaceuticalPress

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP602T	Pharmacology- III (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Define[1] and **classify[1]** the drugs acting on GIT and Respiratory system, infectionsand cancer.

CLO2. Illustrate[3] the pharmacological effects, therapeutic value and adverse effects* ofdrugs used to treat GIT and Respiratory diseases and disorders.

CLO3. Discuss[2] the principles and pharmacological effects of various chemotherapeuticdrugs, Immunomodulators and protein drugs*.

CLO4. Illustrate[3] the principles of toxicology and treatment of various poisonings.

CLO5. Elaborate[2] the concept chronopharmacology with its significance.

Course Content

UNIT	Description	Hrs
I	**Pharmacology of drugs acting on Respiratory system** a) Anti-asthmatic drugs b) Drugs used in the management of COPD c) Expectorants and antitussives d) Nasal decongestants e) Respiratory stimulants **Pharmacology of drugs acting on the Gastrointestinal Tract** a) Antiulcer agents. b) Drugs for constipation and diarrhea. c) Appetite stimulants and suppressants. d) Digestants and carminatives. e) Emetics and anti-emetics	10
II	**Chemotherapy** a) General principles of chemotherapy. b) Sulfonamides and cotrimoxazole. c) Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	10

III	**Chemotherapy** a) Antitubercular agents b) Antileprotic agents c) Antifungal agents d) Antiviral drugs e) Anthelmintics f) Antimalarial drugs g) Antiamoebic agents	10
IV	**Chemotherapy** a) Urinary tract infections and sexually transmitted diseases. b) Chemotherapy of malignancy. **Immunopharmacology** a) Immunostimulants b) Immunosuppressant **Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars**	08
V	**Principles of toxicology** a) Definition and basic knowledge of acute, subacute and chronic toxicity. b) Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity c) General principles of treatment of poisoning d) Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning. **Chronopharmacology** a) Definition of rhythm and cycles. b) Biological clock and their significance leading to chronotherapy	07

Recommended Books (Latest Editions)

1. Satoskar RS, Rege N, Bhandarkar SD. **Pharmacology and Pharmacotherapeutics**. Elsevier India
2. Rang HP, Dale MM, Ritter JM, Flower RJ. **Rang and Dale's Pharmacology.** Churchil Livingstone Elsevier
3. Katzung BG, Masters SB, Trevor AJ. **Basic and clinical pharmacology.** Tata McGraw-Hill
4. Brunton L, Chabner BA, Knollman B. **Goodman and Gilman's, The Pharmacological Basis of Therapeutics**. McGraw Hill Education
5. Marry Anne KK, Lloyd Yee Y, Brian KA, Robbin LC, Joseph G B, Wayne AK, Bradley RW. **Applied Therapeutics, The Clinical use of Drugs.** Lippincott Williams &Wilkins
6. Mycek MJ, Gelnet SB, Perper MM. **Lippincott's Illustrated Reviews- Pharmacology**. Lippincott Williams and Wilkins
7. K.D.Tripathi. **Essentials of Medical Pharmacology.** JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
8. Sharma HL, Sharma KK. **Principles of Pharmacology**. Paras medical publisher.
9. Craig CR, Stitzel RE. **Modern Pharmacology with clinical Applications**. Lippincott Williams and Wilkins
10. Udupa N, Gupta PD. **Concept in Chronopharmacology**. Shyam Prakashan Jaypur.

BP608P. PHARMACOLOGY-III (Practical)

4 Hours/week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP608P	Pharmacology-III (Practical)	-	-	4	2	Practical (50 Marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

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

CLO1. Determine[3] the dose for the pharmacological experiments.

CLO2. Interpret[4] the experimental data using parametric and nonparametric tests.

CLO3. Demonstrate[3] various biological activities of drugs using bioassay, and pharmacological screening methods.

CLO4. Determine[3] oral acute toxicity andskin/eye irritation*.

No.	Description
1.	Dose calculation in pharmacological experiments
2.	Antiallergic activity by mast cell stabilization assay
3.	Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4.	Study of the effect of drugs on gastrointestinal motility
5.	Effect of agonist and antagonists on guinea pig ileum
6.	Estimation of serum biochemical parameters by using semi- autoanalyser
7.	Effect of saline purgative on frog intestine
8.	Insulin hypoglycemic effect in rabbit
9.	Test for pyrogens (rabbit method)
10.	Determination of acute oral toxicity (LD50) of a drug from a given data
11.	Determination of acute skin irritation/corrosion of a test substance
12.	Determination of acute eye irritation/corrosion of a test substance
13.	Calculation of pharmacokinetic parameters from a given data
14.	Biostatistics methods in experimental pharmacology(student's t-test, ANOVA)
15.	Biostatistics methods in experimental pharmacology (Chi-square test, Wilcoxon Signed Rank test)

Recommended Books (Latest Editions)

1. Ghosh MN. **Fundamentals of Experimental Pharmacology**. Hilton & Company, Kolkata.
2. Kulkarni SK. **Handbook of experimental pharmacology.** Vallabh Prakashan.
3. Vogel HG, Vogel WH. **Drug Discovery and Evaluation: Pharmacological Assays**. Springer-Verlag Berlin Heidelberg.
4. CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) **Standard Operating Procedures for Institutional Animal Ethics Committee** (IEAC). Animal Welfare Division, Ministry of Environment and Forest

BP603T. HERBAL DRUG TECHNOLOGY (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP603T	Herbal Drug Technology (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course student shall able to

CLO1. Explain[2] methods for identification, authentication, cultivation, collection, pest control of herbal drugs.

CLO2. Elaborate[3]* basic principles of traditional medicinal systems with the method of preparation and standardization of related formulations and their interactions

CLO3. Illustrate[3] various aspects of nutraceuticals, herbal cosmetics, herbal formulation,Herbal Excipients and their interactions with drugs and food*.

CLO4. Explain[2] regulatory requirements for assessment and manufacture of herbal drugsand its formulations based on the traditional medicinal system.

CLO5. Describe[2] current trends, Good Manufacturing Practice and infrastructural requirements in the herbal industry

Course Content

UNIT	Description	Hours
I	**Herbs as raw materials:** Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation. Source of Herbs: Selection, identification and authentication of herbal materials. Processing of herbal raw material. **Biodynamic Agriculture:** Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides. **Indian Systems of Medicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma	11
II	**Nutraceuticals:** General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in	07

	ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastrointestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic,Honey, Amla, Ginseng, Ashwagandha, Spirulina **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypericum, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra	
III	**Herbal Cosmetics:** Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gum colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products. **Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes. **Herbal formulations:** Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes	10
IV	**Evaluation of Drugs:** WHO & ICH guidelines for the assessment of herbal drug stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem. **Regulatory Issues:**- Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs	10
V	**General Introduction to Herbal Industry:** Herbal drugs industry: Present scope and future prospects. A brief account of plant-based industries and institutions involved in work on medicinal and aromatic plants in India. **Schedule T**: Good Manufacturing Practice of Indian systems of medicine. Components of GMP (Schedule – T) and its objectives. Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records	07

Recommended Books (Latest Editions)

1. Evans WC. **Trease and Evans Pharmacognosy**. W.B. Saunders & Co., London, 2009.
2. Tyler VE, Brady LR, Robbers JE. **Pharmacognosy** Lea and Febiger, Philadelphia,
3. Kokate CK, Purohit AP, Gokhlae SB. **Textbook of Pharmacognosy**. New Delhi: Nirali Prakashan
4. Rangari VD. **Pharmacognosy and Phytochemistry.** Career Publications
5. Ansari SH. **Essentials of Pharmacognosy.** 2nd edition, Birla publications, New Delhi.

BP609P. HERBAL DRUG TECHNOLOGY (Practical)

4 Hours / Week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP609P	Herbal Drug Technology (Practical)	-	-	4	2	Practical (50 Marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Objectives:

Upon completion of the course, student shall able to

CLO1. Evaluate[4] crude drugs and excipient of natural origin.

CLO2. Develop[5] cosmetic and oral formulations of various crude drugs/extracts.

CLO3. Evaluate[6] Herbal drugs and formulations* as per Pharmacopoeial standards

CLO4. Determine[3] aldehyde, alcohol*, phenol and alkaloid contents

No.	Description
1.	To perform preliminary phytochemical screening of crude drugs.
2.	Determination of the alcohol content of Asava and Arista
3.	Evaluation of excipients of natural origin
4.	Incorporation of a prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5.	Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements
6.	Monograph analysis of herbal drugs from recent Pharmacopoeias
7.	Determination of Aldehyde content
8.	Determination of Phenol content
9.	Determination of total alkaloids

Recommended Books (Latest Editions)

1. Gokhale SB, Kokate CK. **Practical Pharmacognosy**.Nirali Prakashan
2. Iyengar MA. **Anatomy of Crude Drugs.** PharmaMed Press.
3. Khandelwal KR. **Practical Pharmacognosy**. Nirali Prakashan
4. Mukherjee PW. **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons Publishers, New Delhi, India, 2002.
5. **Pharmacopoeal standards for Ayurvedic Formulation** (Council of Research in Indian Medicine & Homeopathy.
6. **Quality Control Methods for Herbal Material**. World Health Organisation. 2011

BP604T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP604T	Biopharmaceutics and Pharmacokinetics (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional -2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, students shall be able to –

CLO1. Illustrate[3] the basic concepts of absorption, distribution, metabolism and elimination,their significance and factors affecting them.

CLO2. Describe[2] the objectives, types, measurement of bioavailability and bioequivalence,and methods for their enhancement.

CLO3. Explain[2] pharmacokinetic models and determination of pharmacokinetic parameters, their significance and applications.

CLO4. Outline[2] multiple dosage regimens based on pharmacokinetic parameters for maximizing patient compliance and therapeutic effectiveness

CLO5. Discuss[2] various pharmacokinetic parameters for drugs exhibiting non-linear kinetics

Course content

UNIT	Description	Hours
I	**Introduction to Biopharmaceutics** **Absorption:** Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution:** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein-binding of drugs	10
II	**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Nonrenal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and	10

	bioavailability of poorly soluble drugs.	
III	**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartmentmodels, Non-compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extravascular administrations. Pharmacokinetics parameters - KE, t1/2, Vd, AUC, Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application	10
IV	**Multicompartment models:** Two compartment open model. IV bolusKinetics of multiple dosing, steady-state drug levels, calculation of loading and mainetnance doses and their significance in clinical settings.	08
V	**Nonlinear Pharmacokinetics:** a) Introduction b) Factors causing Non-linearity. c) Michaelis-menton method of estimating parameters, Explanation with example of drugs.	07

Recommended Books (Latest Editions)

1. Gibaldi M. **Biopharmaceutics and Clinical Pharmacokinetics.** Pharma Book Syndicate
2. Notari RE. **Biopharmaceutics and pharmacokinetics: An introduction.** Marcel Dekker, Inc., New York
3. Notari RE. **Biopharmaceutics and clinical pharmacokinetics**, Marcel Dekker, Inc., New York.
4. Shargel L, Andrew B CYu. **Applied Biopharmaceutics & Pharmacokinetics.** 8th edition McGraw-Hill. 2021
5. Brahmankar DM, Jaiswal SB. **Biopharmaceutics and Pharmacokinetics-A Treatise**. Vallabh Prakashan Pitampura, Delhi.
6. Gibaldi M, Perrier D. **Pharmacokinetics.** Marcel Dekker, New York, NY
7. Gibaldi M. Prescott L. **Handbook of clinical pharmacokinetics.** Adis Health Science Press. New York.
8. James S. Biopharmaceutics
9. Rowland M, Tozer TN. **Clinical pharmacokinetics: Concepts and applications**. (Lea & Febiger. Philadelphia.) Lippincott Williams & Wilkins. 4th edition. 2010.
10. Abdou HM. **Dissolution, bioavailability and bioequivalence**. Mack Publishing Company: Easton, PA.
11. Adejare A**. (Ed) Remington: The Science and Practice of Pharmacy.** Academic Press

BP605T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP605T	Pharmaceutical Biotechnology (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Illustrate[3] the basic concepts of biotechnology with respect to enzyme technology, biosensors, industrial microbiology*, genetic engineering and protein engineering.

CLO2. Comprehend[2]* the fundamentals of recombinant technology, concepts of immunology and products using principles of biotechnology

CLO3. Describe[2] the genetic organization of different types of cells and detection by immunological, genomic level, mutation and gene transfer methods.

CLO4. Explain[2] the general requirements of fermentation* and biotechnological production of pharmaceuticals.

CLO5. Summarize[2] the microbial genetics, biotransformation and various immunologicaland blood products

Course content

UNIT	Description	Hours
I	a) **A brief introduction** to Biotechnology with reference to Pharmaceutical Sciences. b) **Enzyme Biotechnology**: Methods of enzyme immobilization and applications. c) **Biosensors:** Working and applications of biosensors in Pharmaceutical Industries. d) **A brief introduction to Protein Engineering**. e) **Use of microbes in industry. Production of Enzymes**: General consideration -Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. **f) Basic principles of genetic engineering**	10
II	a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in	10

	medicine. c) Application of rDNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines: hepatitis B iii) Hormones- Insulin. d) Brief introduction to PCR	
III	**Types of immunity- humoral immunity, cellular immunity** a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substitutes	10
IV	a) Immunoblotting techniques: ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. e) Mutation: Types of mutation/mutants	08
V	a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of: penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin. d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.	07

Recommended books (Latest edition):

1. Glick BR, Pasternak JJ, Patten CL. **Molecular biotechnology: principles and applications of recombinant DNA**. ASM Press, Washington, DC. 2010.
2. Janis Kuby, Goldsby RA, Kindt TJ, Osborne BA. **Kuby immunology**. W. H. Freeman & Co Ltd. New York: 2007
3. Goding J. **Monoclonal Antibodies: Principles and Practice**. 3rd Edition. Academic Press.
4. Walker JM, Gingold EB. **Molecular Biology and Biotechnology**. Royal Society of Chemistry, London.
5. Zaborsky O. **Immobilized Enzymes**. CRC Press, Cleveland, Ohio, USA
6. Primrose SB. **Molecular Biotechnology.** Blackwell Scientific Publication.
7. Stanbury FP, Whitakar A, Hall JS. **Principles of fermentation technology**, Aditya books Ltd., New Delhi.

BP606T PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45Hrs

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP606T	Pharmaceutical Quality Assurance (Theory)	3	1	-	4	Theory (100 Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. Describe[2] the concepts of quality assurance, quality management, ICH guidelines,ISO, NABL and concepts of QbD in pharmaceutical industry

CLO2. Identify[1] the organization and personnel responsibilities along with requirements ofpremises and basis of selection of equipment and raw materials.

CLO3. Illustrate[3] quality control parameters and good laboratory practices in the pharmaceutical industry.

CLO4. Describe[2] the complaints and its evaluation, and document maintenance in theindustry with required regulatory guidelines.

CLO5. Elaborate[2] on the calibration, validation procedures and good warehousing practices.

Course content

UNIT	Description	Hours
I	**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines:** purpose, participants, the process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD):** Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration **NABL accreditation:** Principles and procedures	10
II	**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records.	10

	Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. **Equipment and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	
III	**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	10
IV	**Complaints:** Complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal. **Document maintenance in the pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	08
V	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management.	07

Recommended books (Latest edition):

1. Quality Assurance Guide by organization of Pharmaceutical Products of India
2. Sandy Weinberg. **Good Laboratory Practice Regulations**. Marcel Dekker, Inc. New York.
3. **Quality Assurance of Pharmaceuticals**- A compendium of Guidelines and Related materials Vol- I WHO Publications.
4. Maitra K, Ghosh SK. **A guide to Total quality management.**
5. Sharma PP**. How to Practice GMP's.** Vandana Publications Pvt Ltd New Delhi. 2020.
6. Ghosh SG. **ISO 9000 and Total Quality Management**.
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
8. **Good laboratory Practices** – Marcel Deckker Series
9. **ICH guidelines**.
10. ISO 9000 and 14000 guidelines

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