Sanjay Ghodawat University

Kolhapur

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

Empowering Lives Globally!

School of Pharmaceutical Science

Final Year 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 (Final Year 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 May2017, with the approval of the UGC and the State Government. "For the true measure of giving is giving without measure" Spread across150Acres, Sou. Sushila Danchand Ghodawat Charitable Trust's Sanjay Ghodawat University (SGU) is situated in a serene atmosphere amidstidyllic 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. SGU always 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 the equalities would be nurtured, encouraged, and blossomed. 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 guide the 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-onexperience,challenge-basedcasestudies,maximumparticipationofstudentsintheclassroom, 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

VISION

Internationally recognized university of excellence in creating and disseminating knowledge through value-based quality education leading to the betterment of mankind

MISSION

- To prepare students for life-long learning and leadership in a global academic culture
- To create intellectual manpower relevant to the industry and society at large
- To collaborate with institutions of international repute for academic excellence
- To promote research and development through a conducive environment
- To encourage entrepreneurship and skill development programs

COREVALUES

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

QUALITYPOLICY

Sanjay Ghodawat University is committed to establish high standards in value-based quality education to enhance and nurture young minds to excel in their chosen profession and develop into socially responsible citizens through resourceful collaboration, innovation and 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 believes 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 with a 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 program.

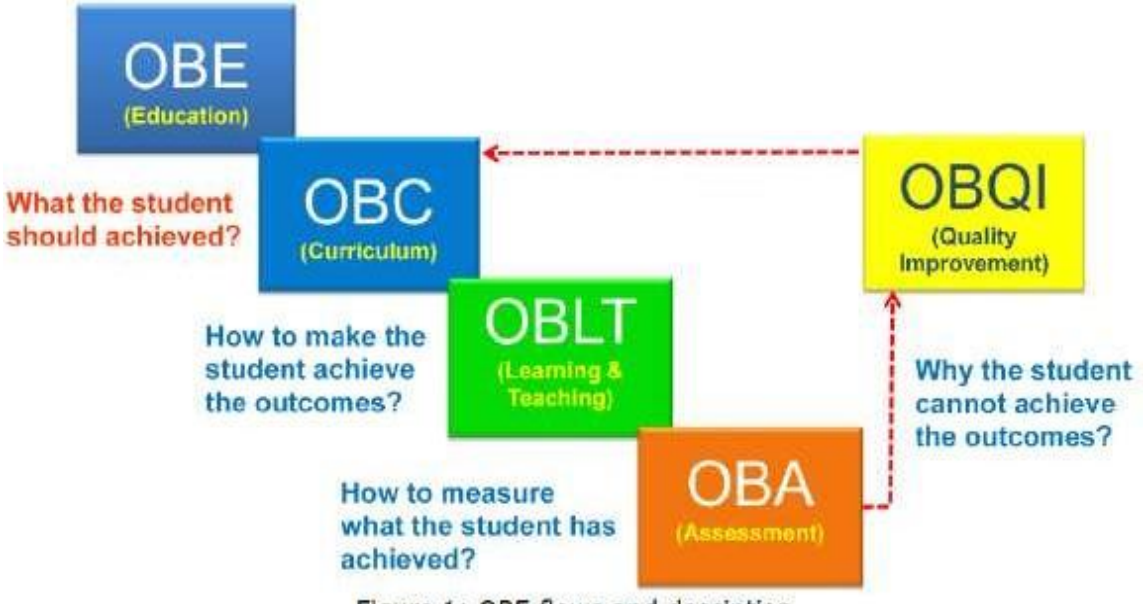
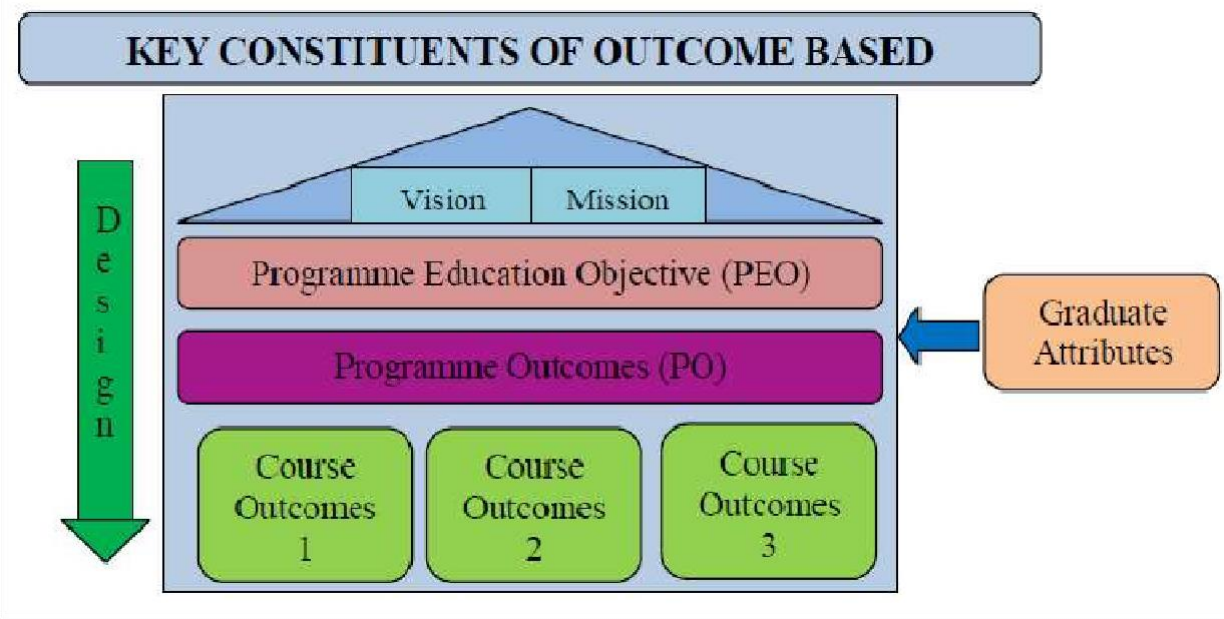


Figure 1: OBE flows and desciption

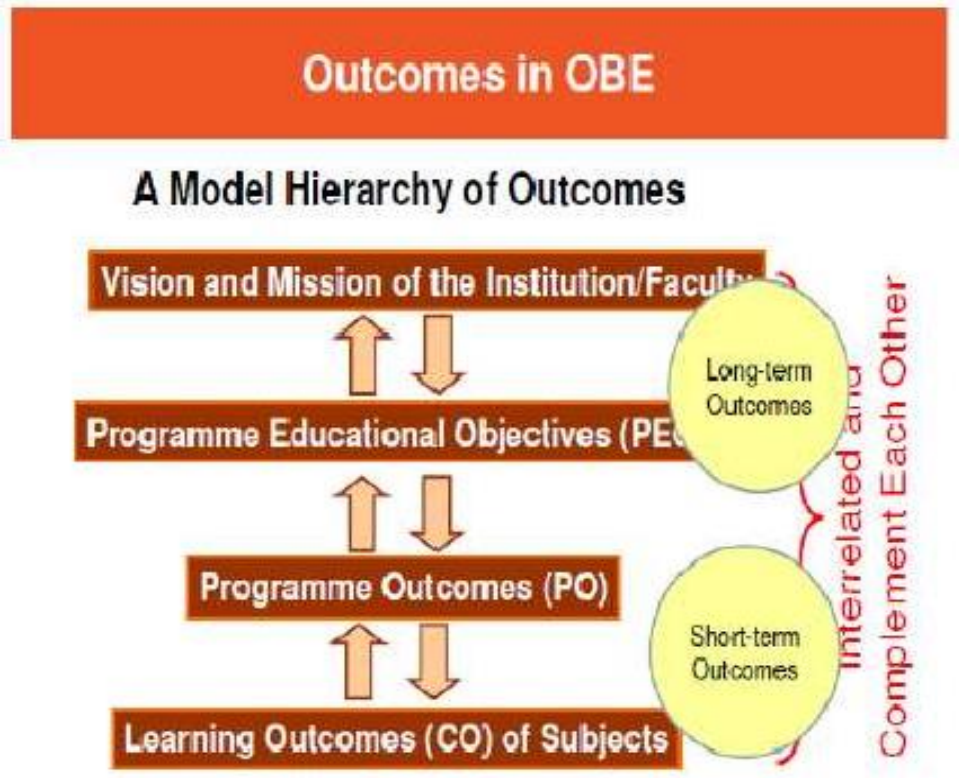


The OBE model measures the progress of the graduate in three parameters, which are

- 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 statements that describe what students are expected to know and be able to do by the time of graduation. 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 is measure 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 as "The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the Pharmacy Council of India.

2. **Minimum qualification for admission**

2.1 First-year B. Pharm:

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

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

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

3. **Duration of the program**

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

7.1 Credit assignment

7.1.1 Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits

(C) for a course is dependent on the number of hours of instruction per week in that course and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout the semester carries a credit of 2.

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

7.2 Minimum credit requirements

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

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

8. Academic work

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

9. Course of study

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

Table I: Course of study for Semester-I

Course code	Name of the course	No. of hours	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
	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	4	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			
BP813ET	Pharmaceutical Product Development			
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 a steric 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–VII

Course Code	Course Title	L	T	P	C	Component (Marks)	Exam	WT		Passing Min.(%)
BP701T	Instrumental Methods of Analysis – (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP702T	Industrial Pharmacy-II (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP703T	Pharmacy Practice – (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP704T	Novel Drug Delivery System (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP705P	Instrumental Methods of Analysis (Practical)	-	-	4	2	Practical (50)	CA	5	5	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	
BP706PS	Practice School*	12	-	5	6	Practical (150)	CA	25	25	50
							Sessional-1	-		
							Sessional-2	-		
							ESE		125	
Total		**28**	**4**	**12**	**24**				**600**	
		32								

Table X: SEMESTER-VIII

Course Code	Course Title	L	T	P	C	Component (Marks)	Exam	WT		Passing Min (%)
BP801T	Biostatistics and Research Methodology (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	
BP802T	Social and Preventive Pharmacy (Theory)	3	1	-	4	Theory (100)	CA	10	10	50
							Sessional-I	15	15	
							Sessional-II	15		
							ESE		75	
BP803ET	Pharmaceutical Marketing (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP804ET	Pharmaceutical Regulatory Science(Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP805ET	Pharmacovigilance (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP806ET	Quality Control and Standardization of Herbals (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP807ET	Computer Aided Drug Design (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP808ET	Cell and Molecular Biology (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP809ET	Cosmetic Science (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP810ET	Experimental Pharmacology (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP811ET	Advanced Instrumental Techniques (Theory)	6	2	-	8	Theory (200)	CA	20	20	50
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	

BP812ET	Dietary supplements and Nutraceuticals	3	1	-	4	Theory (200)	CA	20	20	
							Sessional-I	15	30	
							Sessional-II	15		
							ESE		150	
BP813ET	Pharmaceutical Product Development	3	1	-	4					
BP813 PW	Project Work	12	-	-	6	150	ESE		150	
Total		**24**	**4**	**-**	**22**				**550**	

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,openbooktest,fieldwork,groupdiscussionan dseminar)	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**

Table XIII: Assessment criteria and standards for Practice School

Assessment task	**Marks**	**Rubrics**
Assessment :	150	Internal Marks - 25 External Marks-125

Assessment task	Marks	Rubrics
Internal Assessment	**25**	
Assessment 1: **Mid- Seminar Presentation**	15	1. Content: 4 marks 2. Confidence: 4 marks 3. Presentation: 4 marks 4. Language command: 3 mark

	10	1. Activity-03 2. Attendance-04 3. Student teacher interaction-03
External Assessment	**125**	
Assessment 2: **Dissertation**	75	1. Objectives of the work done- 15 marks 2. Methodology adopted- 10 marks 3. Skill assessment- 10 marks 4. Results and Discussion- 20 marks 5. Conclusion and outcomes- 20 marks
Assessment 3: **Presentation**	50	1. Presentation of work- 20 marks 2. Communication skills- 10 marks 3. Subject knowledge- 20 marks

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 15marks. Similarly, Sessional exam for practical shall be conducted for 40 marks and shall be computed for10 marks.

Question paper pattern for theory Sessional examinations for subjects having University examination

I	Multiple Choice Questions (MCQs)(10x1) OR Objective Type Questions (5x2) (Answer all questions)	10x1=10 05x2=10
II	Long Answer Questions(Answer1outof2)	01x10=10
III	Short Answers (Answer2outof3)	02x05 =10
	Total	**30marks**

For subjects having Non University Examination

I	Long Answers(Answer1outof2)	1x10=10
II	Short Answers(Answer4outof6)	4x5=20
	Total	**30marks**

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 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However, his/ her marks of the Internal Assessment shall be carried over and he/ she shall be entitled 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 theory examinations.

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 (10x2) (Answer all the questions)	20x1=20OR 10x2=20
II	Long Answers (Answer 2outof3)	2x10=20
III	Short Answers (Answer7outof9)	7x5=35
	Total	**75marks**
For 50 marks paper		
I.	Long Answers (Answer2outof3)	2x10=20
II.	Short Answers (Answer6outof8)	6x05 =30
	Total	**50marks**
For 35 marks paper		
I.	Long Answers (Answer1outof2)	1x10=10
II.	Short Answers (Answer5outof7)	5x5 =25
	Total	**35marks**
Question paper pattern for end semester practical examinations		
I.	Synopsis	5

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

16. Academic Progression:

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

A student shall be eligible to carry forward all the courses of I, II, and III semesters till the IV semester examinations. However, he/ she shall not be eligible to attend the courses of 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 with in the stipulated time period as per the norms specified in 26.

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

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

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

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

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

17. Grading of performances

17.1 Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table– 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**
Lessthan50	F	0	**Fail**
Absent	**AB**	**0**	**Fail**

Table XV: Letter grades and grade points equivalent to percentage of marks and performance Practice School (BP706PS)

Grading of course : Practice School (BP706P)				
Range of Marks obtained out of 150	**Percentage of marks obtained**	**Letter Grade**	**Grade point**	**Performance**
135-150	**90.00-100**	**O**	**10**	**Outstanding**
120-134	**80.00-89.99**	**A**	**9**	**Excellent**
105-119	**70.00-79.99**	**B**	**8**	**Good**
90-104	**60.00-69.99**	**C**	**7**	**Fair**
75-89	**50.00-59.99**	**D**	**6**	**Average**
Less than 75	**Less than 50**	**F**	**0**	**Fail**
Absent	**Absent**	**AB**	**0**	**Fail**

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

18. The Semester grade point average (SGPA)

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

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

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 For ABS grade in course 4, the GPA shall then be computed as:

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in 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:

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

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 to7.49**
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 5in number. The project report shall be submitted in triplicate (typed & bound copy not lessthan25pages).

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

Evaluation of Dissertation Book:

Objective(s)of the work done		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 it, 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 150hours 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 regular course required to be done as per structure 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:

29.1 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 if the 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 hardcopy. It shall be mandatory for students/faculty to strictly adhere to the academic calendar for the completion of academic activities.

CHAPTER-II:

SYLLABUS

Semester VII

Course code	Name of the course	No. of Hr/wk	Tutorial	Credit points	Internal		ESE
					CA	SE	
BP701T	Instrumental Methods of Analysis (T)	3	1	4	10	15	75
BP702T	Industrial Pharmacy-II(T)	3	1	4	10	15	75
BP703T	Pharmacy Practice (T)	3	1	4	10	15	75
BP704T	Novel Drug Delivery System (T)	3	1	4	10	15	75
BP705P	Instrumental Methods of Analysis(P)	4		2	5	10	35
BP706PS	Practice School*	12		6	25	-	125
	Total	**28**	**4**	**24**	70	70	460
					= 600		

BP701T. Instrumental Methods of Analysis (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP701T	Instrumental Methods of Analysis – (Theory)	3	1	-	4	Theory (100 marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1. State1 the definition and meaning and classes of different terminologies used in different instrumental method of analysis.

CLO2. Illustrate4 the principle, theory and methodology employed for the characterization and analysis of drugs.

CLO3. Illustrate 4the principle, procedure, applications used in various spectroscopic methods

CLO4. Evaluate5 the drugs by quantitative & qualitative analysis using various analytical techniques.

CLO5. Interpret5 merit demerit and differences in the selected instrumental method of analysis.

Course Content

UNIT	Description	Hours
I	**UV Visible spectroscopy** Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. **Instrumentation** - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. **Applications** - Spectrophotometric titrations, Single component and multi component analysis **Fluorimetry** Theory, Concepts of singlet, doublet and triplet electronic states, internal and external Conversions, factors affecting fluorescence, quenching, instrumentation and applications.	10
II	**IR spectroscopy** Introduction, fundamental modes of vibrations in poly atomic	10

molecules, sample handling, factors affecting vibrations.

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

Flame Photometry- Principle, interferences, instrumentation and applications.

Atomic absorption spectroscopy-Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications.

III	**Introduction to chromatography** **Adsorption and partition column chromatography-** Methodology, advantages, disadvantages and applications. **Thin layer chromatography-** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications. **Paper chromatography**-Introduction, methodology, development techniques, advantages, disadvantages and applications **Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.	**10**
IV	**Gas chromatography** Introduction, theory, instrumentation, derivatization, temperature programming, Advantages, disadvantages and applications. **High performance liquid chromatography (HPLC)-**Introduction, theory, Instrumentation, advantages and applications.	**08**
V	**Ion exchange chromatography** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications **Gel chromatography-** Introduction, theory, instrumentation and applications Affinity chromatography- Introduction, theory, instrumentation and applications.	**07**

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein R.

BP705P. Instrumental Methods of Analysis (Practical)

4 Hours/Week

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP705P	Instrumental Methods of Analysis	-	-	4	2	Practical (50 marks)	CA	05	05	50
							Sessional-1	10	10	
							Sessional-2	10		
							ESE		35	

Scope:

This course includes quantitative and qualitative analysis of drugs using various analytical techniques. This also understand the chromatographic separation and analysis of drug. This course include interaction of matter with electromagnetic radiations and its applications in drug analysis.

Objectives:

Upon completion of the course students shall be able to

CLO1.**State1** the principles involved in various analytical techniques and instruments.

CLO2.Determine5 of drugs/ions by using UV, Visible spectroscopy, fluorimetry, and flame photometry
CLO3.Estimate5 the organic compounds/amino acids/plant pigments by using various chromatographic, electrophoretic and spectroscopic techniques.

CLO4.Analyze4 the various organic compounds using nephelo turbidometry.

CLO5.Demonstrate3instrumentation, working and application of HPLC and Gas chromatography.

No	Description
1	Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2	Estimation of dextrose by colorimetry
3	Estimation of sulfanilamide by colorimetry
4	Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5	Assay of paracetamol by UV- Spectrophotometry
6	Estimation of quinine sulfate by fluorimetry
7	Study of quenching of fluorescence
8	Determination of sodium by flame photometry
9	Determination of potassium by flame photometry
10	Determination of chlorides and sulphates by nephelo turbidometry
11	Separation of amino acids by paper chromatography
12	Separation of sugars by thin layer chromatography
13	Separation of plant pigments by column chromatography
14	Demonstration experiment on HPLC
15	Demonstration experiment on Gas Chromatography

Recommended Books: (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP702T. INDUSTRIAL PHARMACY-II (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP702T	Industrial Pharmacy-II (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 fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Objectives:

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

CLO1. State1 the meaning of various terminologies involved in pilot plant scale up, technology transfer, regulatory affairs and quality management.

CLO2. Illustrate4 pilot plant scale up techniques, SUPAC guidelines and various quality management systems in pharmacy

CLO3. Outline3 various aspects of drug approvals and technology transfer involved from R & D to production.

CLO4. Describe2 the history, constitution, roles, responsibilities, and requirements for drug approval of regulatory affairs department

CLO5.Illustrate4 the regulatory requirement, approval procedures and accreditations for pharmaceuticals.

Course Content:

UNIT	Description	Hours
I	**Pilot plant scale up techniques:** General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.	**10**
II	**Technology development and transfer** WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R& D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues.	**10**

III	**Regulatory affairs** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals. **Regulatory requirements for drug approval** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies**.**	**10**
IV	**Quality management systems** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ICH guidelines for QbD (Q8 to Q12) Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.	**08**
V	**Indian Regulatory Requirements** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	**07**

Recommended Books: (Latest Editions)

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

BP 703T. PHARMACY PRACTICE (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP703T	Pharmacy Practice (Theory)	3	1	-	4	Theory (100marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, students shall be able to

CLO1.State1 the meaning of various terminologies of pharmacy practice

CLO2.Illustrate4 the organizational structure, classification, functions and policies (including formularies) of hospitals and pharmacy organizations.

CLO3.Describe2 the personnel and their responsibilities in hospital and pharmacy organizations.

CLO4.Illustrate4 the distribution, use and monitoring of drug, clinical interpretations, Patient counseling and pharmacy management.

CLO5.Explain2 the importance of drug information services, education and training programmes in hospitals and the role of pharmacist therein.

Course Content:

UNIT	Description	Hours
I	**a) Hospital and it's organization** Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital and Medical staffs involved in the hospital and their functions. **b) Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **c) Adverse drug reaction** Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. **d) Community Pharmacy** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and Wholesale drug store.	**10**

II	**a) Drug distribution system in a hospitals** Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs **b) Hospital formulary** Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from Hospital formulary **c) Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. **d) Medication adherence** Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. **e) Patient medication history interview** Need for the patient medication history interview, medication interview forms. **f) Community pharmacy management** Financial, materials, staff, and infrastructure requirements.	**10**
III	**a) Pharmacy and therapeutic committee** Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. **b) Drug information services** Drug and Poison information Centre, Sources of drug information, computerized services, and storage and retrieval of information. **c) Patient counseling** Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist. **d) Education and training program in the hospital** Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. **e) Prescribed medication order and communication skills** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	**10**
IV	**a) Budget preparation and implementation** Budget preparation and implementation **b) Clinical Pharmacy** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. **c) Over the counter (OTC) sales**	**08**

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

V **a) Drug store management and inventory control** **07**

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

b) Investigational use of drugs

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

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger;1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

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

BP704T. Novel Drug Delivery system (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP704T	Novel Drug Delivery system (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 basic knowledge on the area of novel drug delivery.

Objectives:

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

CLO1. State[1]the meaning of various NDDS.

CLO2. Discuss[2] **t**he fundamentals, polymers and its applications used in the design of controlled drug delivery systems.

CLO3. Classify[3]the polymers and different drug delivery systems

CLO4. Summarize[5]the formulation, evaluation, advantages, disadvantages and applications of various DDS.

CLO5. Illustrate[4]the principles and fundamentals of drug targeting, ocular drug delivery and IUDDS.

Course content:

UNIT	Description	Hours
I.	**Controlled drug delivery systems:** Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery system. Introduction to large scale manufacturing of CDDS with example.	10
II.	**Microencapsulation:** Definition, advantages and disadvantages, microspheres/microcapsules, microparticles, methods of microencapsulation, applications. Mucosal Drug Delivery system: Introduction, Principles of bioadhesion/ mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump. Introduction to large scale manufacturing of IDDS with example.	10

III.	**Transdermal drug delivery systems**. Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications **Gastroretentive drug delivery systems**: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications Introduction to large scale manufacturing of GRDDS with example. **Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers	**10**
IV.	**Target drug delivery system** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications. Introduction to large scale manufacturing of TDDS with example.	**08**
V.	**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts. **Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications. Introduction to large scale manufacturing of ODDS with example.	**07**

Recommended Books: (Latest Editions)

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

Journals

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

BP706PS. PRACTICE SCHOOL

Course Objectives

Each student is trained to develop their:

1. Problem solving, critical thinking and innovation abilities
2. Curiosity to learn
3. Teamwork and Responsibility
4. Professional and Ethical behavior
5. Attitude and Discipline

Course structure

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall come in **any one of the domains** enclosed in this course structure. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded. There are total 6 credit points for this course.

Examination Pattern

The total marks allotted for the course of Practice School is 150 Marks. Out of this 25 marks are for internal assessment based on the Continues mode. The remaining 125 Marks is for End Semester examination.

Domains

Sr. No	Practice School (Domain)	Department
1.	Practice School 1: Formulation Development (product manufacturing and evaluation)	Pharmaceutics
2.	Practice school 2 – Quality control and Quality assurance of Pharmaceuticals	Quality Assurance
3.	Practice School 3 – Herbal Technology	Pharmacognosy
4.	Practice School 4 – Drug design and Process chemistry	Pharmaceutical Chemistry
5.	Practice School 5 – Pharmacovigilance	Pharmacology

Practice School 1: Formulation Development (product manufacturing and evaluation)

Course Learning Outcomes:

CLO 1: Discuss[2] about the basic and advanced literature review amalgated with SOP and GMP guidelines

CLO 2: Select[5] the modern tools, sophisticated instruments for drug testing, discovery & development process.

CLO 3:Develop[6] the skills that would inculcate entrepreneurship and industrial orientation.

CLO 4: Evaluate[5] assigned modules individually as a team to create an innovative ideas related to health care system.

CLO 5: Appraise[5] a sense of understanding to undertake a project, its financial implication and necessity for continuous learning.

CLO 6:Design[6] and evaluate NDDS

CLO 7:Create[6] preformulation, validation of product with the view of tech transfer.

Course Contents

Module –I Introduction (25Hrs)

• Pharma industry

• General aspects to be considered on formulation selection

• SOP handling

• Steps in Pharmaceutical Manufacturing

• GMP

Module –II Industrial Aspects of Tablet Technology (25Hrs)

• Literature review for tablet manufacturing

• Preformulation

• Providing Control number and documentation

• Trial batch and optimization

• Lab Validation

• Scale up validation

• Tech transfer

• Regulatory clearance in detail

Module –III Instruments handling (50Hrs)

- Tablet compression, coating
- Dissolution and disintegration apparatus
- Orbitary shaker
- High speed homogenizer
- Stability chamber

Module –IV Novel Drug Delivery systems (50Hrs)

- Control/sustain drug delivery system
- Liposomes
- Fast dissolving/disintegrating drug delivery
- Nano-emulsions

Practice school 2 – Quality control and Quality assurance of Pharmaceuticals

Course Learning Outcomes:

CLO 1: Discuss[2] about the basic and advanced literature review amalgated with SOP and GMP guidelines

CLO 2: Select[5] the modern tools, sophisticated instruments for drug testing, discovery & development process.

CLO 3:Develop[6] the skills that would inculcate entrepreneurship and industrial orientation.

CLO 4: Evaluate[5] assigned modules individually as a team to create an innovative ideas related to health care system.

CLO 5: Appraise[5] a sense of understanding to undertake a project, its financial implication and necessity for continuous learning.

CLO 6: Understand[2] significance and concept of advanced instrumentation & become proficient in advanced instruments.

CLO7: Interpret[2] the quality assurance processes in pharma industry and documentation process.

Course Contents

Module – I Introduction (25 Hrs)

- Introduction to analytical techniques
- Importance and preparation of SOPs
- Guidelines for GLP as per the regulatory aspects
- Introduction to GC/MS and LC/MS

Module – II Industrial Aspects of QA & QC (25 Hrs)

- Calibration of glasswares
- Calibration of analytical instruments
- Preparation of analytical reagents and working standards
- Monograph analysis of Pharmaceuticals
- Analytical method developments and validation

Module – III Instruments handling (75 Hrs)

- Digital balance
- UV Spectrophotometer

• HPLC

• FTIR

• Dissolution and disintegration apparatus

• Friability and hardness tester

Module – IV Documentation (25 Hrs)

• Preparation of Reports

• GLP, GDP

Practice School 3 – Herbal Technology

Course Learning Outcomes:

CLO 1: Discuss[2] about the basic and advanced literature review amalgated with SOP and GMP guidelines

CLO 2: Select[5] the modern tools, sophisticated instruments for drug testing, discovery & development process.

CLO 3:Develop[6] the skills that would inculcate entrepreneurship and industrial orientation.

CLO 4: Evaluate[5] assigned modules individually as a team to create an innovative ideas related to health care system.

CLO 5: Appraise[5] a sense of understanding to undertake a project, its financial implication and necessity for continuous learning.

CLO 6: Develop[6] advance extraction, isolation and identification techniques for herbal drugs by using standard guidelines of WHO

CLO7: Formulate[6] and evaluate herbal products by using AYUSH guidelines

Course Contents

Module – I Identification and Extraction of Herbs (15 Hrs)

- WHO guidelines for standardization of plant material
- AYUSH guidelines for herbal products
- Advanced extraction techniques
- Introduction to phytochemical markers

Module – II Isolation techniques (60 Hrs)

- General and advanced Isolation techniques
- Chromatographic techniques
- Column chromatography, HPTLC, HPLC.
- Rotary evaporator
- Preparative chromatography

Module – III Quantitative evaluation of Phytoconstituents (10 Hrs)

- Assay for phenols, alkaloids, glycosides and tannins.

Module – IV Formulation and evaluation of herbal product (65 Hrs)

- Preparation and evaluation of herbal formulations Tablet, Syrup, Asava, Granules etc.,

Practice School 4 – Drug design and Process chemistry

Course Learning Outcomes:

CLO 1: Discuss[2] about the basic and advanced literature review amalgated with SOP and GMP guidelines

CLO 2: Select[5] the modern tools, sophisticated instruments for drug testing, discovery & development process.

CLO 3:Develop[6] the skills that would inculcate entrepreneurship and industrial orientation.

CLO 4: Evaluate[5] assigned modules individually as a team to create an innovative ideas related to health care system.

CLO 5: Appraise[5] a sense of understanding to undertake a project, its financial implication and necessity for continuous learning.

CLO 6: Discuss[2] various tools available for *in-silico* studies

CLO7:Design[6]and Development of medicinal agents possessing specific pharmacological action

Course Contents

Module – I Basic Experimental Techniques in chemistry (30 Hrs)

- Introduction to hazardous chemicals and MSD
- Handling of hazardous chemicals and safety requirements
- Purification of organic solvents
- Crystallization techniques for purification of chemical compounds

Module – II Synthetic Chemistry (70 Hrs)

- Microwave assisted organic Synthesis
- Development of thin layer chromatography using silica gel
- Column chromatographic techniques

Module – III In-silico techniques (10 Hrs)

- Protein crystallographic data and protein data bank
- Protein modelling techniques

Module – IV New drug design techniques (40 Hrs)

- Introduction to software's
- Docking study, QSAR and ADMET prediction and interpretation

Practice School 5 – Pharmacovigilance

Course Learning Outcomes:

CLO 1: Discuss[2] about the basic and advanced literature review amalgated with SOP and GMP guidelines

CLO 2: Select[5] the modern tools, sophisticated instruments for drug testing, discovery & development process.

CLO 3:Develop[6] the skills that would inculcate entrepreneurship and industrial orientation.

CLO 4: Evaluate[5] assigned modules individually as a team to create an innovative ideas related to health care system.

CLO 5: Appraise[5] a sense of understanding to undertake a project, its financial implication and necessity for continuous learning.

CLO 6: Create[6] questionnaires in relation to case studies of diseases.

CLO7: To understand[2] adverse events reporting system in pharmacovigilance.

Course Contents

Module –I Introduction of Pharmacovigilance (25Hrs)

- Overview of Pharmacovigilance
- Standard Terms and Terminology in Pharmacovigilance
- Vaccine safety

Module –II Medical Evaluation of Adverse Events in Pharmacovigilance (50Hrs)

- Adverse Event Reporting System and Form
- Diagnosis and Managements of ADRs
- Medical Evaluation of AE

Module –III Case Processing (25Hrs)

- Global Perspective of Pharmacovigilance
- Single Case Processing
- Case Narrative Writing

Module –IV Pharmacovigilance Reporting and Risk assessment & Evaluation (50Hrs)

- Quality System in PV

- Expedited Reporting Criteria
- PSUR & PBRER
- PV Database and Signal detection
- Risk Assessment & Managements

Semester VIII

Course Code	Name of the course	No. of hours	Tutorial	Credit points	Internal		ESE
					CA	SE	
BP801T	Biostatistics and Research Methodology	3	1	4	10	15	75
BP802T	Social and Preventive Pharmacy	3	1	4	10	15	75
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	**4 + 4 = 8**	**20**	**30**	**150**
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**	-	-	150
	Total	24	4	22	40	60	450
					550		

BP801T.Biostatistics and Research Methodology (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP801T	Biostatistics and Research Methodology (Theory)	3	1	-	4	Theory(100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

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

CLO1.State1 the meaning of different statistical terms.

CLO2.Discuss2 the fundamentals of statistical techniques

CLO3.Evaluate5 experimental data using various statistical techniques**.**

CLO4.Illustrate4 the research, graphical presentation, research methodology and experimental designs in pharmacy.

CLO5.Employ3 statistical software's in industrial and clinical trial problems.

Course Content:

UNIT	Description	Hours
I	**Introduction:** Statistics, Biostatistics, Frequency distribution **Measures of central tendency:** Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion:** Dispersion, Range, standard deviation, Pharmaceutical problems **Correlation:** Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	**10**
II	**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression, Logistical regression, Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test:** t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference. Applications of statistical tests in pharmacy.	**10**

III	**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **Introduction to Research**: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	**10**
IV	Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials Problems:** Statistical Analysis Using Excel, SPSS, MINITAB ®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's with its applications to Industrial and Clinical trial approach**.**	**8**
V	**Design and Analysis of experiments:** **Factorial Design:** Definition, 2^2, 2^3 design. Advantage of factorial design **Response Surface methodology:** Central composite design, Historical design, Screening and Optimization Techniques	**7**

Recommended Books (Latest Editions)

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

BP802T.Social and Preventive Pharmacy (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP802T	Social and Preventive Pharmacy (Theory)	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges.

Objectives:

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

CLO1.State1 the meaning of various terminologies involved in social and Preventive pharmacy.

CLO2.Explain2 the concept of health education, nutrition and disease along with factors affecting them.

CLO3.Illustrate4 the measures of prevention and control for communicable and non-communicable diseases.

CLO4.Describe2 the aspects of various national and WHO health and welfare Programme.

CLO5. Illustrate5 the impact of socio-cultural factors and urbanization on health.

Course Content

UNIT	Description	Hrs
I	**Concept of health and disease:** Terminologies used related to health and disease**.** Definition, concepts and evaluation of Public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. **Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. **Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health **Hygiene and health:** personal hygiene and health care; avoidable habits	**10**
II	**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken, guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, metabolic syndrome drug addiction-drug substance abuse.	**10**
III	**National health programs, its objectives, functioning and outcome of the following:**	**10**

	HIV AND AIDS control Programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal Immunization programme, National programme for control of blindness, Pulse polio programme.	
IV	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	**08**
V	**Community services in rural, urban and school health:** Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	**07**

Recommended Books (Latest edition):

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

Recommended Journals:

Research in Social and Administrative Pharmacy, Elsevier, Ireland

BP803ET. Pharma Marketing Management (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP803ET	Pharma Marketing Management (Theory)	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course student shall able to

CLO1. State1 the types and meaning of various terminologies in pharmaceutical marketing management.

CLO2. Describe2market and its emerging concepts, characteristics, strategies, analysis and research in pharmaceutical market.

CLO3. Explain2 the product design and promotional activities in pharmaceutical industry.

CLO4 Illustrate4 the channels, its importance and personnel involved in pharmaceutical marketing.

CLO5. Illustrate4 the price control of pharmaceutical products.

Course Content

UNIT	Description	Hours
I	**Marketing:** Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior. **Pharmaceutical market:** Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio- psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research. Preparation of questionnaire, design survey, building business plan and introduction to data analytics software	**10**
II	**Product decision:** Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	**10**
III	**Promotion:** Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.	**10**
IV	**Pharmaceutical marketing channels: Designing channel, channel members,**	**10**

selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

V	**Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). **Emerging concepts in marketing:** Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	**10**

Recommended Books (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S &Nanakamari, S: Marketing Managemnt:Global Perspective, Indian Context, Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP804ET	PHARMACEUTICAL REGULATORY SCIENCE	3	1	-	4	Theory(100Marks)	CA	10	10	100
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, student shall able to

CLO1. State[1] the meaning of various terminologies of Regulatory Science.

CLO2. Illustrate[4]the regulatory authorities, agencies and approval processes.

CLO3. Describe[2] new drug discoveries and development process and its registration.

CLO4. Explain[2] clinical trials, initiation, conduction, monitoring and evaluation.

CLO5. Describe[2] the concepts of Regulatory science in pharmaceutical industry.

Course content

UNIT	Description	Hours
I	**New Drug Discovery and Development** Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.	10
II	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), and Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. **Regulatory authorities and agencies** Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada, Brazil, South Africa and Russia (Organization structure and types of applications)	10
III	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research	10

IV Clinical trials **08**

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

V Regulatory Concepts **07**

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

Recommended books (Latest edition):

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

BP805ET. PHARMACOVIGILANCE (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP805ET	Pharmacovigilance (Theory)	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives

CLO1. State[1] history, terminologies, basic concept of pharmacovigilance, adverse drug reactions and pharmacogenomics.

CLO2. Describe[2] drug & disease classification, drug dictionaries, coding, information resources, and establishing programs in pharmacovigilance as per regulatory guidelines.

CLO3. Illustrate[3] vaccine safety surveillance, methods and communication in pharmacovigilance and ADR.

CLO4. Summarise[5] drug safety data generation and its evaluation.

CLO5. Explain[4] guidelines and requirements of pharmacovigilance as per CDSCO, ICH, and CIOMs.

Course content

UNIT	Description	Hours
I	**Introduction to Pharmacovigilance** ▪ History and development of Pharmacovigilance ▪ Importance of safety monitoring of Medicine ▪ WHO international drug monitoring programme ▪ Pharmacovigilance Program of India (PvPI) ▪ Roles and responsibilities of clinical pharmacist **Introduction to adverse drug reactions** • Definitions and classification of ADRs • Detection and reporting • Methods in Causality assessment • Severity and seriousness assessment • Predictability and preventability assessment • Management of adverse drug reactions	10

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

II Drug and disease classification **10**

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialized resources for ADRs

Establishing pharmacovigilance programme

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

Software resources

- Micromedex software

III Vaccine safety surveillance **10**

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

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

Poison information surveillance Communication in Pharmacovigilance

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

IV Safety data generation **08**

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

ICH Guidelines for Pharmacovigilance

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

V. Pharmacogenomics of adverse drug reactions 07

- Genetics related ADR with example focusing PK parameters

Drug safety evaluation in special population

- Pediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

Chronic diseases

- HIV and multiple organ failure
-

Recommended books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and **Bartlett Publishers.**
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata

BP806ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Passing Min. (%)
BP806ET	Quality Control & Standardization of Herbals	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

Upon completion of the course, student shall be able to

CLO1. State[1] the types and meaning of various terminologies related to quality control and standardization of herbal drugs.

CLO2. Describe[2] WHO, ICH, TCM and EU Guidelines for quality control of herbal drugs.

CO3. Illustrate[4] the development, standardization, evaluation and clinical monitoring of herbal drugs and cosmetics.

CO4. Summarize[5] the herbal research guidelines and pharmacopoeias.

CO5. Explain[2] the regulatory requirements for approval of herbal medicine in national and international markets.

Course content

UNIT	Description	Hours
I	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage Forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intened for use, Adulteration and methods to evaluate adulteration	10
II	**Quality assurance in herbal drug industry** cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines. WHO Guidelines on GACP for Medicinal Plants.	10

III	EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines. Guidelines regarding traditional Chinese medicines (TCM)	**10**
IV	Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.	**08**
V	Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	**07**

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-
8. WHO. Quality Control Methods for Medicinal Plant Materials,World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn.
10. World Health Organization, Geneva, 1981.
11. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
12. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
13. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP807ET	Computer aided drug design (Theory)	3	1	-	4	Theory(100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

CLO1.State[1]the definition and meaning and classes of different terminologies used in CADD.
CLO2.Determine[5]the physiochemical parameters of drugs using molecular modeling, QSAR and virtual screening techniques.
CLO3.Illustrate[4]the stages in drug discovery, drug development and drug design.
CLO4. Illustrate[4] the role and applications and methods of Informatics and molecular modelling in drug design.
CLO5.Compare[4] between various methods used in drug discovery, drug development and drug design.

Course content

UNIT	Description	Hours
I		10
	Introduction to Drug Discovery and Development: Stages of drug discovery and development **Lead discovery and Analog Based Drug Design:** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. **Analog Based Drug Design:** Bioisosterism, Classification, Bioisosterice placement. Any three case studies	
II		10
	Quantitative Structure Activity Relationship (QSAR): SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.	

III **10**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

IV **08**

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

V **07**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended books (Latest edition):

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" JohnWiley& Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP808ET	Cell and molecular biology (Elective subject)	3	1	-	4	Theory(100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objective:

CLO1. **Summarize**[5]history, basic concepts of cell and molecular biology with its applications.
CLO2.Explain[2]concept of DNA and RNA its functioning, transcription and translation.
CLO3. **Illustrate**[3]amino acids and proteins structure, synthesis, cellular processes, regulations and significance.
CLO4. **Illustrate**[3]concept of genetics, cellular activities, division, checkpoints and analysis of cell cycle
CLO5. **Illustrate**[3]cell signaling, receptors, pathways and controlling mechanisms.

Course content

UNIT	Description	Hours
I		**10**
	a) **Cell and Molecular Biology:** Definitions theory and basics and Applications. b) **Cell and Molecular Biology:** History and Summation. c) **Properties of cells and cell membrane** d) **Prokaryotic versus Eukaryotic** e) **Cellular Reproduction** f) **Chemical Foundations** – an Introduction and Reactions (Types)	
II		**10**
	a) **DNA and the Flow of Molecular Information** b) **DNA Functioning** c) **DNA and RNA** d) **Types of RNA** e) **Transcription and Translation**	

III **10**

a) **Proteins**: Defined and Amino Acids pool and its significance
b) **Protein Structure**
c) **Regularities in Protein Pathways**
d) **Cellular Processes**
e) **Positive Control and significance of Protein Synthesis**
f) **Introduction to proteomics**

IV **08**

a) **Science of Genetics**
b) **Transgenic and Genomic Analysis with its application**
c) **Cell Cycle analysis**
d) **Mitosis and Meiosis**
e) **Cellular Activities and Checkpoints**

V **07**

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

Recommended books (Latest edition):

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

BP809ET. COSMETIC SCIENCE (Theory)

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP809ET	Cosmetic science(theory)	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

The purpose of this course is to introduce to students with number of materials and ingredient research related to cosmetics, therapeutic options for skin, hair and body care, product formulations and ingredients, cosmetic olfactory research developments, technologies in cosmetic product development, testing of skin and hair products.

Objective:

CLO1. **State**[1]the types and meaning of various terminologies related to cosmetic science.

CLO2. **Explain**[2]the anatomy and associated problems of skin, hair and oral cavity.

CLO3. **Illustrate**[4]the categories, applications of cosmetic excipients, products and their formulations.

CLO4. **Describe**[2]the formulation, merits, demerits, mechanisms of cosmetics and oral care products.

CLO5. Illustrate[4]the principles, methods and techniques of cosmetics evaluation.

Course content

UNIT	Description	Hours
I		**10**
	Classification of cosmetic and cosmeceutical products **Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs** **Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application **Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle. **Nail:** Basic structure and function of nail. **Oral Cavity:** Common problem associated with teeth and gums**.**	
II		**10**
	Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream, Anti-ageing creams and their advantages and disadvantages. Application of these products in formulation of cosmecuticals. **Antiperspants & deodorants**- Actives & mechanism of action. **Principles of formulation and building blocks of Hair care products:** Conditioning shampoo, Hair conditioner, anti-dandruff shampoo, Hair oils, Hair strengthening and waving products **Principles of formulation and building blocks of oral care products:** Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash, Denture cleaners	

Principles of formulation and building blocks of Eye care products: Eye drops, eye lotions, ointments, contact lens solutions and mascara, eyeliners, eye makeup remover and eye shadow

Principles of formulation and building blocks of Nail care products: Nail lacquer, Enamel remover, nail cream, nail bleach, cuticle remover, cuticle softener.

Introduction, formulation and evaluation of Lipsticks: Raw material, Manufacturing process, defects and evaluation parameters

Introduction, formulation and evaluation of Rouge: Raw material, Manufacturing process, defects and evaluation parameters

III **10**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

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

IV **08**

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

V **07**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes.

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

Recommended books (Latest edition):

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.

2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.

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

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing(%)
BP810ET	Pharmacological screening methods	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

CLO1. Explain[2] breeding, pharmacological aspects and guidelines for experiments on laboratory animals.
CLO2.Summarise[5] basic concept of preclinical screening and methods.
CLO3.Describe[2] preclinical screening of bioactive of various pharmacological classes.
CLO4.Analyze[4] dose of drug and experimental data.
CLO5.Explain[2] fundamentals of bio-statistics and research methodology.

Course content

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

III	**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anesthetic	**10**
IV	**Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	**12**
V	**Research methodology and Bio-statistics** Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students't' test and One-way ANOVA. Graphical representation of data	**05**

Recommended books (Latest edition):

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

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP811ET	Advanced instrumentation techniques	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

CLO1. State[1] the definition, different classes, terminologies, principle, procedure and applications used in different instrumentation techniques.

CLO2.Explain[2] the principle and sample preparation techniques involved in the radio-immuno assay.

CLO3. Evaluate[5] the drugs by spectroscopic and thermal techniques and their characterization.

CLO4. Discuss[2] the importance of calibration and validation process of analytical instruments as per ICH and USFDA guidelines.

CLO5.Compare[5] merit, demerit and differences in the selected instrumental analytical techniques

Course content

UNIT	Description	Hours
I	**Nuclear Magnetic Resonance spectroscopy** Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications. **Mass Spectrometry** Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications	**10**
II	**Thermal Methods of Analysis:** Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, X ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.	**10**

III		**10**
	Calibration and validation-as per ICH and USFDA guidelines **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC	
IV		**08**
	Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay **Extraction techniques**: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction	
V		**07**
	Hyphenated techniques -LC-MS/MS, GC-MS/MS, HPTLC-MS.	

Recommended books (Latest edition):

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing (%)
BP812ET	Dietary Supplements and Nutraceuticals	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

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

Objectives:

CLO1. State[1] the types and meaning of various terminologies related to dietary Supplements, nutraceuticals and phytopharmaceuticals.

CLO2. Explain[2] the nutraceuticals, dietary supplements, functional foods, antioxidants, their pharmacology and role in public health.

CLO3. Describe[2] the phytochemicals as nutraceuticals including occurrence and characteristics.

CLO4. Summarize[5] the free radicals and their role in various disease conditions.

CLO5. Discuss[2] regulatory aspects of dietary supplements and phytopharmaceuticals.

Course content

UNIT	Description	Hours
I		07
	a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as Nutraceuticals /functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.	
II		15
	Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin b) Sulfides: Diallyl sulfides, Allyl trisulfide. c) Polyphenolics: Reservetrol d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics.:Fructo oligosaccharides, Lacto bacillum	

f) Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans

g) Tocopherols

h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

III **07**

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

B) Dietary fibers and complex carbohydrates as functional food ingredients.

IV **10**

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

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

C) Functional foods for chronic disease prevention.

V **06**

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

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

C) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

Recommended books (Latest edition):

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

BP 813 ET. PHARMACEUTICAL PRODUCT DEVELOPMENT

45 Hours

Course Code	Course Title	L	T	P	C	Component	Exam	WT		Min. Passing(%)
BP813ET	Pharmaceutical product development	3	1	-	4	Theory (100Marks)	CA	10	10	50
							Sessional-1	15	15	
							Sessional-2	15		
							ESE		75	

Scope:

This course includes the formulation of product and selected for further development is fully optimized and complies with the design specification and critical quality parameters.

Objectives:

CLO1. State[1] the definition, objectives, regulations related to preformulation, development and stability. Quality control testing of different dosage forms.

CLO2. Explain[2] the pharmaceutical excipients used in pharmaceutical product development.

CLO3. Discuss[2] the pharmaceutical excipients used in tablet, capsules, parenteral, aerosols product, formulation of NDDS, Coating material and compressible vehicles with industrial applications.

CLO4. Discribe[2] the optimization techniques used in pharmaceutical product development with applications.

CLO5. Illustrate[5] the Selection and quality control testing of packaging materials and regulatory consideration for pharmaceutical Product development.

Course content

UNIT	Description	Hours
I	Introduction to pharmaceutical product development, objectives, and regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms	10
II	An advanced study of Pharmaceutical Excipients in pharmaceutical product Development with a special reference to the following categories i. Solvents and solubilizers ii. Cyclodextrins and their applications iii. Non - ionic surfactants and their applications iv. Polyethylene glycols and sorbitols v. Suspending and emulsifying agents vi. Semi solid excipients	10
III	An advanced study of Pharmaceutical Excipients in pharmaceutical product Development with a special reference to the following categories i. Tablet and capsule excipients ii. Directly compressible vehicles iii. Coat materials iv. Excipients in parenteral and aerosols products	10

v. Excipients for formulation of NDDS

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

IV **08**

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

V **07**

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

Recommended Books (Latest editions)

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

Facilities


Administrative Building


Auditorium


Reading Hall


Well Equipped Classroom


Sophisticated Computer Lab


Advanced Laboratories


Workshop


Food Court


Stadium


Gymnasium


Music Academy


Transport

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