

## **School of Pharmacy (AVIPS)**



Shobhit University, Gangoh

**(Established by UP Shobhit University Act No. 3,  
2012)**

**School Of Pharmacy**

**Ordinances, Regulations & Syllabus**

**For**

**Master of Pharmacy (M.Pharm) 2 Year Programme  
Semester Pattern  
(w.e.f. session 2019-2020)**

**Approved by PCI and adopted in the  
year 2019 (13<sup>th</sup> Meeting ,Board of  
Studies)**

## **CHAPTER -I:REGULATIONS**

### **1. Short Title and Commencement**

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) 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 authorities of the university.

### **2. Minimum qualification for admission**

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

### **3. Duration of the program**

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

### **4. Medium of instruction and examinations**

Medium of instruction and examination shall be in English.

### **5. Working days in each semester**

Each semester shall consist of not less than 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 the month of December/January to May/June in every calendar year.

## 6. Attendance and progress

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

## 7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, 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/per activity.

### Credit assignment

#### Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) 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 a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits, i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

### Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, 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.

## 8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

## 9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmacology	MPL

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry -I	4	4	4	100
MPC103T	Advanced Medicinal chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 4: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Experimental Pharmacology practical- II	4	4	4	100
MPL 205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650



Table – 5: Course of study for M. Pharm. III Semester  
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

\* Non University Exam

Table – 6: Course of study for M. Pharm. IV Semester  
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table – 7: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

\*Credit Points for Co-curricular Activities

Table – 8: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals	02

Note: International Conference: Held Outside India International Journal:

The Editorial Board Outside India

\*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.

## 10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:  
A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme 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 Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

## **11. Examinations/Assessments**

The schemes for internal assessment and end semester examinations are given in Table – 9.

### **End semester examinations**

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

Tables – 9 : Schemes for internal assessments and end semester  
(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH	Cosmetic	10	15	1 Hr	25	75	3 Hrs	100

204T	and Cosmeceuticals							
MPH 205P	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

table: 10 (Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Cont inuous Mode	Sessional Exams		Total	Mar ks	Du rati on	
			Mar ks	Durati on				
SEMESTER I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Organic Chemistry –I	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC105P	Pharmaceutic al Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry –II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutic al Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic	20	30	6 Hrs	50	100	6	150

	al Chemistry Practical II						Hrs	
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

	Assurance							
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3Hrs	100
MPA205P	Pharmaceutical Analysis- II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 11: Schemes for internal assessments and end semester examinations(Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL10 5P	Experimental Pharmacology – I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL20 1T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL20 3T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL20 4T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL20 5P	Experimental Pharmacology – II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650



Tables – 12: Schemes for internal assessments and end semester examinations(Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion Presentation / (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion Presentation / (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

\*Non University Examination

## Internal assessment: Continuous mode

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

Table – 13: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 14: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

### 11.2.1. Sessional Exams

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

## 12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm programme if he/she secures at least 50% marks in that particular course including internal assessment.

## 13. Carry forward of marks

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

#### 14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

#### 15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 15. The exact dates of examinations shall be notified from time to time.

Table – 15: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

#### 16. Allowed to keep terms (ATKT):

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

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

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

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

#### 17. Grading of performances

##### Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 16.

Table – 16: Letter grades and grade points equivalent to  
Percentage of marks and performances

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

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

### 18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C<sub>1</sub>, C<sub>2</sub>, C<sub>3</sub> and C<sub>4</sub> and the student’s grade points in these courses

are G<sub>1</sub>, G<sub>2</sub>, G<sub>3</sub> and G<sub>4</sub>, respectively, and then students’ SGPA is equal to:

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

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

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

### 19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA

shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

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

## 20. Declaration of class

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

Distinction = CGPA of 7.50 and above

First Class

Second Class

= CGPA of 6.00 to 7.49

= CGPA of 5.00 to 5.99

## 21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

### Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks

Total	500 Marks
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### Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks

Total	250 Marks
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## **22. Award of Ranks**

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

## **23. Award of degree**

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

## **24. 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.

## **25. Revaluation I Retotaling of answer papers**

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

## **26. Re-admission after break of study**

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

**Course Programme-  
Pharmaceutics**

### **Program Educational Objectives (PEOs)**

Program Educational Objectives (PEOs) for a Master of Pharmacy (M.Pharm) with a focus on Pharmaceutics program typically outline the broad goals that graduates are expected to achieve in their professional careers and further education.

**PEO1 Comprehensive Understanding of Pharmaceutics:** Graduates will possess a thorough understanding of the principles and practices of pharmaceutical formulation, design, and delivery systems, including their biochemical and biopharmaceutical aspects.

**PEO2 Research and Development Expertise:** Graduates will engage in innovative research and development, contributing to the advancement of novel drug formulations and technologies that enhance therapeutic efficacy and safety.

**PEO3 Application of Advanced Analytical Techniques:** Graduates will demonstrate proficiency in employing advanced analytical techniques for the characterization and quality assessment of pharmaceutical products.

**PEO4 Regulatory Knowledge and Compliance:** Graduates will understand regulatory frameworks and guidelines related to pharmaceutical development, ensuring compliance throughout the drug development process.

**PEO5 Critical Thinking and Problem-Solving Skills:** Graduates will apply critical thinking and problem-solving skills to address complex challenges in drug formulation and delivery, optimizing therapeutic outcomes.

**PEO6 Collaborative Skills in Interdisciplinary Teams:** Graduates will effectively collaborate with healthcare professionals and researchers from diverse disciplines to enhance drug development and patient care.

**PEO7 Ethical and Professional Standards:** Graduates will uphold high ethical standards and professional integrity in their research and practice, prioritizing patient safety and the responsible conduct of research.

**PEO8 Effective Communication Skills:** Graduates will be able to communicate complex pharmaceutical concepts and research findings clearly and effectively to various stakeholders, including peers, regulatory agencies, and the public.

**PEO9 Global Health Awareness:** Graduates will understand global health issues and contribute to developing pharmaceutical solutions that improve access to essential medicines and enhance public health outcomes.



### **Programme Specific Objectives (PSO's)**

**PSO1 Advanced Pharmaceutical Knowledge:** Graduates will demonstrate a deep understanding of drug development processes, including formulation, synthesis, and quality control of pharmaceutical products.

**PSO2 Clinical Pharmacy Skills:** Graduates will apply clinical knowledge to assess patient medication regimens, provide pharmaceutical care, and contribute to interdisciplinary healthcare teams.

**PSO3 Research Methodology:** Graduates will be proficient in research methodologies, enabling them to design, conduct, and analyze pharmaceutical research effectively, including clinical trials and drug studies.

**PSO4 Pharmacokinetics and Pharmacodynamics:** Graduates will understand the principles of pharmacokinetics and pharmacodynamics, applying this knowledge to optimize drug therapy for diverse patient populations.

**PSO5 Regulatory Affairs Expertise:** Graduates will navigate regulatory frameworks and guidelines, ensuring compliance in the development and marketing of pharmaceutical products.

**PSO6 Formulation Development:** Graduates will be skilled in the development and evaluation of various dosage forms, utilizing modern techniques and technologies for innovative drug delivery systems.

**PSO7 Quality Assurance and Control:** Graduates will implement quality assurance and control measures in pharmaceutical manufacturing and laboratory settings, ensuring the safety and efficacy of products.

**PSO8 Patient Counseling and Education:** Graduates will effectively communicate medication-related information to patients, enhancing adherence and promoting safe medication use.

**PSO9 Ethical and Professional Responsibility:** Graduates will adhere to ethical guidelines and professional standards, promoting integrity and accountability in their pharmacy practice.

**PSO10 Interprofessional Collaboration:** Graduates will work collaboratively with healthcare professionals, understanding the roles of various team members in providing comprehensive patient care.

### **(Programme Outcome Objectives (POO's)**

**POO1 Pharmaceutical Knowledge Application:** Graduates will apply advanced knowledge of pharmaceutics to develop, formulate, and evaluate pharmaceutical products effectively.

**POO2 Research Competence:** Graduates will demonstrate the ability to design and conduct independent research in pharmaceutics, utilizing appropriate methodologies and analytical techniques.

**POO3 Formulation Development Skills:** Graduates will be skilled in developing various drug delivery systems, optimizing formulations for different routes of administration.

**POO4 Analytical Proficiency:** Graduates will utilize advanced analytical techniques to assess the quality and stability of pharmaceutical formulations, ensuring compliance with regulatory standards.

**POO5 Clinical Application:** Graduates will apply their knowledge of pharmacokinetics and pharmacodynamics to optimize drug therapy and improve patient outcomes.

**POO6 Regulatory Compliance:** Graduates will understand and navigate regulatory requirements and guidelines affecting pharmaceutical development and commercialization.

**POO7 Ethical Standards:** Graduates will uphold ethical principles in research and practice, ensuring patient safety and adherence to professional standards.

**POO8 Communication Skills:** Graduates will effectively communicate complex pharmaceutical concepts and research findings to a variety of audiences, including healthcare professionals and regulatory agencies.

**POO9 Collaborative Teamwork:** Graduates will work effectively in interdisciplinary teams, contributing to collaborative problem-solving and enhancing healthcare delivery.

**POO10 Commitment to Lifelong Learning:** Graduates will demonstrate a commitment to lifelong learning, actively engaging in professional development and staying updated on advancements in pharmaceutics.

## PHARMACEUTICS(MPH)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 HOURS

- |    |   |           |
|----|---|-----------|
| 1. | a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy.  | 11<br>Hrs |
|    | b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy  |           |
|    | c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.   |           |
|    | d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.  |           |
| 2  | NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy. | 11<br>Hrs |

- |   |  |           |
|---|--|-----------|
| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy   | 11<br>Hrs |
| 4 | Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography b) Thin Layer chromatography<br>c) Ion exchange chromatography d) Column chromatography<br>e) Gas chromatography f) High Performance Liquid chromatography<br>g) Affinity chromatography   | 11<br>Hrs |
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction. | 11<br>Hrs |
| 6 | Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.  |           |

#### REFERENCES

5 Hrs

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## DRUG DELIVERY SYSTEMS (MPH 102T)

### SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

### OBJECTIVES

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

### THEORY

60 Hrs

- |    |   |           |
|----|---|-----------|
| 1. | Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. | 10<br>Hrs |
| 2  | Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.  | 10<br>Hrs |
| 3  | Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.  | 10<br>Hrs |
| 4  | Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.  |           |

06  
Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

## REFERENCES

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, Editor- Edith Mathiowitz, Published by WileyInterscience 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) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

## MODERN PHARMACEUTICS (MPH 103T)

### Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

### Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

### THEORY

60 HRS

- |    |    |   |           |
|----|----|---|-----------|
| 1. | a. | Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.  | 10<br>Hrs |
|    | b. | Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation   | 10<br>Hrs |
| 2  |    | Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.  | 10<br>Hrs |
| 3  |    | cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. | 10<br>Hrs |

- |   |  |           |
|---|--|-----------|
| 4 | Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.  | 10<br>Hrs |
| 5 | Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f <sub>2</sub> and f <sub>1</sub> , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. | 10<br>Hrs |

## REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.



## REGULATORY AFFAIRS (MPH 104T)

### Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

### Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

### THEORY

60 Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs
- b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

## REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer,Marcel Dekker series, Vol.143
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 AGuarino, 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. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
- 10.<https://www.tga.gov.au/tga-basics>

**PHARMACEUTICS PRACTICALS - I**  
**(MPH 105P)**

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

# MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

## Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

## Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

## THEORY

60 Hrs

- |  |           |
|--|-----------|
| 1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.  | 12<br>Hrs |
| 2 Targeting Methods: introduction preparation and evaluation.<br>Nano Particles & Liposomes: Types, preparation and evaluation.  | 12<br>Hrs |
| 3 Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.   | 12<br>Hrs |
| 4 Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.  | 12<br>Hrs |
| 5 Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. | 12<br>Hrs |

## REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

### Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

### Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

### THEORY

60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs

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|---|---|-----------|
| 2 | Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.                       | 12<br>Hrs |
| 3 | Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of $k_{max}$ and $v_{max}$ . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.   | 12<br>Hrs |
| 4 | Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. | 12<br>Hrs |
| 5 | Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.   | 12<br>Hrs |

## REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmarkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2<sup>nd</sup> edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1<sup>st</sup> edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

## COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

### Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

### Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

### THEORY

60 Hrs

1. a. Computers in Pharmaceutical Research and Development: 12  
 A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development; Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling Hrs  
 b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.
- 2 Computational Modeling Of Drug Disposition: Introduction  
 ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside 12  
 Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. Hrs



3	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

#### REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1<sup>st</sup> Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James G. Boylan, Marcel Dekker Inc, New York, 1996.

## COSMETICS AND COSMECEUTICALS (MPH 204T)

### Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

### Objectives

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

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

### THEORY

60 Hrs

1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12 Hrs
  - 2 Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs
  - 3 Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. 12 Hrs
- Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

- Controversial ingredients: Parabens, formaldehyde liberators, dioxane.
- |   |   |           |
|---|---|-----------|
| 4 | Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. | 12<br>Hrs |
| 5 | Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like Cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.           | 12<br>Hrs |

## REFERENCES

1. Harry's Cosmeticology. 8<sup>th</sup> edition.
2. Poucher's perfume cosmetics and Soaps, 10<sup>th</sup> edition.
3. Cosmetics - Formulation, Manufacture and quality control, P.P. Sharma, 4<sup>th</sup> edition
4. Handbook of cosmetic science and Technology A.O. Bareil, M. Paye and H.I. Maibach. 3<sup>rd</sup> edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

## PHARMACEUTICS PRACTICALS - II

### (MPH 205P)

1. To study the effect of temperature change , non solvent addition,incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly proteinbound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline<sup>R</sup> software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert<sup>®</sup> Software
13. Formulation data analysis Using Design Expert<sup>®</sup> Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, dandruff

**Course Programme-  
Pharmaceutical chemistry**

### **Program Educational Objectives (PEOs)**

Program Educational Objectives (PEOs) for a Master of Pharmacy (M.Pharm) program typically outline the broad goals that graduates are expected to achieve in their professional careers and further education. Here are some common PEOs for an M.Pharm program:

**PEO1 Professional Competence:** Graduates will demonstrate advanced knowledge and skills in pharmaceutical sciences, enabling them to contribute effectively in various sectors such as industry, academia, and healthcare.

**PEO2 Research and Innovation:** Graduates will engage in research activities, promoting innovation and development of new drug formulations, therapeutic approaches, and pharmaceutical technologies.

**PEO3 Leadership and Teamwork:** Graduates will exhibit leadership qualities and the ability to work collaboratively in multidisciplinary teams, enhancing their effectiveness in professional settings.

**PEO4 Ethical Practice:** Graduates will uphold ethical standards and practices in pharmacy, ensuring patient safety, regulatory compliance, and responsible conduct in research and practice.

**PEO5 Ethical Lifelong Learning:** Graduates will demonstrate a commitment to lifelong learning and professional development, staying updated with the latest advancements in the pharmaceutical field.

**PEO6 Ethical Community Engagement:** Graduates will engage with the community, promoting public health initiatives and contributing to the education of patients and healthcare professionals about medication use and safety.

**PEO7 Critical Thinking and Problem-Solving:** Graduates will apply critical thinking and analytical skills to address complex pharmaceutical problems, making informed decisions based on scientific evidence.

**PEO8 Regulatory Knowledge:** Graduates will possess a thorough understanding of regulatory frameworks governing pharmaceutical development, approval processes, and marketing, ensuring compliance in their practices.

**PEO9 Interdisciplinary Collaboration:** Graduates will effectively collaborate with healthcare professionals, researchers, and industry partners to enhance patient care and drive pharmaceutical innovation.

**PEO10 Communication Skills:** Graduates will demonstrate strong oral and written communication skills, effectively conveying complex pharmaceutical concepts to diverse audiences, including patients, colleagues, and regulatory bodies.

**PEO11 Pharmacovigilance and Safety:** Graduates will be equipped to monitor, evaluate, and manage drug safety, actively participating in pharmacovigilance activities to ensure the well-being of patients.

**PEO12 Global Perspective:** Graduates will develop a global perspective on healthcare and pharmaceutical practices, understanding the impact of cultural, economic, and policy factors on medication management.

### **Programme Specific Objectives (PSO's)**

**PSO1 Advanced Chemical Knowledge:** Graduates will demonstrate a thorough understanding of organic, inorganic, and medicinal chemistry principles as they apply to drug design and development.

**PSO2 Synthesis and Characterization:** Graduates will be skilled in the synthesis, purification, and characterization of pharmaceutical compounds using modern analytical techniques.

**PSO3 Drug Design and Development:** Graduates will apply knowledge of structure-activity relationships (SAR) and molecular modeling to design and develop new pharmaceutical agents.

**PSO4 Analytical Method Development:** Graduates will be proficient in developing and validating analytical methods for the quantitative and qualitative analysis of pharmaceutical substances.

**PSO5 Quality Assurance and Control:** Graduates will understand and implement quality assurance and control measures in pharmaceutical manufacturing processes to ensure product safety and efficacy.

**PSO6 Regulatory Affairs Knowledge:** Graduates will possess a comprehensive understanding of the regulatory frameworks governing the pharmaceutical industry, including drug approval processes and compliance requirements.

**PSO7 Interdisciplinary Collaboration:** Graduates will effectively collaborate with professionals in related fields, including pharmacology and pharmacognosy, to enhance drug development and therapeutic outcomes.

**PSO8 Research and Innovation:** Graduates will engage in innovative research projects, contributing to the field of pharmaceutical chemistry through publications and presentations.

**PSO9 Ethical Practice:** Graduates will adhere to ethical guidelines in research and pharmaceutical practice, ensuring integrity in all scientific endeavors.



### **Programme Outcome Objectives (POO's)**

**POO1 Knowledge Application:** Graduates will apply advanced knowledge of pharmaceutical sciences to solve complex problems in drug development, formulation, and patient care.

**POO2 Research Proficiency:** Graduates will demonstrate the ability to conduct independent research, critically analyze data, and contribute to scientific literature in the field of pharmacy.

**POO3 Clinical Judgment:** Graduates will make informed clinical decisions based on evidence-based practices, optimizing therapeutic outcomes for patients.

**POO4 Communication Skills:** Graduates will effectively communicate pharmaceutical information, both orally and in writing, to diverse audiences, including patients, healthcare professionals, and regulatory bodies.

**POO5 Ethical Standards:** Graduates will adhere to ethical principles in all aspects of pharmaceutical practice, ensuring patient safety and promoting public health.

**POO6 Team Collaboration:** Graduates will work effectively in interdisciplinary teams, contributing to comprehensive patient care and fostering collaboration among healthcare providers.

**POO7 Lifelong Learning:** Graduates will exhibit a commitment to lifelong learning, seeking out continuing education opportunities to stay updated with advancements in the pharmaceutical field.

**POO8 Regulatory Knowledge:** Graduates will understand and navigate the regulatory landscape governing pharmaceutical products, ensuring compliance with laws and guidelines.

**POO9 Patient-Centered Care:** Graduates will provide patient-centered pharmaceutical care, considering individual patient needs, preferences, and values in their practice.

**POO10 Innovation and Entrepreneurship:** Graduates will demonstrate the ability to innovate and explore entrepreneurial opportunities in the pharmaceutical industry, contributing to the development of new products and services.

## PHARMACEUTICAL CHEMISTRY (MPC)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs  
b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.  
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. 10 Hrs

- |   |   |           |
|---|---|-----------|
| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.   | 10<br>Hrs |
| 4 | <p>Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:</p> <ul style="list-style-type: none"> <li>a) Thin Layer chromatography</li> <li>b) High Performance Thin Layer Chromatography</li> <li>c) Ion exchange chromatography</li> <li>d) Column chromatography</li> <li>e) Gas chromatography</li> <li>f) High Performance Liquid chromatography</li> <li>g) Ultra High Performance Liquid chromatography</li> <li>h) Affinity chromatography</li> <li>i) Gel Chromatography</li> </ul> | 10<br>Hrs |
| 5 | <p>a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:</p> <ul style="list-style-type: none"> <li>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing</li> <li>b) X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.</li> </ul>   | 10<br>Hrs |
| 6 | <p>a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.</p> <p>b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation</p>   | 10<br>Hrs |

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2<sup>nd</sup> edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.

## ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

### Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

### Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

### THEORY

60 Hrs

#### 1. Basic Aspects of Organic Chemistry:

12

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them,
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Hrs

#### Addition reactions

- a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- c) Rearrangement reaction

#### 2 Study of mechanism and synthetic applications of following named Reactions:

12

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

Hrs

- 3     **Synthetic Reagents & Applications:** 12 Hrs  
 Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).
- Protecting groups**
- Role of protection in organic synthesis
  - Protection for the hydroxyl group, including 1,2-and1,3-diols:ethers, esters, carbonates, cyclic acetals & ketals
  - Protection for the Carbonyl Group: Acetals and Ketals
  - Protection for the Carboxyl Group: amides and hydrazides,esters
  - Protection for the Amino Group and Amino acids: carbamatesand amides
- 4     **Heterocyclic Chemistry:** 12 Hrs  
 Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.
- Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline , Mercaptopurine and Thioguanine.
- 5     **Synthon approach and retrosynthesis applications**
- Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA) 12 Hrs
  - C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
  - Strategies for synthesis of three, four, five and six-membered ring.

## REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", JMarch, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchartand Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., OxfordUniversity Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (OrientLongman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford& IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen RWilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5<sup>th</sup> Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, NelsonThorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IV<sup>th</sup> Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

## ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

### Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

### Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

### THEORY

60 Hrs

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

- 2 Prodrug Design and Analog design: 12 Hrs
  - a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
  - b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
  - c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,



alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

- |   |  |           |
|---|--|-----------|
| 3 | a) Medicinal chemistry aspects of the following class of drugs   | 12<br>Hrs |
|   | Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:  |           |
|   | a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.   |           |
|   | b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.                      |           |
| 4 | <b>Rational Design of Enzyme Inhibitors</b><br>Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.  | 12<br>Hrs |
| 5 | <b>Peptidomimetics</b><br>Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones. | 12<br>Hrs |

## REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12<sup>th</sup> Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7<sup>th</sup> Edition, IppincottWilliams & Wilkins, Wolters Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers,Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by RichardB.Silverman, II Edition, Elsevier Publishers, New Delhi.
- 10.An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition,Oxford University Press, USA.
- 11.Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B.Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
- 12.Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarnaand Andrea Trabocchi, First edition, Wiley publishers.

## CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

### Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

### Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

### THEORY

60 Hrs

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|----|--|--------|
| 1. | Study of Natural products as leads for new pharmaceuticals for the following class of drugs  | 12 Hrs |
|    | a) Drugs Affecting the Central Nervous System: Morphine Alkaloids  |        |
|    | b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide   |        |
|    | c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol  |        |
|    | d) Neuromuscular Blocking Drugs: Curare alkaloids  |        |
|    | e) Anti-malarial drugs and Analogues   |        |
|    | f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and $\beta$ - Lactam antibiotics (Cephalosporins and Carbapenem)  |        |
| 2  | a) Alkaloids   |        |
|    | General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. | 12 Hrs |

- b) **Flavonoids**  
Introduction, isolation and purification of flavonoids; General methods of structural determination of flavonoids; Structural elucidation of quercetin.
- c) **Steroids**  
General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).
- 3 a) **Terpenoids** 12 Hrs  
Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotinoids ( $\beta$  carotene).
- b) **Vitamins**  
Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.
- 4 a). **Recombinant DNA technology and drug discovery** 12 Hrs  
rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation
- b). **Active constituent of certain crude drugs used in Indigenous system** Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulata*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenum graecum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.
- 5 **Structural Characterization of natural compounds** 12 Hrs  
Structural characterization of natural compounds using IR, <sup>1</sup>HNMR, <sup>13</sup>CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and *Digitalis* glycosides.

## REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer –Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13<sup>th</sup> edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

**PHARMACEUTICAL CHEMISTRY PRACTICAL - I**  
**(MPC 105P)**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

**To perform the following reactions of synthetic importance**

1. Purification of organic solvents, column chromatography
2. Claisen-schmidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

## ADVANCED SPECTRAL ANALYSIS (MPC 201T)

### Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

### Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

### THEORY

60Hrs

- |    |   |           |
|----|---|-----------|
| 1. | <b>UV and IR spectroscopy:</b><br>Woodward – Fieser rule for 1,3- butadienes, cyclic dienes and $\alpha$ , $\beta$ -carbonyl compounds and interpretation of enones. ATR-IR, IR Interpretation of organic compounds.  | 12<br>Hrs |
| 2  | <b>NMR spectroscopy:</b><br>1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.  | 12<br>Hrs |
| 3  | <b>Mass Spectroscopy</b><br><br>Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.  | 12<br>Hrs |
| 4  | <b>Chromatography:</b><br>Principle, Instrumentation and Applications of the following :<br>a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS<br>g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography | 12<br>Hrs |

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|---|---|-----------|
| 5 | <p>a). Thermal methods of analysis<br/>Introduction, principle, instrumentation and application of DSC,DTA and TGA.</p> <p>b). Raman Spectroscopy<br/>Introduction, Principle, Instrumentation and Applications.</p> <p>c). Radio immuno assay<br/>Biological standardization , bioassay, ELISA, Radioimmunoassay of digitalis and insulin.</p> | 12<br>Hrs |
|---|---|-----------|

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7<sup>th</sup> edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D SETHI, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D SETHI, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series



## ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

### Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

### Objectives

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

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY		60 Hrs
1. Green Chemistry:		12 Hrs
a. Introduction, principles of green chemistry		
b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis		
c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications		
d. Continuous flow reactors: Working principle, advantages and synthetic applications.		
2. Chemistry of peptides		12 Hrs
a. Coupling reactions in peptide synthesis		
b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides		
c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies		
d. Side reactions in peptide synthesis: Deletion peptides, side		

reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

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| 3 | <b>Photochemical Reactions</b><br>Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.  | 12<br>Hrs |
|   | <b>Pericyclic reactions</b><br>Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples   |           |
| 4 | <b>Catalysis:</b><br>a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages<br>b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.<br>c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs<br>d. Transition-metal and Organo-catalysis in organic synthesis:<br>Metal-catalyzed reactions<br>e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.<br>f. Phase transfer catalysis - theory and applications | 12<br>Hrs |
| 5 | <b>Stereochemistry &amp; Asymmetric Synthesis</b><br>a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.<br>b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.  | 12<br>Hrs |

## REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", JMarch, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchartand Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers.

## COMPUTER AIDED DRUG DESIGN (MPC 203T)

### Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

### Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

### Theory

60 Hrs

#### 1. Introduction to Computer Aided Drug Design (CADD)

12

Hrs

History, different techniques and applications.

#### Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

#### 2 Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis.

12

Hrs

Statistical methods used in QSAR analysis and importance of statistical parameters.

#### 3 Molecular Modeling and Docking

a) Molecular and Quantum Mechanics in drug design.

12

b) Energy Minimization Methods: comparison between global

Hrs

minimum conformation and bioactive conformation

- c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase ( AchE & BchE)
- 
- 4    **Molecular Properties and Drug Design** 12
    - a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design. Hrs
    - b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
    - c) Homology modeling and generation of 3D-structure of protein.
  - 5    **Pharmacophore Mapping and Virtual Screening**  
Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. 12 Hrs

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based  
In-silico virtual screening protocols.

## REFERENCES

1. Computational and structural approaches to drug discovery, Robert MStroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press,Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, ElsevierPublishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor &Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.

7. An Introduction to Medicinal Chemistry –Graham L. Patrick, OxfordUniversity Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, PergamonPublishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

## PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

### Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

### Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

### THEORY

60 Hrs

#### 1. Process chemistry

12

Introduction, Synthetic strategy

Hrs

Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process.

Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxic impurities

#### 2 Unit operations

12

- a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. Hrs
- b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- c) Distillation: azeotropic and steam distillation
- d) Evaporation: Types of evaporators, factors affecting evaporation.
- e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

- |   |  |           |
|---|--|-----------|
| 3 | Unit Processes - I   | 12<br>Hrs |
|   | <ul style="list-style-type: none"> <li>a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,</li> <li>b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.</li> <li>c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as <math>H_2O_2</math>, sodium hypochlorite, Oxygen gas, ozonolysis.</li> </ul>  |           |
| 4 | Unit Processes - II  | 12<br>Hrs |
|   | <ul style="list-style-type: none"> <li>a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.</li> <li>b) Fermentation: Aerobic and anaerobic fermentation. Production of               <ul style="list-style-type: none"> <li>i. Antibiotics; Penicillin and Streptomycin,</li> <li>ii. Vitamins: B2 and B12</li> <li>iii. Statins: Lovastatin, Simvastatin</li> </ul> </li> <li>c) Reaction progress kinetic analysis               <ul style="list-style-type: none"> <li>i. Streamlining reaction steps, route selection,</li> <li>ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.</li> </ul> </li> </ul> |           |
| 5 | Industrial Safety  | 12<br>Hrs |
|   | <ul style="list-style-type: none"> <li>a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)</li> <li>b) Fire hazards, types of fire &amp; fire extinguishers</li> <li>c) Occupational Health &amp; Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management</li> </ul>   |           |



## REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3<sup>rd</sup> edition, Volume 2.
3. Medicinal Chemistry by Burger, 6<sup>th</sup> edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemicalengineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: HG Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles,Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis:Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
- 10.M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
- 11.Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
- 12.Lowenheim & M.K. Moran: Industrial Chemicals
- 13.S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II,Vikas Publishing House
- 14.J.K. Stille: Industrial Organic Chemistry (PH)
- 15.Shreve: Chemical Process, Mc Grawhill.
- 16.B.K.Sharma: Industrial Chemistry, Goel Publishing House
- 17.ICH Guidelines
- 18.United States Food and Drug Administration official website [www.fda.gov](http://www.fda.gov)

PHARMACEUTICAL CHEMISTRY PRACTICALS – II  
(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
  - a) Oxidation
  - b) Reduction/hydrogenation
  - c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Woodward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH<sub>4</sub> reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechmann reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares  
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

**Course Programme-  
Pharmacology**

## **Program Educational Objectives (PEOs)**

Program Educational Objectives (PEOs) for a Master of Pharmacy (M.Pharm) program typically outline the broad goals that graduates are expected to achieve in their professional careers and further education. Here are some common PEOs for an M.Pharm program:

**PEO1 Professional Competence:** Graduates will demonstrate advanced knowledge and skills in pharmaceutical sciences, enabling them to contribute effectively in various sectors such as industry, academia, and healthcare.

**PEO2 Research and Innovation:** Graduates will engage in research activities, promoting innovation and development of new drug formulations, therapeutic approaches, and pharmaceutical technologies.

**PEO3 Leadership and Teamwork:** Graduates will exhibit leadership qualities and the ability to work collaboratively in multidisciplinary teams, enhancing their effectiveness in professional settings.

**PEO4 Ethical Practice:** Graduates will uphold ethical standards and practices in pharmacy, ensuring patient safety, regulatory compliance, and responsible conduct in research and practice.

**PEO5 Ethical Lifelong Learning:** Graduates will demonstrate a commitment to lifelong learning and professional development, staying updated with the latest advancements in the pharmaceutical field.

**PEO6 Ethical Community Engagement:** Graduates will engage with the community, promoting public health initiatives and contributing to the education of patients and healthcare professionals about medication use and safety.

**PEO7 Critical Thinking and Problem-Solving:** Graduates will apply critical thinking and analytical skills to address complex pharmaceutical problems, making informed decisions based on scientific evidence.

**PEO8 Regulatory Knowledge:** Graduates will possess a thorough understanding of regulatory frameworks governing pharmaceutical development, approval processes, and marketing, ensuring compliance in their practices.

**PEO9 Interdisciplinary Collaboration:** Graduates will effectively collaborate with healthcare professionals, researchers, and industry partners to enhance patient care and drive pharmaceutical innovation.

**PEO10 Communication Skills:** Graduates will demonstrate strong oral and written communication skills, effectively conveying complex pharmaceutical concepts to diverse audiences, including patients, colleagues, and regulatory bodies.

**PEO11 Pharmacovigilance and Safety:** Graduates will be equipped to monitor, evaluate, and manage drug safety, actively participating in pharmacovigilance activities to ensure the well-being of patients.

**PEO12 Global Perspective:** Graduates will develop a global perspective on healthcare and pharmaceutical practices, understanding the impact of cultural, economic, and policy factors on medication management.

### **Programme Specific Objectives (PSO's)**

**PSO1 Advanced Pharmaceutical Knowledge:** Graduates will demonstrate a deep understanding of drug development processes, including formulation, synthesis, and quality control of pharmaceutical products.

**PSO2 Clinical Pharmacy Skills:** Graduates will apply clinical knowledge to assess patient medication regimens, provide pharmaceutical care, and contribute to interdisciplinary healthcare teams.

**PSO3 Research Methodology:** Graduates will be proficient in research methodologies, enabling them to design, conduct, and analyze pharmaceutical research effectively, including clinical trials and drug studies.

**PSO4 Pharmacokinetics and Pharmacodynamics:** Graduates will understand the principles of pharmacokinetics and pharmacodynamics, applying this knowledge to optimize drug therapy for diverse patient populations.

**PSO5 Regulatory Affairs Expertise:** Graduates will navigate regulatory frameworks and guidelines, ensuring compliance in the development and marketing of pharmaceutical products.

**PSO6 Formulation Development:** Graduates will be skilled in the development and evaluation of various dosage forms, utilizing modern techniques and technologies for innovative drug delivery systems.

**PSO7 Quality Assurance and Control:** Graduates will implement quality assurance and control measures in pharmaceutical manufacturing and laboratory settings, ensuring the safety and efficacy of products.

**PSO8 Patient Counseling and Education:** Graduates will effectively communicate medication-related information to patients, enhancing adherence and promoting safe medication use.

**PSO9 Ethical and Professional Responsibility:** Graduates will adhere to ethical guidelines and professional standards, promoting integrity and accountability in their pharmacy practice.

**PSO10 Interprofessional Collaboration:** Graduates will work collaboratively with healthcare professionals, understanding the roles of various team members in providing comprehensive patient care.

### **(Programme Outcome Objectives (POO's)**

**POO1 Knowledge of Drug Mechanisms:** Understand the pharmacokinetics and pharmacodynamics of various drug classes and how they interact with biological systems.

**POO2 Clinical Application:** Apply pharmacological principles in clinical settings to optimize drug therapy and improve patient outcomes.

**POO3 Safety and Efficacy:** Evaluate the safety, efficacy, and potential side effects of medications, including understanding drug interactions and contraindications.

**POO4 Research Skills:** Conduct and interpret pharmacological research, including the ability to critically analyze scientific literature and apply findings to practice.

**POO5 Ethical Considerations:** Understand ethical issues related to pharmacotherapy, including informed consent, drug regulation, and the implications of new therapies.

**POO6 Patient-Centered Care:** Develop communication skills to educate patients about their medications, including dosage, administration, and potential side effects.

**POO7 Interprofessional Collaboration:** Work effectively as part of a healthcare team to ensure comprehensive patient care and medication management.





## PHARMACOLOGY (MPL)

### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

#### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

#### Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

#### THEORY

60 Hrs

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation 10 Hrs  
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.  
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.  
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.  
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. 10 Hrs

- |   |   |           |
|---|---|-----------|
| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.   | 10<br>Hrs |
| 4 | Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:<br>j) Thin Layer chromatography<br>k) High Performance Thin Layer Chromatography<br>l) Ion exchange chromatography<br>m) Column chromatography<br>n) Gas chromatography<br>o) High Performance Liquid chromatography<br>p) Ultra High Performance Liquid chromatography<br>q) Affinity chromatography<br>r) Gel Chromatography   | 10<br>Hrs |
| 5 | Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis<br>d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.  | 10<br>Hrs |
| 6 | Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.<br>Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. | 10<br>Hrs |

## REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2<sup>nd</sup> edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A.Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.

## ADVANCED PHARMACOLOGY - I (MPL 102T)

### Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

### Objectives

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

- ☐ Discuss the pathophysiology and pharmacotherapy of certain diseases
- ☐ Explain the mechanism of drug actions at cellular and molecular level
- ☐ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY		60 Hrs
1. General	Pharmacology	12 Hrs
a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.		
b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.		
2 Neurotransmission		12 Hrs
a. General aspects and steps involved in neurotransmission.		
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).		
c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).		
d. Non adrenergic non cholinergic transmission (NANC). Co-transmission		

## Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

## Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting

neuromuscular junction

12

## 3 Central nervous system Pharmacology

Hrs

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

12

## 4 Cardiovascular Pharmacology

Hrs

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs

## 5 Autocoid Pharmacology

12

The physiological and pathological role of Histamine, Serotonin, Kinins

Hrs

Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

## REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K. Srivastava published by APC Avichal Publishing Company
12. K.D. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

# PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING

## METHODS - I

### (MPL 103T)

#### Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

#### Objectives

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

- ☐ Appraise the regulations and ethical requirement for the usage of experimental animals.
- ☐ Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- ☐ Describe the various newer screening methods involved in the drug discovery process
- ☐ Appreciate and correlate the preclinical data to humans

#### THEORY

60 Hrs

#### 1. Laboratory Animals

12

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Hrs

Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

#### 2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

12

Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and

depressants, anxiolytics, anti-psychotics, anti epileptics andnootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

- 3 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergies. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti - emetic, anti- diarrheal and laxatives.

- 4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

- 5 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans



## REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3<sup>rd</sup> Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2<sup>nd</sup> Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

## CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

### Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

### Objectives:

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

- ☐ Explain the receptor signal transduction processes.
- ☐ Explain the molecular pathways affected by drugs.
- ☐ Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- ☐ Demonstrate molecular biology techniques as applicable for pharmacology

### THEORY

60 Hrs

#### 1. Cell biology

12

Structure and functions of cell and its organelles

Hrs

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death— events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

#### 2 Cell signaling

12

Intercellular and intracellular signaling pathways.

Hrs

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

- |   |  |           |
|---|--|-----------|
| 3 | <p>Principles and applications of genomic and proteomic tools<br/> DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,<br/> <b>Recombinant DNA technology and gene therapy</b><br/> Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.<br/> Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.</p> | 12<br>Hrs |
| 4 | <p><b>Pharmacogenomics</b><br/> Gene mapping and cloning of disease gene.<br/> Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism<br/> Genetic variation in drug transporters<br/> Genetic variation in G protein coupled receptors<br/> Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics<br/> Types of immunotherapeutics, humanisation antibody therapy,<br/> Immunotherapeutics in clinical practice</p>                       | 12<br>Hrs |
| 5 | <p>a. <b>Cell culture techniques</b><br/> Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.<br/> Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays<br/> Principles and applications of flow cytometry</p> <p>b. <b>Biosimilars</b></p>   | 12<br>Hrs |

#### REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M-L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current protocols in molecular biology vol I to VI edited by Frederick M. Ausubel et al.

## PHARMACOLOGICAL PRACTICAL - I

### (MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

#### Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs,  $\alpha$  amylase,  $\alpha$  glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drug in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drug in biological fluids using different analytical techniques (HPLC)

## REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

## ADVANCED PHARMACOLOGY - II (MPL 201T)

### Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

### Objectives

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

- ☐ Explain the mechanism of drug actions at cellular and molecular level
- ☐ Discuss the Pathophysiology and pharmacotherapy of certain diseases
- ☐ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY	60 Hrs
1. <b>Endocrine Pharmacology</b>	12
Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones	Hrs
Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.	
Drugs affecting calcium regulation	
2. <b>Chemotherapy</b>	12
Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as $\beta$ -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	Hrs
3. <b>Chemotherapy</b>	12
Drugs used in Protozoal Infections	Hrs
Drugs used in the treatment of Helminthiasis	
Chemotherapy of cancer Immunopharmacology	
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.	
Immunosuppressants and Immunostimulants	

- |   |   |           |
|---|---|-----------|
| 4 | <b>GIT Pharmacology</b><br>Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.<br><b>Chronopharmacology</b><br>Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer                         | 12<br>Hrs |
| 5 | <b>Free radicals Pharmacology</b><br>Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant<br><b>Recent Advances in Treatment:</b><br>Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus | 12<br>Hrs |

## REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gilman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cotran Pathologic Basis of Disease, 9<sup>th</sup> Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K. Srivastava published by APC Avichal Publishing Company.
11. K.D. Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H. Tashjian Jr, Ehrin J. Armstrong, April W. Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

# PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING

## METHODS-II

### (MPL 202T)

#### Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

#### Objectives:

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

- ☐ Explain the various types of toxicity studies.
- ☐ Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- ☐ Demonstrate the practical skills required to conduct the preclinical toxicity studies.

#### THEORY

		60 Hrs
1.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)	12
	Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y	Hrs
	OECD principles of Good laboratory practice (GLP)	
	History, concept and its importance in drug development	
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.	12
	Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.	Hrs
	Test item characterization- importance and methods in regulatory toxicology studies	
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)	12
	Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)	Hrs
	In vivo carcinogenicity studies	
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12
		Hrs



Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

- 5 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics 12  
Importance and applications of toxicokinetic studies. Hrs  
Alternative methods to animal toxicity testing.

## REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3<sup>rd</sup> Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

## PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

### Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

### Objectives:

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

- ☐ Explain the various stages of drug discovery.
- ☐ Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- ☐ Explain various targets for drug discovery.
- ☐ Explain various lead seeking method and lead optimization
- ☐ Appreciate the importance of the role of computer aided drug design in drug discovery

### THEORY

60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 12 Hrs  
 Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.
2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12 Hrs  
 Protein structure  
 Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction
3. Rational Drug Design 12 Hrs  
 Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

- |   |   |           |
|---|---|-----------|
|   | Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,  |           |
| 4 | Molecular docking: Rigid docking, flexible docking, manualdocking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.   | 12<br>Hrs |
| 5 | QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design | 12<br>Hrs |

## REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007Humana Press Inc.
2. Darryl León. Scott MarkellIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods andProtocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methodsand Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

## CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

### Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

### Objectives:

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

- ☐ Explain the regulatory requirements for conducting clinical trial
- ☐ Demonstrate the types of clinical trial designs
- ☐ Explain the responsibilities of key players involved in clinical trials
- ☐ Execute safety monitoring, reporting and close-out activities
- ☐ Explain the principles of Pharmacovigilance
- ☐ Detect new adverse drug reactions and their assessment
- ☐ Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

### THEORY

60 Hrs

1. **Regulatory Perspectives of Clinical Trials:** 12  
 Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR  
 Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process Hrs
2. **Clinical Trials: Types and Design**  
 Experimental Study- RCT and Non RCT, 12  
 Observation Study: Cohort, Case Control, Cross sectional Hrs  
 Clinical Trial Study Team  
 Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

- |   |   |           |
|---|---|-----------|
| 3 | <p>Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT</p> <p>Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.</p>   | 12<br>Hrs |
| 4 | <p>Basic aspects, terminologies and establishment of pharmacovigilance</p> <p>History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance</p>    | 12<br>Hrs |
| 5 | <p>Methods, ADR reporting and tools used in Pharmacovigilance</p> <p>International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.</p> | 12<br>Hrs |
| 6 | <p>Pharmacoepidemiology, pharmacoeconomics, safety pharmacology</p>   | 12<br>Hrs |

## REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

## PHARMACOLOGICAL PRACTICAL - II

### (MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of  $PA_2$  values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations.
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

### REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakami
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbalchoudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

## Semester III

### MRM 301T - Research Methodology & Biostatistics

#### UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

#### UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

#### UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

#### UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

#### UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care







# Shobhit University, Gangoh

(Established by UP Shobhit University Act No. 3, 2012)

## School Of Pharmacy

### Ordinances, Regulations & Syllabus

For

**Bachelor of Pharmacy (B.Pharm) 4 Year Programme Semester  
Pattern  
(w.e.f.session2013-14)**

**Approved by Pharmacy Council of India and  
adopted in the year 2013, 1<sup>st</sup> Meeting, Board of  
Studies.**

[Frame under Regulation 6,7 & 8 of the Bachelor of Pharmacy (B. Pharm)]

## **CHAPTER- I: REGULATIONS**

### **1. Short Title and Commencement**

These regulations shall be called as “The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

### **2. Minimum qualification for admission**

#### **First year B. Pharm:**

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

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

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

### **3. Duration of the program**

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

### **4. Medium of instruction and examinations**

Medium of instruction and examination shall be in English.

### **5. Working days in each semester**

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

### **6. Attendance and progress**

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

## **7. Program/Course credit structure**

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

### **Credit assignment**

#### **Theory and Laboratory courses**

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

#### **Minimum credit requirements**

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

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

## **8. Academic work**

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

### 9. Course of study

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

**Table-I: Course of study for semester I**

Course code	Name of the course	No. of hours	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/ BP105TA/ BP105TB/ BP105TC	Communication skills–Theory*/English Grammar and Creative Writing/Speaking and Presentation Skills/ Life Management and Soft Skills	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/ BP111PA/ BP111PB/ BP111PC	Communication skills–Practical*/ English Grammar and Creative Writing/Speaking and Presentation Skills/ Life Management and Soft Skills	2	-	1
BP112RBP	Remedial Biology–Practical*	2	-	1
<b>Total</b>		<b>32/34<sup>\$</sup>/36<sup>#</sup></b>	<b>4</b>	<b>27/29<sup>\$</sup>/30<sup>#</sup></b>

<sup>#</sup>Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

<sup>\$</sup>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**

<b>Course Code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
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
<b>Total</b>		<b>32</b>	<b>4</b>	<b>29</b>

\*Non University Examination (NUE)

**Table-III: Course of study for semester III**

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

**Table-IV: Course of study for semester IV**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
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
<b>Total</b>		<b>31</b>	<b>5</b>	<b>28</b>

**Table-V: Course of study for semester V**

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

**Table-VI: Course of study for semester VI**

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

**Table-VII: Course of study for semester VII**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit Points</b>
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/ BP706PSA/ BP706PSB/ BP706PSC	Practice School*/Skill Enhancement Course Practical (Qualifying course) Data Analysis / Computer Programming / Python Programming.	12	-	6
<b>Total</b>		<b>28</b>	<b>5</b>	<b>24</b>

\* Non University Examination (NUE)



**Table-VIII: Course of study for semester VIII**

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
<b>Total</b>		<b>24</b>	<b>4</b>	<b>22</b>

**Table-IX: Semester wise credits distribution**

Semester	Credit Points
I	27/29 <sup>§</sup> /30 <sup>#</sup>
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
<b>Total credit points for the program</b>	<b>209/211<sup>§</sup>/212<sup>#</sup></b>

\* 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.

<sup>§</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

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

## **10. Program Committee**

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

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

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

## **11. Examinations/Assessments**

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

### **End semester examinations**

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

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

**Semester I**

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

<sup>#</sup>Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

<sup>§</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

\* Non University Examination (NUE)

## Semester II

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

\* The subject experts at college level shall conduct examinations

### Semester III

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

### Semester IV

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

### Semester V

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

## Semester VI

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



## Semester VII

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

\* The subject experts at college level shall conduct examinations

### Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150

<b>Total</b>	<b>40</b>	<b>60</b>	<b>4 Hrs</b>	<b>100</b>	<b>450</b>	<b>16 Hrs</b>	<b>550</b>
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**Internal assessment: Continuous mode**

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

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

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

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

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

**11.2.1. Sessional Exams**

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

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

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

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

**For subjects having Non University Examination**

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

**Question paper pattern for practical sessional examinations**

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05
		-----
Total	=	40 marks
		-----

**12. Promotion and award of grades**

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

**13. Carry forward of marks**

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

**14. Improvement of internal assessment**

A student shall have the opportunity to improve his/her performance only once in the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

**15. Re-examination of end semester examinations**

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

**Table-XIII: Tentative schedule of end semester examinations**

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

**Question paper pattern for end semester theory examinations****For 75 marks paper**

I. Multiple Choice Questions(MCQs) = 20 x 1 = 20  
OR

Objective Type Questions (10 x 2) = 10 x 2 = 20  
(Answer all the questions)

II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

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Total = 75 marks  
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**For 50 marks paper**

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks  
-----

**For 35 marks paper**

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

II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks  
-----

**Question paper pattern for end semester practical examinations**

I. Synopsis = 5

II. Experiments = 25

III. Viva voce = 5

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Total = 35 marks  
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**16. Academic Progression:**

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

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

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

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

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

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

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

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

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

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

## 17. Grading of performances

### Letter grades and grade points allocations:

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

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

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

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the saidevaluation/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 a F or ABS grade in course 4, the SGPA shall then be computed as:

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

### 19. Cumulative Grade Point Average (CGPA)

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

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

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

### 20. Declaration of class

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

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

### 21. Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

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



***Evaluation of Dissertation Book:***

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks

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<b>Total</b>	<b>75 Marks</b>
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***Evaluation of Presentation:***

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

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<b>Total</b>	<b>75 Marks</b>
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*Explanation:* The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

**22. Industrial training (Desirable)**

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

**23. Practice School**

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

**24. Award of Ranks**

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

**25. Award of degree**

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

**26. Duration for completion of the program of study**

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

**27. Re-admission after break of study**

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

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

## **Programme Educational Objectives (PEOs)**

**PEO1 Applying principles and technologies:** Graduates should be able to apply principles and technologies to develop, formulate, and manufacture drugs and pharmaceuticals.

**PEO2 Serving society:** Graduates should be able to use medications and devices appropriately to achieve optimal therapeutic outcomes.

**PEO3 Promoting leadership and ethics:** Graduates should be able to demonstrate leadership and entrepreneurship qualities, as well as professional ethics and human values.

**PEO4 Lifelong learning :** Graduates should be able to absorb new technologies and continue learning throughout their lives.

**PEO5 Communicating effectively:** Graduates should be able to communicate well with other healthcare professionals.

**PEO6 Meeting industry needs:** Graduates should be able to meet the needs of the pharmaceutical industry and provide clinical services to the community.

**PEO7 Academic excellence:** Graduates should have knowledge of fundamental principles and their applications in pharmaceutical sciences and technology.

**PEO8 Technical competence:** Graduates should have strong fundamental concepts and high technical competence in pharmaceutical sciences.

**PEO9 Professional Competence:** Graduates will demonstrate the knowledge and skills necessary to practice pharmacy effectively in various healthcare settings, ensuring safe and effective medication use.

**PEO10 Patient-Centered Care:** Graduates will provide high-quality, patient-centered care, including medication management, counseling, and health promotion, to improve patient outcomes.

**PEO11 Inter-professional Collaboration:** Graduates will work collaboratively within interdisciplinary healthcare teams to optimize patient care and contribute to public health initiatives.

### **Programme Specific Objectives (PSO's)**

**PSO1 Pharmaceutical Care Skills:** Students will demonstrate the ability to assess patient medication needs, develop individualized care plans, and implement appropriate therapeutic interventions.

**PSO2 Drug Development and Management:** Students will gain knowledge in drug formulation, development processes, and the management of pharmaceutical products throughout their lifecycle.

**PSO3 Clinical Knowledge Application:** Students will apply pharmacological principles and clinical knowledge to evaluate and optimize drug therapy in diverse patient populations.

**PSO4 Regulatory and Compliance Understanding:** Students will understand the regulatory frameworks governing pharmacy practice, including drug approval processes, safety, and quality assurance.

**PSO5 Communication Proficiency:** Students will develop effective communication skills to counsel patients, collaborate with healthcare professionals, and convey complex information clearly.

**PSO6 Health Promotion and Disease Prevention:** Students will engage in public health initiatives, providing education on disease prevention and health promotion strategies.

**PSO7 Research and Evidence-Based Practice:** Students will engage in research activities and apply evidence-based practices to inform clinical decisions and improve patient outcomes.

**PSO8 Ethical Decision-Making:** Students will learn to navigate ethical dilemmas in pharmacy practice, demonstrating professional judgment and integrity.

### **Programme Outcome Objectives (POO's)**

**POO1 Clinical Competence:** Graduates will be able to conduct comprehensive medication reviews, assess patient health needs, and design effective therapeutic regimens.

**POO2 Pharmaceutical Knowledge:** Graduates will possess a thorough understanding of pharmacology, pharmacotherapy, drug interactions, and the mechanisms of drug action.

**POO3 Ethical Practice:** Graduates will demonstrate professionalism and ethical behavior in all aspects of pharmacy practice, including patient interactions and professional relationships.

**POO4 Communication Skills:** Graduates will effectively communicate with patients, caregivers, and healthcare team members, ensuring clarity and understanding of medication information.

**POO5 Critical Thinking and Problem Solving:** Graduates will apply critical thinking skills to analyze patient data, identify medication-related problems, and develop appropriate solutions.

**POO6 Research and Evidence-Based Practice:** Graduates will be able to conduct research, critically evaluate scientific literature, and apply evidence-based guidelines in clinical practice.

**POO7 Interprofessional Collaboration:** Graduates will work effectively within interdisciplinary teams to enhance patient care and contribute to overall healthcare delivery.

**POO8 Lifelong Learning:** Graduates will demonstrate a commitment to continuous professional development and lifelong learning in the rapidly evolving field of pharmacy.

**POO9 Public Health Awareness:** Graduates will engage in community health initiatives, promoting wellness and preventive care through education and outreach.

## **CHAPTER - II: SYLLABUS**

## **Semester I**

## **BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **Unit I**

**10 hours**

- **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

- **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

- **Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

#### **Unit II**

**10 hours**

- **Integumentary system**

Structure and functions of skin

- **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction



- **Joints**

Structural and functional classification, types of joints movements and its articulation

**Unit III**

**10 hours**

- **Body fluids and blood**

- Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

- **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

**Unit IV**

**08 hours**

**Peripheral nervous system:**

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

- **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

**Unit V**

**07 hours**

- **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

## **BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

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

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

### **Recommended Books (Latest Editions)**

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

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books (Latest Editions)**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

## BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

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

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

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

### Course Content:

#### UNIT-I

10 Hours

(a) **Pharmaceutical analysis**- Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

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

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

#### UNIT-II

10 Hours

- **Acid base titration:** Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- **Non aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

#### UNIT-III

10 Hours

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

## **UNIT-IV**

**08 Hours**

### **Redox titrations**

(a) Concepts of oxidation and reduction

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

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

## **UNIT-V**

**07 Hours**

### **• Electrochemical methods of analysis**

- **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
- **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

## **BP108P. PHARMACEUTICAL ANALYSIS (Practical)**

**4 Hours / Week**

### **I Limit Test of the following**

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

### **II Preparation and standardization of**

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

### **III Assay of the following compounds along with Standardization of Titrant**

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

### **IV Determination of Normality by electro-analytical methods**

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

### **Recommended Books: (Latest Editions)**

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

## **BP103T. PHARMACEUTICS- I (Theory)**

**45 Hours**

**Scope:** This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

### **Course Content:**

#### **UNIT – I**

**10 Hours**

- **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

#### **UNIT – II**

**10 Hours**

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

### UNIT – III

08 Hours

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

### UNIT – IV

08 Hours

- **Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

### UNIT – V

07 Hours

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms



**1 . Syrups**

- a) Syrup IP'66
- b) Compound syrup of Ferrous Phosphate BPC'68

**2. Elixirs**

- a) Piperazine citrate elixir
- b) Paracetamol pediatric elixir

**3.Linctus**

- a) Terpin Hydrate Linctus IP'66
- b) Iodine Throat Paint (Mandles Paint)

**4. Solutions**

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution
- c) Lugol's solution

**5. Suspensions**

- a) Calamine lotion
- b) Magnesium Hydroxide mixture
- c) Aluminium Hydroxide gel

**6. Emulsions**

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

**7. Powders and Granules**

- a) ORS powder (WHO)
- b) Effervescent granules
- c) Dusting powder
- d) Divided powders

**8. Suppositories**

- a) Glycero gelatin suppository
- b) Cocoa butter suppository
- c) Zinc Oxide suppository

**8. Semisolids**

- a) Sulphur ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel

**9. Gargles and Mouthwashes**

- a) Iodine gargle
- b) Chlorhexidine mouthwash

**Recommended Books: (Latest Editions)**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

## **BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT I**

**10 Hours**

- **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

**General methods of preparation**, assay for the compounds superscripted with **asterisk (\*)**, properties and medicinal uses of inorganic compounds belonging to the following classes

#### **UNIT II**

**10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- **Major extra and intracellular electrolytes:** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

#### **UNIT III**

**10 Hours**

- **Gastrointestinal agents**

**Acidifiers:** Ammonium chloride\* and Dil. HCl

**Antacid:** Ideal properties of antacids, combinations of antacids, Sodium

Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture

**Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

**Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

#### UNIT IV

08 Hours

- **Miscellaneous compounds**

**Expectorants:** Potassium iodide, Ammonium chloride\*.

**Emetics:** Copper sulphate\*, Sodium potassium tartarate

**Haematinics:** Ferrous sulphate\*, Ferrous gluconate

**Poison and Antidote:** Sodium thiosulphate\*, Activated charcoal, Sodium nitrite333

**Astringents:** Zinc Sulphate, Potash Alum

#### UNIT V

07 Hours

- **Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of  $\alpha$ ,  $\beta$ ,  $\gamma$  radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.

## **BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)**

**4 Hours / Week**

### **I Limit tests for following ions**

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

### **II Identification test**

Magnesium hydroxide  
Ferrous sulphate  
Sodium bicarbonate  
Calcium gluconate  
Copper sulphate

### **III Test for purity**

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

### **IV Preparation of inorganic pharmaceuticals**

Boric acid  
Potash alum  
Ferrous sulphate

### **Recommended Books (Latest Editions)**

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

Pharmacopoeia

## **BP105T.COMMUNICATION SKILLS (Theory)**

**30 Hours**

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

### **Objectives:**

Upon completion of the course the student shall be able to

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

### **Course content:**

#### **UNIT – I**

**07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

#### **UNIT – II**

**07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

### UNIT – III

07 Hours

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

### UNIT – IV

05 Hours

- **Interview Skills:** Purpose of an interview, Do's and Don't's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

### UNIT – V

04 Hours

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Don't's of group discussion

## English Grammar and Creative Writing (BP105T-A)

### CO: COURSE OBJECTIVES

**CO-1 Understanding of Grammar:** Students will demonstrate a solid understanding of English grammar rules and conventions, including sentence structure, punctuation, and usage.

**CO-2 Application of Grammar in Writing:** Students will effectively apply grammatical concepts to enhance clarity and coherence in their writing, ensuring their work is polished and professional.

**CO-3 Creative Expression:** Students will develop their unique voice and style in creative writing, experimenting with different genres and forms, such as poetry, short stories, and narrative essays.

**CO-4 Revision and Editing Skills:** Students will engage in the revision process, applying constructive feedback to improve their writing and develop skills in self-editing.

**CO-5 Critical Reading Skills:** Students will analyze various texts, recognizing the use of grammar, style, and narrative techniques, and articulating their effects on meaning and reader engagement.

**CO-6: Presentation Skills:** Students will present their creative work to peers, articulating their writing choices and engaging with audience feedback.

## Course Contents

### UnitI: Proficiency in English Grammar

- Understand the fundamental rules of English grammar, including sentence structure, verb tenses, punctuation, and usage.
- Apply grammatical concepts in writing and speaking with accuracy and clarity.

### UnitII: Development of Writing Skills

- Develop clear and effective writing techniques for different purposes, such as descriptive, narrative, expository, and persuasive writing.
- Organize and structure ideas cohesively in paragraphs and essays.

### UnitIII: Creativity in Writing

- Explore and express creativity through various forms of writing like short stories, poetry, and essays.
- Experiment with different literary styles, tones, and voices to enhance personal expression.

### UnitIV: Understanding of Literary Techniques

- Recognize and apply literary devices such as metaphors, similes, imagery, symbolism, and personification in creative writing.
- Analyze and appreciate the use of these devices in literature and use them to improve personal writing.

### UnitV: Enhanced Reading and Interpretation Skills

- Read and interpret various literary and non-literary texts to understand different styles, perspectives, and techniques.
- Engage critically with texts to enhance understanding and application of grammar rules.

### UnitVI: Confidence in Communication

- Gain confidence in expressing ideas, opinions, and creative thoughts through well-structured, grammatically correct writing.
- Develop oral communication skills through discussions, presentations, and creative recitations.

### Suggested Readings:

- *Wren & Martin's High School English Grammar and Composition" by P.C. Wren and H. Martin*

*A comprehensive guide to grammar rules, sentence structure, and composition that is widely used in academic courses.*

- *"English Grammar in Use" by Raymond Murphy*



*A popular self-study grammar reference book, ideal for intermediate learners to clarify grammatical concepts.*

- *"Practical English Usage" by Michael Swan*  
*An authoritative reference book covering problem areas in English grammar and usage.*
- *"The Elements of Style" by William Strunk Jr. and E.B. White*  
*A concise handbook on writing style, grammar, and clarity in writing.*

## **COURSE OUTCOMES-**

**COs-1** Students will develop the ability to write clearly and concisely for a variety of purposes, including essays, reports, and formal communications.

**COs-2** Students will be able to understand and apply advanced grammar rules, including sentence structures, punctuation, verb usage, and tenses.

**COs-3** Students will develop skills in self-editing and revising drafts to improve grammar, clarity, and overall style. And learn the peer-review process and incorporate constructive feedback to refine writing.

**COs-4** Students will develop skills to gain confidence in articulating thoughts and ideas in written form, particularly in creative genres.

## **Speaking and Presentation Skills (BP105T-B)**

### **CO: COURSE OBJECTIVES**

**CO-1** Learn about improve the ability to articulate thoughts clearly and confidently in various contexts, including discussions, debates, and presentations.

**CO-2** Learn techniques to manage speech anxiety and develop a strong stage presence. Build confidence in delivering speeches or presentations to an audience, with emphasis on clarity, organization, and engagement.

**CO-3** Learn to structure a presentation logically with a clear introduction, body, and conclusion to communicate messages effectively.

**CO-4** Develop an understanding of how to tailor presentations and speeches according to the needs, expectations, and interests of different audiences. And learn the strategies to engage the audience through storytelling, questions, and visual aids.

**CO-5** Learn to improve body language, facial expressions, eye contact, and gestures to complement verbal communication and create a stronger impact.

### ***Course Contents***

#### **Unit I: Develop Effective Oral Communication**

- Improve the ability to articulate thoughts clearly and confidently in various contexts, including discussions, debates, and presentations.
- Enhance fluency, pronunciation, and diction for effective verbal communication.

- Build confidence in delivering speeches or presentations to an audience, with emphasis on clarity, organization, and engagement.
- Learn techniques to manage speech anxiety and develop a strong stage presence.

## **Unit II: Master the Art of Public Speaking**

- Build confidence in delivering speeches or presentations to an audience, with emphasis on clarity, organization, and engagement.
- Learn techniques to manage speech anxiety and develop a strong stage presence.

## **Unit III: Structure and Organize Presentations**

- Learn to structure a presentation logically with a clear introduction, body, and conclusion to communicate messages effectively.
- Focus on the use of transitions, signposting, and summary techniques to guide audiences through content seamlessly.

## **Unit IV: Audience Analysis and Engagement**

- Develop an understanding of how to tailor presentations and speeches according to the needs, expectations, and interests of different audiences.
- Learn strategies to engage the audience through storytelling, questions, and visual aids.

## **Unit V: Handle Q&A Sessions and Impromptu Speaking**

- Learn techniques for handling questions confidently and effectively during Q&A sessions, discussions, or after presentations.
- Practice impromptu speaking to improve the ability to think and respond quickly and coherently in unplanned scenarios.

### **Suggested Readings:**

**Public Speaking: An Audience-Centered Approach** by Steven A. Beebe and Susan J. Beebe

This book emphasizes the importance of understanding the audience while preparing and delivering speeches.

**"Speak With No Fear: Go from a Nervous, Nauseated, and Sweaty Speaker to an Excited, Energized, and Passionate Presenter"** by Mike Acker

Provides practical tips and strategies for overcoming fear and anxiety in public speaking.

## **COURSE OUTCOMES**

**COs-1** Students will develop the ability to communicate ideas clearly and confidently in various speaking situations, including formal and informal contexts. And also to improve pronunciation, and fluency in spoken English.

**COs-2** Learn to engage an audience effectively, maintain attention, and deliver impactful presentations. Develop the ability to tailor communication to different audiences, understanding the importance of audience demographics, interests, and feedback.

**COs-3** Build confidence to speak in front of large or small groups, handling nerves and overcoming the fear of public speaking. Gain practical experience through various public speaking activities and assignments that boost self-assurance.

**COs-4** Develop skills in delivering persuasive and informative speeches, including the use of evidence, logic, and emotional appeal. Learn how to construct well-reasoned arguments and present them convincingly to an audience.

**COs-5** Learn to manage speaking time efficiently, adhering to time limits while ensuring all key points are addressed. Develop the ability to adjust content and pace according to time constraints without sacrificing clarity or effectiveness.

### **Additional Benefits:**

- Improved teamwork and collaboration through group presentations.
- Enhanced critical thinking and problem-solving abilities when addressing audience questions or unexpected issues during presentations.

## **Life Management and Soft Skills (BP105T-C)**

### **CO: COURSE OBJECTIVES**

**CO-1** Enhance self-awareness by understanding personal strengths, weaknesses, values, and emotions. Improve emotional intelligence to better manage stress, emotions, and interpersonal relationships.

**CO-2** Develop organizational skills to balance personal, academic, and professional responsibilities effectively. Learn techniques to manage time efficiently, prioritize tasks, and set realistic goals.

**CO-3** Improve the ability to work collaboratively with others, including in team settings, by fostering cooperation, adaptability, and conflict resolution. Strengthen interpersonal skills to build strong, respectful relationships with peers, colleagues, and mentors.

**CO-4** Develop the ability to solve problems creatively, assess risks, and evaluate options effectively. Learn critical thinking and analytical skills to approach challenges logically and make informed decisions.

**CO-5** Understand the key principles of leadership and develop skills to inspire, motivate, and guide others. Learn influencing techniques to build trust, persuade effectively, and lead with empathy and confidence.

**CO-6** Develop a strong work ethic, accountability, and professionalism in both academic and workplace settings. Understand the importance of integrity, ethics, and responsibility in personal and professional life.

**CO-7** Explore career opportunities and develop strategies for career planning, setting short-term and long-term

goals. Learn how to prepare resumes, cover letters, and practice interview skills for job readiness.

## **Course Contents**

### **Unit I: Introduction to Life Management and Soft Skills**

- **Definition and Importance**  
Understanding the concept of life management and soft skills, and why they are crucial for personal and professional success.
- **Key Areas of Life Management**  
Time management, stress management, decision-making, and problem-solving skills.

### **Unit II: Time Management**

- **Principles of Time Management**  
Prioritizing tasks, setting goals, and creating effective schedules.
- **Time-Management Tools and Techniques**  
Using planners, to-do lists, digital tools, and calendars to manage time efficiently.
- **Work-Life Balance**  
Techniques for balancing personal and professional responsibilities.

### **Unit III: Interpersonal Skills**

- **Building Positive Relationships**  
Developing trust, empathy, and respect in personal and professional relationships.
- **Teamwork and Collaboration**  
Understanding the dynamics of working in teams, effective collaboration, and conflict resolution.
- **Networking and Social Skills**  
Building professional networks, improving social skills, and expanding connections.

### **Unit IV: Interview and Job-Readiness Skills**

- **Preparing for Interviews**  
Resume building, preparing for common interview questions, and conducting mock interviews.
- **Workplace Adaptation**  
Adjusting to new work environments, understanding corporate culture, and integrating into teams smoothly.

### **Unit V Professional Etiquette and Workplace Skills**

- **Professionalism in the Workplace**  
Maintaining a positive attitude, dressing appropriately, and upholding workplace etiquette.
- **Business Etiquette**  
Understanding professional conduct in meetings, email communication, and corporate environments.
- **Workplace Ethics and Integrity**  
Importance of ethical behavior and maintaining integrity in professional settings.

### **Suggested Readings:**

1. **"Emotional Intelligence: Why It Can Matter More Than IQ"** by Daniel Goleman  
A foundational book that explores the concept of emotional intelligence (EQ) and how it impacts personal and professional success.
2. **"The Seven Habits of Highly Effective People"** by Stephen R. Covey  
A classic on personal and professional effectiveness, focusing on habit formation, self-management, and interpersonal relations.
3. **"Difficult Conversations: How to Discuss What Matters Most"** by Douglas Stone, Bruce Patton, and Sheila Heen. A practical guide for navigating challenging conversations, resolving conflicts, and maintaining strong relationships

**4. The Art of Thinking Clearly"** by Rolf Dobelli .Focuses on cognitive biases and common errors in thinking, helping individuals make better decisions in both personal and professional contexts.

### **COURSE OUTCOMES**

**COs-1** Apply problem-solving techniques to resolve conflicts and challenges both in personal and professional contexts. Develop critical thinking skills to analyze situations and make informed decisions.

**COs-2** Strengthen both verbal and non-verbal communication skills for clear, confident, and effective interaction. Develop listening skills to engage in meaningful conversations and foster positive relationships.

**COs-3** Understand the importance of professionalism, work ethics, and integrity in the workplace. Learn business etiquette, including dress code, behavior, and professional interactions in various contexts.

**COs-4** Gain confidence in delivering speeches, presentations, and engaging in public discussions. Learn how to organize ideas, articulate thoughts clearly, and present effectively to different audiences.

**COs-5** Learn to set realistic, achievable personal and professional goals using the SMART (Specific, Measurable, Achievable, Relevant, Time-bound) framework.

## **BP111P.COMMUNICATION SKILLS (Practical)**

**2 Hours / week**

The following learning modules are to be conducted using wordsworth® English language lab software

### **Basic communication covering the following topics**

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

### **Pronunciations covering the following topics**

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

### **Advanced Learning**

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

### **Recommended Books: (Latest Edition)**

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

### **English Grammar and Creative Writing (BP111P-A) Practical**

#### **CO: COURSE OBJECTIVES**

**CO-1** Ensure a solid understanding of English grammar, including sentence structure, verb tenses, punctuation, parts of speech, and syntax. Students will demonstrate correct usage of grammar in written and spoken communication.

**CO-2** Students will be able to write clear, coherent, and structured essays, stories, and reports. Introduce and practice various writing techniques, such as descriptive writing, narrative structure, and persuasive writing.

**CO-3** Foster creative thinking and the ability to express ideas imaginatively through written language. Enhance students' ability to read and analyze various forms of written texts for structure, grammar, and style.

**CO-4** Improve overall communication skills, both written and oral, for different audiences and purposes. Encourage students to develop their unique voice and style in writing.

#### **Practical:**

1. **Writing Prompts:** Daily or weekly writing exercises to foster creativity.
2. **Workshops:** Collaborative peer reviews and group critiques.
3. **Assignments:** Submission of short stories, essays, or poetry with revisions based on feedback.
4. **Journaling:** Regular personal writing journals to track progress, reflections, and ideas.
5. **Quizzes and Tests:** Focused on grammar, vocabulary, and punctuation.
6. **Creative Projects:** Submission of polished pieces of creative writing (stories, poems, or essays).
7. **Class Participation:** Engagement in peer reviews, discussions, and workshops.

## **COURSE OUTCOMES**

**COs-1** Students will demonstrate a comprehensive understanding of English grammar, including sentence structure, syntax, punctuation, and usage rules. This will aid in improving both written and spoken communication skills.

**COs-2** Students will develop the ability to craft original works of fiction, poetry, and other creative writing forms by exploring various techniques such as characterization, plot development, and narrative voice.

**COs-3** Through the analysis of literary works and creative writing exercises, students will enhance their critical thinking and analytical abilities, helping them understand the subtleties of language and meaning.

**COs-4** Students will learn to communicate their ideas clearly, coherently, and persuasively in writing, both in creative formats (stories, poems, etc.) and more structured forms (essays, reports).

**COs-5** Students will gain skills in self-editing and peer editing, learning how to refine and improve their drafts through multiple revisions and constructive feedback from peers and instructors.

**COs-6** Students will be exposed to various literary genres and forms, fostering an appreciation for diverse writing styles and approaches in literature and creative writing.

**COs-7** By experimenting with different genres and writing techniques, students will be able to discover and refine their personal writing style and voice.

## **Speaking and Presentation Skills (BP111P-B) Practical**

### **CO: COURSE OBJECTIVES**

**CO-1** Enhance students to improve clarity, tone, and articulation for effective verbal communication. Practice structuring coherent and concise spoken messages.

**CO-2** Build confidence in speaking before an audience. And to overcome common speech-related anxieties.

**CO-3** Learn to design and deliver engaging and professional presentations.

**CO-4** Develop strategies for maintaining audience interest and attention. Practice appropriate non-verbal cues to reinforce spoken messages.

**CO-5** Learn how to integrate slides, charts, graphs, and other visual tools seamlessly into presentations. Practice peer review and learn from others' speaking techniques.

**CO-6** Practice adhering to time limits while maintaining content quality and flow. Organize presentation content effectively to fit within allotted time.

### **Practical:**

1. **Confidence Building:** Overcoming stage fright and anxiety.
2. **Vocal Techniques:** Projection, tone modulation, clarity, and articulation.
3. **Body Language:** Posture, gestures, eye contact, and facial expressions.
4. **Audience Engagement:** Interacting with and addressing the audience's needs.
5. **Visual Aids:** Using PowerPoint, info graphics, and other visual tools effectively.
6. **Group Discussions:** Techniques for leading and contributing to group conversations.



7. **Debates:** Structuring arguments, listening actively, and providing counterpoints.
8. **Interviews and Networking:** Practicing one-on-one professional communication, including mock interviews
9. **Online Presentations:** Practicing virtual communication platforms such as Zoom, Google Meet, or Microsoft Teams.

## **COURSE OUTCOMES**

**COs-1** Students will develop the ability to articulate ideas clearly and confidently in both spoken and written formats, using appropriate communication techniques.

**COs-2** Students will demonstrate proficiency in public speaking by delivering structured and impactful presentations, taking into account audience needs and context.

**COs-3** Students will learn to use both verbal and non-verbal cues effectively to enhance their communication, including body language, eye contact, and tone.

**COs-4** Students will gain experience in incorporating various visual aids (PowerPoint, charts, props, etc.) into their presentations to improve clarity and engagement.

**COs-5** Students will be able to respond to questions and manage discussions confidently, handling both expected and unexpected queries during and after presentations.

**COs-6** Students will learn techniques to engage the audience, ensuring active participation and maintaining attention throughout their presentations.

**COs-7** Students will practice structuring presentations to fit within given time limits, focusing on key points and delivering concise messages without rushing.

### **Suggested Readings:**

- **"The Art of Public Speaking" by Dale Carnegie** A classic that covers the fundamentals of effective public speaking, providing techniques for confidence-building, engagement, and audience connection.
- **"Presentation Zen: Simple Ideas on Presentation Design and Delivery" by Garr Reynolds** Focuses on creating presentations that are visually engaging and effectively delivered. This book covers everything from slide design to storytelling techniques.
- **"The Quick and Easy Way to Effective Speaking" by Dale Carnegie** Another excellent resource from Dale Carnegie that provides actionable advice for improving public speaking through practice and understanding audience psychology.

## **Life Management and Soft Skills (BP111PC) Practical**

### **COURSE OBJECTIVES**

**CO-1** To promote self-awareness and personal growth by encouraging self-reflection and introspection. To help students understand their strengths, weaknesses, and areas of improvement.

**CO-2** To improve students' communication, collaboration, and relationship-building skills. And to develop effective teamwork and leadership skills by working in diverse groups.

**CO-3** To introduce students to techniques for managing stress and resolving conflicts constructively.

**CO-4** To improve professional etiquette, work ethics, and adaptability in diverse work environments. And to help students develop essential skills like presentation, negotiation, and public speaking.

**CO-5** To teach students strategies to maintain mental and physical health while managing various life domains.

### **Practical:**

1. Create a daily and weekly schedule for better productivity.
  2. Deliver a short presentation or speech
  3. Break down long-term goals into actionable steps.
  4. Keep a journal on stress triggers and how you manage them.
  5. Reflect on team dynamics, leadership roles, and collaboration methods.
  6. Solve a problem using critical thinking and a structured approach.
  7. Attend a networking event or connect with professionals on LinkedIn.
  8. Develop a personal development plan (PDP) for improving skills over time.
  9. Create a plan to better manage work, studies, and personal time.
- **Workshops:** To practice interpersonal skills, presentations, and team collaboration.
  - **Group Discussions:** To simulate real-life workplace scenarios and team interactions.
  - **Presentations:** Practicing public speaking and confidence building.

### **COURSE OUTCOMES**

**COs-1** Develop self-awareness, including strengths, weaknesses, emotional intelligence, and personal goals. Learn how to manage time, stress, and personal resources effectively.

**COs-2** Enhance verbal and non-verbal communication skills, including listening, articulation, public speaking, and presentation techniques.

**COs-3** Students will strengthen interpersonal skills such as teamwork, collaboration, conflict resolution, and empathy to build effective relationships in personal and professional settings.

**COs-4** Students will understand leadership dynamics and acquire skills to work in teams, including leadership, delegation, motivation, and conflict resolution in group activities.

**COs-5** Students will be able to develop skills for setting realistic career goals, understanding career paths, and creating strategies for career advancement, including personal branding and networking.

**COs-6** Students will learn techniques to engage the audience, ensuring active participation and maintaining attention throughout their presentations.

**COs-7** Learn about professional behavior, workplace ethics, and etiquette, such as dressing, communication in formal settings, and adherence to ethical guidelines in professional environments.

### **Suggested Readings:**

- *Emotional Intelligence: Why It Can Matter More Than IQ* by Daniel Goleman
- *Getting Things Done: The Art of Stress-Free Productivity* by David Allen
- *The Relaxation and Stress Reduction Workbook* by Martha Davis, Elizabeth Robbins Eshelman, and Matthew McKay
- *The 7 Habits of Highly Effective People* by Stephen R. Covey



## **BP 106RBT.REMEDIAL BIOLOGY (Theory)**

**30 Hours**

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

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

### **UNIT I**

**07 Hours**

#### **Living world:**

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

#### **Morphology of Flowering plants**

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

### **UNIT II**

**07 Hours**

#### **Body fluids and circulation**

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

#### **Digestion and Absorption**

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

#### **Breathing and respiration**

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

### **UNIT III**

**07 Hours**

#### **Excretory products and their elimination**

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

#### **Neural control and coordination**

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

#### **Chemical coordination and regulation**

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

#### **Human reproduction**

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

### **UNIT IV**

**05 Hours**

#### **Plants and mineral nutrition:**

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

#### **Photosynthesis**

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

### **UNIT V**

**04 Hours**

**Plant respiration:**Respiration, glycolysis, fermentation (anaerobic).

#### **Plant growth and development**

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

#### **Cell - The unit of life**

- Structure and functions of cell and cell organelles.Cell division

#### **Tissues**

- Definition, types of tissues, location and functions.

**Text Books**

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

**Reference Books**

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

## **BP112RBP.REMEDIAL BIOLOGY (Practical)**

**30 Hours**

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

### **Reference Books**

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

## BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

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

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

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

### Course Content:

#### UNIT – I

06 Hours

- **Partial fraction**

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

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function:**

Real Valued function, Classification of real valued functions,

- **Limits and continuity :**

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

#### UNIT –II

06 Hours

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations



### UNIT – III

06 Hours

- **Calculus**

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

### UNIT – IV

06 Hours

- **Analytical Geometry**

**Introduction:** Signs of the Coordinates, Distance formula,

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

**Integration:**

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

### UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

### Recommended Books (Latest Edition)

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

## **Semester II**

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

**45 Hours**

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

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

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

### **Course Content:**

#### **Unit I**

**10 hours**

- **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

#### **Unit II**

**06 hours**

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, ( Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

### **Unit III**

- **Respiratory system**

**10 hours**

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

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

- **Urinary system**

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

### **Unit IV**

**10 hours**

- **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

### **Unit V**

**09 hours**

- **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

## **BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

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

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

### **Recommended Books (Latest Editions)**

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

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

**Reference Books:**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

## BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

**45 Hours**

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

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

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

### Course Content:

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

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

### UNIT-I

**07 Hours**

- **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

### UNIT-II 10 Hours

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

SP<sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes

E<sub>1</sub> and E<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E<sub>1</sub> versus E<sub>2</sub> reactions, Factors affecting E<sub>1</sub> and E<sub>2</sub> reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

### UNIT-III 10 Hours

- **Alkyl halides\***

SN<sub>1</sub> and SN<sub>2</sub> reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN<sub>1</sub> versus SN<sub>2</sub> reactions, Factors affecting SN<sub>1</sub> and SN<sub>2</sub> reactions

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

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

#### **UNIT-IV 10 Hours**

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

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

#### **UNIT-V**

**08 Hours**

- **Carboxylic acids\***

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

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

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



## **BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)**

**4 Hours / week**

1. Systematic qualitative analysis of unknown organic compounds like
  1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  3. Solubility test
  4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
  5. Melting point/Boiling point of organic compounds
  6. Identification of the unknown compound from the literature using melting point/ boiling point.
  7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
  8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

### **Recommended Books (Latest Editions)**

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

## **BP203 T. BIOCHEMISTRY (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT I**

**08 Hours**

- **Biomolecules**

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

- **Bioenergetics**

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

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

#### **UNIT II**

**10 Hours**

- **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

### **UNIT III**

**10 Hours**

- **Lipid metabolism**

β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

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

Catabolism of heme; hyperbilirubinemia and jaundice

#### **UNIT IV**

**10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

## UNIT V

07 Hours

- **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

### BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

### **Recommended Books (Latest Editions)**

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

## **BP 204T.PATHOPHYSIOLOGY (THEORY)**

**45Hours**

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

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

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

### **Course content:**

#### **Unit I**

**10Hours**

##### ☐ **Basic principles of Cell injury and Adaptation:**

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

☐ **Basic mechanism involved in the process of inflammation and repair:**

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

**Unit II**

**10Hours**

☐ **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

☐ **Respiratory system:** Asthma, Chronic obstructive airways diseases.

☐ **Renal system:** Acute and chronic renal failure .

**Unit II**

**10Hours**

☐ **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia

☐ **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones

☐ **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

☐ **Gastrointestinal system:** Peptic Ulcer

☐

**Unit IV**

**8 Hours**

☐ Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

☐ **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout

☐ **Principles of cancer:** classification, etiology and pathogenesis of cancer

☐ **Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout

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

**Unit V**

**7 Hours**

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

Urinary tract infections

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

**Recommended Books (Latest Editions)**

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

#### **Recommended Journals**

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



## **BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)**

**30 Hrs (2 Hrs/Week)**

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

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

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

### **Course content:**

#### **UNIT – I**

**06 hours**

**Number system:** Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

**Concept of Information Systems and Software :** Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

#### **UNIT –II**

**06 hours**

**Web technologies:** Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

#### **UNIT – III**

**06 hours**

**Application of computers in Pharmacy** – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

#### **UNIT – IV**

**06 hours**

**Bioinformatics:** Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

#### **UNIT-V**

**06 hours**

**Computers as data analysis in Preclinical development:**  
Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs)

### **BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

### **Recommended books (Latest edition):**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

## **BP 206 T. ENVIRONMENTAL SCIENCES (Theory)**

**30 hours**

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

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

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

### **Course content:**

#### **Unit-I**

**10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

#### **Unit-II**

**10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

#### **Unit- III**

**10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

## **SEMESTER III**

## BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

**45 Hours**

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

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

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

### Course Content:

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

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

### UNIT I

**10 Hours**

- **Benzene and its derivatives**

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

### UNIT II

**10 Hours**

- **Phenols\*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines\*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids\*** -Acidity, effect of substituents on acidity and important reactions of benzoic acid.

### UNIT III

**10 Hours**

- **Fats and Oils**

- a. Fatty acids – reactions.

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

#### **UNIT IV**

**08 Hours**

- **Polynuclear hydrocarbons:**

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

#### **UNIT V**

**07 Hours**

- **Cyclo alkanes\***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only



## **BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)**

**4 Hrs/week**

### **I Experiments involving laboratory techniques**

- Recrystallization
- Steam distillation

### **II Determination of following oil values (including standardization of reagents)**

- Acid value
- Saponification value
- Iodine value

### **III Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
- Cinnamic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

### **Recommended Books (Latest Editions)**

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

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

**BP302T. PHYSICAL PHARMACEUTICS-I (Theory)**

**45Hours**

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

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

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

**Course Content:**

**UNIT-I**

**10 Hours**

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

**UNIT-II**

**10Hours**

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

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

**UNIT-III**

**08 Hours**

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

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

#### **UNIT-IV**

**08Hours**

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

#### **UNIT-V**

**07 Hours**

**pH, buffers and Isotonic solutions:** Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

### **BP306P. PHYSICAL PHARMACEUTICS – I (Practical)**

**4 Hrs/week**

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

#### **Recommended Books: (Latest Editions)**

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

## **BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)**

**45Hours**

### **Scope:**

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

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

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

### **Course content:**

#### **Unit I**

**10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

#### **Unit II**

**10 Hours**

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

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

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

### **Unit III**

**10 Hours**

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

Classification and mode of action of disinfectants

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

Evaluation of bactericidal & Bacteriostatic.

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

### **Unit IV**

**08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

### **Unit V**

**07Hours**

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

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

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

Application of cell cultures in pharmaceutical industry and research.

## **BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)**

**4 Hrs/week**

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

### **Recommended Books (Latest edition)**

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

## **BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)**

**45 Hours**

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

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

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

### **Course content:**

#### **UNIT-I**

**10 Hours**

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

#### **UNIT-II**

**10 Hours**

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



- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

### UNIT- III

**08 Hours**

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

### UNIT-IV

**08 Hours**

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

### UNIT- V

**07 Hours**

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

**Recommended Books: (Latest Editions)**

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

## **BP308P - PHARMACEUTICAL ENGINEERING (Practical)**

**4 Hours/week**

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

## **SEMESTER IV**

## **BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)**

**45 Hours**

**Scope:** This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

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

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

### **Course Content:**

**Note: To emphasize on definition, types, mechanisms, examples, uses/applications**

#### **UNIT-I**

**10 Hours**

##### **Stereo isomerism**

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

#### **UNIT-II**

**10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

#### **UNIT-III**

**10 Hours**

**Heterocyclic compounds:**

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

**UNIT-IV****8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

**UNIT-V****07 Hours****Reactions of synthetic importance**

Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

**Recommended Books (Latest Editions)**

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

## **BP402T. MEDICINAL CHEMISTRY – I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

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

### **UNIT- I**

**10 Hours**

#### **Introduction to Medicinal Chemistry**

#### **History and development of medicinal chemistry**

#### **Physicochemical properties in relation to biological action**

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

#### **Drug metabolism**

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

### **UNIT- II**

**10 Hours**

#### **Drugs acting on Autonomic Nervous System**

#### **Adrenergic Neurotransmitters:**

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

#### **Sympathomimetic agents: SAR of Sympathomimetic agents**

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

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

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

#### **Adrenergic Antagonists:**

**Alpha adrenergic blockers:** Tolazoline\*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers:** SAR of beta blockers, Propranolol\*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

### **UNIT-III**

**10 Hours**

#### **Cholinergic neurotransmitters:**

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

#### **Parasympathomimetic agents: SAR of Parasympathomimetic agents**

**Direct acting agents:** Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine.

**Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):** Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathion, Malathion.

**Cholinesterase reactivator:** Pralidoxime chloride.

#### **Cholinergic Blocking agents: SAR of cholinolytic agents**

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

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

### **UNIT- IV**

**08 Hours**

#### **Drugs acting on Central Nervous System**



### **A. Sedatives and Hypnotics:**

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

**Barbiturates:** SAR of barbiturates, Barbitol\*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

#### **Miscellaneous:**

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

### **B. Antipsychotics**

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

**Ring Analogues of Phenothiazines:** Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

**Fluorobutyrophenones:** Haloperidol, Droperidol, Risperidone.

**Beta amino ketones:** Molindone hydrochloride.

**Benzamides:** Sulpieride.

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

**Barbiturates:** Phenobarbitone, Methobarbital. **Hydantoins:**

Phenytoin\*, Mephénytoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide\* **Urea and**

**monoacylureas:** Phenacemide, Carbamazepine\*

**Benzodiazepines:** Clonazepam

**Miscellaneous:** Primidone, Valproic acid, Gabapentin, Felbamate

**UNIT – V**

**07 Hours**

**Drugs acting on Central Nervous System**

**General anesthetics:**

**Inhalation anesthetics:** Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

**Ultra short acting barbiturates:** Methohexital sodium\*, Thiopental sodium, Thiopental sodium.

**Dissociative anesthetics:** Ketamine hydrochloride.\*

**Narcotic and non-narcotic analgesics**

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

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

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

## **BP406P. MEDICINAL CHEMISTRY – I (Practical)**

**4 Hours/Week**

### **I Preparation of drugs/ intermediates**

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

### **II Assay of drugs**

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

### **III Determination of Partition coefficient for any two drugs**

#### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

## **BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)**

**45Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**07 Hours**

**Colloidal dispersions:** Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

#### **UNIT-II**

**10 Hours**

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

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

#### **UNIT-III**

**10 Hours**

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

#### **UNIT-IV**

**10Hours**

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

#### **UNIT-V**

**10 Hours**

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

## **BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)**

**3 Hrs/week**

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

### **Recommended Books: (Latest Editions)**

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

## **BP 404 T. PHARMACOLOGY-I (Theory)**

**45 Hrs**

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

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

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

### **Course Content:**

#### **UNIT-I**

**08 hours**

##### **1. General Pharmacology**

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists( competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

#### **UNIT-II**

**12 Hours**

##### **General Pharmacology**

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.



**UNIT-III****10 Hours****2. Pharmacology of drugs acting on peripheral nervous system**

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

**UNIT-IV****08 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

**UNIT-V****07 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinson's disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

## **BP 408 P.PHARMACOLOGY-I (Practical)**

**4Hrs/Week**

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

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

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

## **BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Introduction to Pharmacognosy:**

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

##### **Classification of drugs:**

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

##### **Quality control of Drugs of Natural Origin:**

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

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

#### **UNIT-II**

**10 Hours**

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

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

##### **Conservation of medicinal plants**

#### **UNIT-III**

**07 Hours**

##### **Plant tissue culture:**

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

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

#### **UNIT IV**

**10 Hours**

##### **Pharmacognosy in various systems of medicine:**

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

##### **Introduction to secondary metabolites:**

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

#### **UNIT V**

**08 Hours**

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

##### **Plant Products:**

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

##### **Primary metabolites:**

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

**Carbohydrates:** Acacia, Agar, Tragacanth, Honey

**Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

**Lipids(Waxes, fats, fixed oils) :** Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

##### **Marine Drugs:**

Novel medicinal agents from marine sources



**BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)****4 Hours/Week**

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

**Recommended Books: (Latest Editions)**

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

## **SEMESTER V**



## BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

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

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

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

<b>Course Content:</b>
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**Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*)**

### UNIT- I

10 Hours

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

**H<sub>1</sub>-antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

**H<sub>2</sub>-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

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

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorothamine\*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

**Antimetabolites:** Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

**Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate

**Miscellaneous:** Cisplatin, Mitotane.

## UNIT – II

10 Hours

**Anti-anginal:**

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

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

**Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

**Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

## UNIT- III

10 Hours

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

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

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

**Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.



## UNIT- IV

08 Hours

### Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

**Sex hormones:** Testosterone, Nandralone, Progestones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

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

**Oral contraceptives:** Mifepristone, Norgestrel, Levonorgestrol

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

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

## UNIT – V

07 Hours

### Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

### Local Anesthetics: SAR of Local anesthetics

**Benzoic Acid derivatives;** Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine.

**Amino Benzoic acid derivatives:** Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

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

**Miscellaneous:** Phenacaine, Dipreron, Dibucaine.\*

### Recommended Books (Latest Editions)

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



## BP 502 T. Industrial PharmacyI (Theory)

**45 Hours**

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

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

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

### Course content:

**3 hours/ week**

#### UNIT-I

**07 Hours**

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

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

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

BCS classification of drugs & its significant

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

#### UNIT-II

**10 Hours**

##### Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

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

### UNIT-III

08 Hours

#### Capsules:

- a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

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

### UNIT-IV

10 Hours

#### Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

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

### UNIT-V

10 Hours

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

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

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

## **BP 506 P. Industrial PharmacyI (Practical)**

**4 Hours/week**

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

### **Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5<sup>th</sup>edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.



## **BP503.T. PHARMACOLOGY-II (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10hours**

##### **1. Pharmacology of drugs acting on cardio vascular system**

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

#### **UNIT-II**

**10hours**

##### **1. Pharmacology of drugs acting on cardio vascular system**

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

##### **2. Pharmacology of drugs acting on urinary system**

- a. Diuretics
- b. Anti-diuretics.

#### **UNIT-III**

**10hours**

##### **3. Autocoids and related drugs**

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

**UNIT-IV****08hours****5. Pharmacology of drugs acting on endocrine system**

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

**UNIT-V****07hours****5. Pharmacology of drugs acting on endocrine system**

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

**6. Bioassay**

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

## BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of  $PA_2$  value of prazosin using rat anococcygeus muscle (by Schild's plot method).
12. Determination of  $PD_2$  value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

### Recommended Books (Latest Editions)

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



## **BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

**45Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**7 Hours**

##### **Metabolic pathways in higher plants and their determination**

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

#### **UNIT-II**

**14 Hours**

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

**Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium,

**Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta

**Steroids, Cardiac Glycosides & Triterpenoids:** Liquorice, Dioscorea, Digitalis

**Volatile oils:** Mentha, Clove, Cinnamon, Fennel, Coriander,

**Tannins:** Catechu, Pterocarpus

**Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

**Glycosides:** Senna, Aloes, Bitter Almond

**Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids

#### **UNIT-III**

**06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

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

#### **UNIT-IV**

**10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

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

#### **UNIT V**

**8 Hours**

##### **Basics of Phytochemistry**

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

**BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**  
**4 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
  - a. Caffeine - from tea dust.
  - b. Diosgenin from Dioscorea
  - c. Atropine from Belladonna
  - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 2<sup>nd</sup> edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.



## **BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

#### **UNIT-II**

**10 Hours**

##### **Drugs and Cosmetics Act, 1940 and its rules 1945.**

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

#### **UNIT-III**

**10 Hours**

- **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and



## Penalties

- **Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

## UNIT-IV

**08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

## UNIT-V

**07 Hours**

- **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

## Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

## **SEMESTER VI**

## BP601T. MEDICINAL CHEMISTRY – III (Theory)

**45 Hours**

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

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

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

### Course Content:

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

### UNIT – I

**10 Hours**

#### Antibiotics

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

**β-Lactam antibiotics:** Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams

**Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

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

### UNIT – II

**10 Hours**

#### Antibiotics

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

**Macrolide:** Erythromycin Clarithromycin, Azithromycin.

**Miscellaneous:** Chloramphenicol\*, Clindamycin.

**Prodrugs:** Basic concepts and application of prodrugs design.

**Antimalarials:** Etiology of malaria.

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

**Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil.

**Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone.

### UNIT – III

**10 Hours**

#### **Anti-tubercular Agents**

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

**Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

#### **Urinary tract anti-infective agents**

**Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

**Miscellaneous:** Furazolidine, Nitrofurantoin\*, Methanamine.

#### **Antiviral agents:**

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

### UNIT – IV

**08 Hours**

#### **Antifungal agents:**

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

**Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole\*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*.

**Anti-protozoal Agents:** Metronidazole\*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

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

### **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

**Folate reductase inhibitors:** Trimethoprim\*, Cotrimoxazole.

**Sulfones:** Dapsone\*.

## **UNIT – V**

**07 Hours**

### **Introduction to Drug Design**

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

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

## **BP607P. MEDICINAL CHEMISTRY- III (Practical)**

**4 Hours / week**

### **I Preparation of drugs and intermediates**

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

### **II Assay of drugs**

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

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

### **IV Drawing structures and reactions using chem draw®**

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

### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.



## **BP602 T. PHARMACOLOGY-III (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10hours**

##### **1. Pharmacology of drugs acting on Respiratory system**

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

##### **2. Pharmacology of drugs acting on the Gastrointestinal Tract**

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

#### **UNIT-II**

**10hours**

##### **3. Chemotherapy**

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

#### **UNIT-III**

**10hours**

##### **3. Chemotherapy**

- a. Antitubercular agents
- b. Antileprotic agents

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

#### **UNIT-IV**

**08hours**

#### **3. Chemotherapy**

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

#### **4. Immunopharmacology**

- a. Immunostimulants
- b. Immunosuppressant

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

#### **UNIT-V**

**07hours**

#### **5. Principles of toxicology**

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

#### **6. Chronopharmacology**

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

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens ( rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology( student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

*\*Experiments are demonstrated by simulated experiments/videos*

**Recommended Books (Latest Editions)**

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

**BP 603 T. HERBAL DRUG TECHNOLOGY****(Theory)****45 hours**

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

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

**Course content:****UNIT-I****11 Hours****Herbs as raw materials**

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

**Biodynamic Agriculture**

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

**Indian Systems of Medicine**

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

**UNIT-II****7 Hours****Nutraceuticals**

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

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

**UNIT-III****10 Hours****Herbal Cosmetics**

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

**Herbal excipients:**

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

**Herbal formulations :**

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

**UNIT- IV**

**10 Hours**

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

**Patenting and Regulatory requirements of natural products:**

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

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

**UNIT-V**

**07 Hours**

**General Introduction to Herbal Industry**

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

**Schedule T – Good Manufacturing Practice of Indian systems of medicine**

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

## **BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

**4 hours/ week**

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

### **Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

## BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

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

### Course Content:

#### UNIT-I

10 Hours

##### Introduction to Biopharmaceutics

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

#### UNIT- II

10 Hours

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

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

#### UNIT- III

10 Hours

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters -  $K_E$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CL_R$ - definitions methods of eliminations, understanding of their significance and application

**UNIT- IV****08 Hours****Multicompartment models:** Two compartment open model. IV bolus

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

**UNIT- V****07 Hours****Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity.

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

**Recommended Books: (Latest Editions)**

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





## **BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

**45 Hours**

### **Scope:**

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

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

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

### **Unit I**

**10 Hours**

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

### **Unit II**

**10 Hours**

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
  - i) Interferon
  - ii) Vaccines- hepatitis- B
  - iii) Hormones-Insulin.
- d) Brief introduction to PCR

### **Unit III**

**10 Hours**

Types of immunity- humoral immunity, cellular immunity

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

### **Unit IV**

**08Hours**

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

### **Unit V**

**07 Hours**

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

### **Recommended Books (Latest edition):**

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

Society of Chemistry.

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

## **BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)**

**45 Hours**

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

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

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

**Course content:**

### **UNIT – I**

**10 Hours**

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

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

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

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

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

**NABL accreditation :** Principles and procedures

### **UNIT - II**

**10 Hours**

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

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

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

### **UNIT – III**

**10 Hours**

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

materials.

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

#### **UNIT – IV**

**08 Hours**

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

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

#### **UNIT – V**

**07 Hours**

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

**Warehousing:** Good warehousing practice, materials management

#### **Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

## **SEMESTER VII**

## **BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT –I**

**10 Hours**

##### **UV Visible spectroscopy**

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

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

Applications - Spectrophotometric titrations, Single component and multi component analysis

##### **Fluorimetry**

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

#### **UNIT –II**

**10 Hours**

##### **IR spectroscopy**

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

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

**Flame Photometry**-Principle, interferences, instrumentation and applications



**Atomic absorption spectroscopy-** Principle, interferences, instrumentation and applications

**Nepheloturbidometry-** Principle, instrumentation and applications

### **UNIT –III**

**10 Hours**

**Introduction to chromatography**

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

**Thin layer chromatography-** Introduction, Principle, Methodology, R<sub>f</sub> values, advantages, disadvantages and applications.

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

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

### **UNIT –IV**

**08 Hours**

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

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

### **UNIT –V**

**07 Hours**

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

**Gel chromatography-** Introduction, theory, instrumentation and applications

**Affinity chromatography-** Introduction, theory, instrumentation and applications

## **BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)**

**4 Hours/Week**

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

### **Recommended Books (Latest Editions)**

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

## **BP 702 T. INDUSTRIAL PHARMACYII (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10 Hours**

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

#### **UNIT-II**

**10 Hours**

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

#### **UNIT-III**

**10 Hours**

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

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

**UNIT-IV****08 Hours**

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

**UNIT-V****07 Hours**

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

**Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7<sup>th</sup> April available at [http://en.wikipedia.org/wiki/Regulatory\\_Affairs](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)**

**45 Hours**

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

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

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

### **Unit I:**

**10 Hours**

#### **a) Hospital and its organization**

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

#### **b) Hospital pharmacy and its organization**

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

#### **c) Adverse drug reaction**

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

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

**d) Community Pharmacy**

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

**Unit II:**

**10 Hours**

**a) Drug distribution system in a hospital**

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

**b) Hospital formulary**

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

**c) Therapeutic drug monitoring**

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

**d) Medication adherence**

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

**e) Patient medication history interview**

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

**f) Community pharmacy management**

Financial, materials, staff, and infrastructure requirements.

**Unit III:**

**10 Hours**

**a) Pharmacy and therapeutic committee**

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

**b) Drug information services**

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

**c) Patient counseling**

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

**d) Education and training program in the hospital**

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

**e) Prescribed medication order and communication skills**

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

**Unit IV**

**8 Hours**

**Budget preparation and implementation**

Budget preparation and implementation

**a) 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.

**b) Over the counter (OTC) sales**

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

**Unit V**

**7 Hours**

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

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

**b) Investigational use of drugs**

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

**c) Interpretation of Clinical Laboratory Tests**

Blood chemistry, hematology, and urinalysis

**Recommended Books (Latest Edition):**

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

**Skill Enhancement Course : Practical (Qualifying course) (BP706PS-A)**

**CO: COURSE OBJECTIVES**

**CO-1** To equip students with hands-on skills and practical knowledge in various areas of pharmaceutical sciences, such as formulation, quality control, and analysis of pharmaceuticals.

**CO-2** To ensure students become proficient in laboratory techniques, including synthesis, testing, and analysis of drugs, as well as handling sophisticated instruments.

**CO-3** To cultivate ethical conduct and adherence to safety guidelines in the laboratory and other professional environments.

**CO-4** To strengthen students' ability to communicate scientific findings, collaborate in team-based projects, and present results effectively.

**CO-5** To prepare students for professional roles in the pharmaceutical industry, hospitals, and research by simulating real-world challenges and work environments.

**CO-6** To promote critical thinking and analytical skills, encouraging students to troubleshoot problems, analyze



data, and optimize processes.

**Practical:**

1. Patient counseling techniques.
2. Drug-drug interaction checks using standard drug databases.
3. Case studies on common diseases (like hypertension, diabetes, etc.)
4. Interpretation of laboratory data relevant to drug therapy.
5. Inventory control and management (FIFO, LIFO methods)
6. Preparation of reports on hospital pharmacy systems (outpatient and inpatient)
7. Practical sessions on Good Manufacturing Practices (GMP) and Quality Control
8. Familiarization with medical equipment used in hospitals and clinics.

**COURSE OUTCOMES**

**COs-1** Students will develop practical skills relevant to the pharmaceutical or technical industry through hands-on experience.

**COs-2** Students will Gain familiarity with standard equipment and techniques used in laboratory or field environments.

**COs-3** Students will learn and apply regulatory, safety, and ethical standards in practical situations, including laboratory work and industrial practices.

**COs-4** Students will develop effective communication and teamwork skills through group projects and collaborative tasks.

**COs-5** Students will be able to learn the skills to plan, execute, and manage time efficiently in practical projects and assignments.

**Suggested Readings:**

- "Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists" by David G. Watson.
- "Practical Skills in Pharmacy" by John Hickey and Marjorie Weiss.
- "Pharmacy Practice" by Kevin Taylor, Geoffrey Harding, and Azzah Al-Muhtadi.

## **Data Analysis / Computer Programming (BP706PS-B)**

### **CO: COURSE OBJECTIVES**

**CO-1** To introduce students to fundamental programming concepts and techniques, including variables, data types, operators, control structures, and functions.

**CO-2** To provide knowledge about common data structures such as arrays, lists, stacks, queues, and their applications in organizing and managing data.

**CO-3** To teach students how to create and interpret various forms of data visualizations (e.g., charts, graphs) using programming tools.

**CO-4** To provide students with knowledge of basic statistical methods and how to apply them to analyze datasets using programming.

**CO-5** To guide students in designing and implementing projects that involve significant data analysis tasks, fostering creativity and problem-solving skills.

### **Practical:**

1. Handling missing values, outliers, and duplicates.
2. Visualizing data using plots (e.g., histograms, box plots, scatter plots), identifying patterns.
3. Retrieving data, joining tables, and performing aggregate functions.
4. Basics of working with databases like MongoDB or Firebase.
5. Students may be required to build a project based on real-world datasets, where they demonstrate data analysis, visualization, and model-building skills.
6. Using visual analytics tools for advanced data presentation.

### **COURSE OUTCOMES**

**COs-1** Students will demonstrate proficiency in at least one programming language, such as Python, R, or Java, by writing clean, efficient, and bug-free code.

**COs-2** Students will perform basic and advanced statistical analyses on datasets using appropriate algorithms and techniques.

**COs-3** Students will demonstrate the ability to work with databases by retrieving, manipulating, and analyzing data using SQL or NoSQL queries.

**COs-4** Students will develop a complete data analysis project from problem identification to solution presentation, demonstrating the ability to apply course concepts to real-world data.

**COs-5** Students will be able to demonstrate an understanding of data privacy laws and ethical considerations in data analysis and programming.

### **Suggested Readings:**

- "Clean Code: A Handbook of Agile Software Craftsmanship" by Robert C. Martin
- "The Pragmatic Programmer: Your Journey to Mastery" by Andrew Hunt and David Thomas

## Python Programming (BP706PS-C)

### CO: COURSE OBJECTIVES

**CO-1** To provide students with an understanding of Python's syntax, basic structure, and built-in data types such as strings, lists, dictionaries, and tuples.

**CO-2** To enable students to implement conditional statements, loops (for and while), and functions to write modular code.

**CO-3** To cultivate problem-solving skills by applying Python to solve computational and real-world problems using logical algorithms.

**CO-4** To introduce object-oriented programming principles in Python, including classes, objects, inheritance, polymorphism, and encapsulation.

**CO-5** To introduce advanced data structures such as stacks, queues, linked lists, and trees, and how to implement them in Python.

**CO-6** To provide an introduction to algorithmic techniques such as searching, sorting, and basic recursion, and implementing these algorithms in Python.

### Practical:

1. **Introduction to Python IDEs** (e.g., PyCharm, Jupyter Notebook, VS Code)
2. Python Syntax and Structure: Variables, Data Types (int, float, str, bool), Basic Input and Output
3. Parameters and Return Values
4. Importing and Using Built-in Modules (e.g., math, random, datetime)
5. **Numpy** (Numerical Python) – Arrays, Matrix Operations
6. Mini Projects that apply the learned concepts, such as: Data Analysis Projects using CSV files and Pandas
7. Debugging Code using Print Statements and Python Debugger (pdb)

### COURSE OUTCOMES

**COs-1** Students will be able to understand Python Syntax and Programming Structure. Ability to write Python code using appropriate syntax.

**COs-2** Students learn to use Python for problem-solving, including mathematical calculations, string manipulation, and list operations.

**COs-3** Students will learn to understand the concept of reusable code through functions and modularization.

**COs-4** Students will develop effective communication and teamwork skills through group projects and collaborative tasks.

**COs-5** Students will be able to understand the concepts of inheritance, encapsulation, and polymorphism.

**COs-6** Ability to design and develop small applications or scripts to automate tasks or solve specific problems.

### Suggested Readings:

- “Python Crash Course” by Eric Matthes
- “Learning Python” by Mark Lutz



## **BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)**

**45 Hours**

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

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

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

### **Course content:**

#### **Unit-I**

**10 Hours**

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

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

#### **Unit-II**

**10 Hours**

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

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

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

#### **Unit-III**

**10 Hours**

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

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

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

#### **Unit-IV**

**08 Hours**

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

## **Unit-V**

**07 Hours**

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

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

### **Recommended Books: (Latest Editions)**

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

### **Journals**

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

## **SEMESTER VIII**

## **BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)**

**45 Hours**

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

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

### **Course content:**

#### **Unit-I**

**10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution

**Measures of central tendency:** Mean, Median, Mode- Pharmaceutical examples

**Measures of dispersion:** Dispersion, Range, standard deviation, Pharmaceutical problems

**Correlation:** Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

#### **Unit-II**

**10 Hours**

**Regression:** Curve fitting by the method of least squares, fitting the lines  $y = a + bx$  and  $x = a + by$ , Multiple regression, standard error of regression– Pharmaceutical Examples

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

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

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

#### **Unit-III**

**10 Hours**

**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test



**Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

**Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

#### **Unit-IV**

**8 Hours**

Blocking and confounding system for Two-level factorials

**Regression modeling:** Hypothesis testing in Simple and Multiple 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 to Industrial and Clinical trial approach

#### **Unit-V**

**7Hours**

**Design and Analysis of experiments:**

**Factorial Design:** Definition,  $2^2$ ,  $2^3$  design. Advantage of factorial design

**Response Surface methodology:** Central composite design, Historical design, Optimization Techniques

#### **Recommended Books (Latest edition):**

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

## **BP 802T SOCIAL AND PREVENTIVE PHARMACY**

**Hours: 45**

### **Scope:**

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

### **Objectives:**

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

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

### **Course content:**

#### **Unit I:**

**10 Hours**

**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

**Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

**Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

**Hygiene and health:** personal hygiene and health care; avoidable habits

#### **Unit II:**

**10 Hours**

**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

#### **Unit III:**

**10 Hours**

**National health programs, its objectives, functioning and outcome of the following:** HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

**Unit IV:**

**08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

**Unit V:**

**07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

**Recommended Books (Latest edition):**

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

**Recommended Journals:**

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

## **BP803ET. PHARMA MARKETING MANAGEMENT (Theory)**

**45 Hours**

### **Scope:**

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

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

### **Unit I**

**10 Hours**

#### **Marketing:**

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

#### **Pharmaceutical market:**

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

### **Unit II**

**10 Hours**

#### **Product decision:**

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

### **Unit III**

**10 Hours**

#### **Promotion:**

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

#### **Unit IV**

**10 Hours**

##### **Pharmaceutical marketing channels:**

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

##### **Professional sales representative (PSR):**

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

#### **Unit V**

**10 Hours**

##### **Pricing:**

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

##### **Emerging concepts in marketing:**

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

##### **Recommended Books: (Latest Editions)**

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



## **BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

**45Hours**

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

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

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

### **Course content:**

#### **Unit I**

**10Hours**

##### **New Drug Discovery and development**

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

#### **Unit II**

**10Hours**

##### **Regulatory Approval Process**

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

##### **Regulatory authorities and agencies**

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

#### **Unit III**

**10Hours**

##### **Registration of Indian drug product in overseas market**

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

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

#### **Unit IV**

**08Hours**

##### **Clinical trials**

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

#### **Unit V**

**07Hours**

##### **Regulatory Concepts**

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

##### **Recommended books (Latest edition):**

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



## BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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

### Objectives:

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

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

## Course Content

### Unit I

10 Hours

#### Introduction to Pharmacovigilance

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

#### Introduction to adverse drug reactions

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

#### Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

## **Unit II**

**10 hours**

### **Drug and disease classification**

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

### **Drug dictionaries and coding in pharmacovigilance**

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

### **Information resources in pharmacovigilance**

- Basic drug information resources
- Specialised resources for ADRs

### **Establishing pharmacovigilance programme**

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

## **Unit III**

**10 Hours**

### **Vaccine safety surveillance**

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

### **Pharmacovigilance methods**

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

### **Communication in pharmacovigilance**

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

## Unit IV

8 Hours

### Safety data generation

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

### ICH Guidelines for Pharmacovigilance

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

## Unit V

7 hours

### Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

### Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

### CIOMS

- CIOMS Working Groups
- CIOMS Form

### CDSCO (India) and Pharmacovigilance

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

### Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology 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
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

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

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

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

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

### **Unit I**

**10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

### **Unit II**

**10 hours**

**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

### **Unit III**

**10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

### **Unit IV**

**08 hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

## **Unit V**

**07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

### **Recommended Books: (Latest Editions)**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

## BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

**45 Hours**

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

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

### Course Content:

#### UNIT-I

**10 Hours**

##### **Introduction to Drug Discovery and Development**

Stages of drug discovery and development

##### **Lead discovery and Analog Based Drug Design**

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

**Analog Based Drug Design:** Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

#### UNIT-II

**10 Hours**

##### **Quantitative Structure Activity Relationship (QSAR)**

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

#### UNIT-III

**10 Hours**

##### **Molecular Modeling and virtual screening techniques**

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

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



**UNIT-IV****08 Hours****Informatics & Methods in drug design**

Introduction to Bioinformatics, chemo informatics. ADME databases, chemical, biochemical and pharmaceutical databases.

**UNIT-V****07 Hours**

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

**Recommended Books (Latest Editions)**

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

## **BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)**

**45 Hours**

### **Scope:**

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

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

### **Course content:**

#### **Unit I**

**10Hours**

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

#### **Unit II**

**10 Hours**

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

#### **Unit III**

**10 Hours**

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

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

#### **Unit IV**

**08 Hours**

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

#### **Unit V**

**07 Hours**

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

#### **Recommended Books (latest edition):**

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

## **BP809ET. COSMETIC SCIENCE(Theory)**

**45Hours**

### **UNIT I**

**10Hours**

Classification of cosmetic and cosmeceutical products

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

**Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

**Skin:** Basic structure and function of skin.

**Hair:** Basic structure of hair. Hair growth cycle.

**Oral Cavity:** Common problem associated with teeth and gums.

### **UNIT II**

**10 Hours**

**Principles of formulation and building blocks of skin care products:**

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

**Antiperspirants & deodorants-** Actives & mechanism of action.

**Principles of formulation and building blocks of Hair care products:**

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

### **UNIT III**

**10 Hours**

Sun protection, Classification of Sunscreens and SPF.

**Role of herbs in cosmetics:**

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

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

### **UNIT IV**

**08 Hours.**

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

## **UNIT V**

**07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

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

Antiperspirants and Deodorants- Actives and mechanism of action

### **References**

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## BP810 ET. PHARMACOLOGICAL SCREENING METHODS

**45 Hours**

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

### Objectives

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

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

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

<b>Unit –III</b>  <b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
<b>Unit –IV</b>  <b>Preclinical screening models:</b> 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.	
<b>Research methodology and Bio-statistics</b> 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	<b>05 Hours</b>

**Recommended Books (latest edition):**

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

## **BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES**

**45 Hours**

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

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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

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

#### **UNIT-II**

**10 Hours**

**Thermal Methods of Analysis:** Principles, instrumentation and applications of 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.

#### **UNIT-III**

**10 Hours**

**Calibration and validation-**as per ICH and USFDA guidelines

##### **Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,



Fluorimeter, Flame Photometer, HPLC and GC

**UNIT-IV**

**08 Hours**

**Radio immune assay:**Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

**Extraction techniques:**General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

**UNIT-V**

**07 Hours**

**Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.

**Recommended Books (Latest Editions)**

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

## **BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

**No. of hours :3**

**Tutorial:1**

**Credit point:4**

### **Scope :**

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

### **Objective:**

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

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

### **UNIT I**

**07 hours**

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

### **UNIT II**

**15 hours**

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

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

### **UNIT III**

**07 hours**

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

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

#### **UNIT IV**

**10 hours**

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ - Lipoic acid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

#### **UNIT V**

**06 hours**

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

#### **References:**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
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 2<sup>nd</sup> Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 *Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

## **Semester VIII – Elective course on Pharmaceutical Product Development**

**No of Hours: 3**

**Tutorial:1**

**Credit points:4**

### **Unit-I**

**10 Hours**

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

### **Unit-II**

**10 Hours**

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

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

### **Unit-III**

**10 Hours**

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

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

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

### **Unit-IV**

**08 Hours**

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

### **Unit-V**

**07 Hours**

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



**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, 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 R. P. 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.



# Shobhit University, Gangoh

(Established by UP Shobhit University Act No. 3, 2012)

## School Of Pharmacy

### Ordinances, Regulations & Syllabus

For

**Bachelor of Pharmacy (B.Pharm) 4 Year Programme Semester  
Pattern**

**(w.e.f.session2013-14)**

**Approved by Pharmacy Council of India and  
adopted in the year 2013, 1<sup>st</sup> Meeting, Board of  
Studies.**

**[Frame under Regulation 6,7 & 8 of the Bachelor of Pharmacy (B. Pharm)]**

## **CHAPTER- I: REGULATIONS**

### **1. Short Title and Commencement**

These regulations shall be called as “The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

### **2. Minimum qualification for admission**

#### **First year B. Pharm:**

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

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

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

### **3. Duration of the program**

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

### **4. Medium of instruction and examinations**

Medium of instruction and examination shall be in English.

### **5. Working days in each semester**

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

### **6. Attendance and progress**

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



## **7. Program/Course credit structure**

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

### **Credit assignment**

#### **Theory and Laboratory courses**

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

#### **Minimum credit requirements**

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

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

## **8. Academic work**

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

### 9. Course of study

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

**Table-I: Course of study for semester I**

Course code	Name of the course	No. of hours	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
<b>Total</b>		<b>32/34<sup>§</sup>/36<sup>#</sup></b>	<b>4</b>	<b>27/29<sup>§</sup>/30<sup>#</sup></b>

<sup>#</sup>Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

<sup>§</sup>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**

<b>Course Code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
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
<b>Total</b>		<b>32</b>	<b>4</b>	<b>29</b>

\*Non University Examination (NUE)

**Table-III: Course of study for semester III**

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

**Table-IV: Course of study for semester IV**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
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
<b>Total</b>		<b>31</b>	<b>5</b>	<b>28</b>

**Table-V: Course of study for semester V**

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

**Table-VI: Course of study for semester VI**

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

**Table-VII: Course of study for semester VII**

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

\* Non University Examination (NUE)

**Table-VIII: Course of study for semester VIII**

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
<b>Total</b>		<b>24</b>	<b>4</b>	<b>22</b>

**Table-IX: Semester wise credits distribution**

Semester	Credit Points
I	27/29 <sup>§</sup> /30 <sup>#</sup>
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
<b>Total credit points for the program</b>	<b>209/211<sup>§</sup>/212<sup>#</sup></b>

\* 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.

<sup>§</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

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

## **10. Program Committee**

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

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

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

## **11. Examinations/Assessments**

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

### **End semester examinations**

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

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

**Semester I**

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

<sup>#</sup>Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

<sup>§</sup>Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

\* Non University Examination (NUE)



## Semester II

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

\* The subject experts at college level shall conduct examinations

### Semester III

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

### Semester IV

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

### Semester V

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

## Semester VI

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

## Semester VII

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

\* The subject experts at college level shall conduct examinations

### Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150

<b>Total</b>	<b>40</b>	<b>60</b>	<b>4 Hrs</b>	<b>100</b>	<b>450</b>	<b>16 Hrs</b>	<b>550</b>
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### Internal assessment: Continuous mode

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

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

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

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

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

#### 11.2.1. Sessional Exams

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

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

#### Question paper pattern for theory Sessional examinations

##### For subjects having University examination

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

**For subjects having Non University Examination**

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

**Question paper pattern for practical sessional examinations**

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05
		-----
Total	=	40 marks
		-----

**12. Promotion and award of grades**

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

**13. Carry forward of marks**

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

**14. Improvement of internal assessment**

A student shall have the opportunity to improve his/her performance only once in the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

**15. Re-examination of end semester examinations**

Reexamination of end semester examinations 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) = 20 x 1 = 20  
OR

Objective Type Questions (10 x 2) = 10 x 2 = 20  
(Answer all the questions)

II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

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Total = 75 marks  
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**For 50 marks paper**

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks  
-----

**For 35 marks paper**

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

II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks  
-----

**Question paper pattern for end semester practical examinations**

I. Synopsis = 5

II. Experiments = 25

III. Viva voce = 5

-----  
Total = 35 marks  
-----

**16. Academic Progression:**

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

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

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

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

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

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

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

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

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

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

## 17. Grading of performances

### Letter grades and grade points allocations:

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

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

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

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the saidevaluation/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 AB Sgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

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

### 19. Cumulative Grade Point Average (CGPA)

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

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

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

### 20. Declaration of class

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

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

### 21. Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

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

***Evaluation of Dissertation Book:***

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks

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<b>Total</b>	<b>75 Marks</b>
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***Evaluation of Presentation:***

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

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<b>Total</b>	<b>75 Marks</b>
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*Explanation:* The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

**22. Industrial training (Desirable)**

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

**23. Practice School**

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

**24. Award of Ranks**

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

**25. Award of degree**

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

**26. Duration for completion of the program of study**

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

**27. Re-admission after break of study**

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

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

**Programme Educational Objectives (PEOs)**

**PEO1 Applying principles and technologies:** Graduates should be able to apply principles and technologies to develop, formulate, and manufacture drugs and pharmaceuticals.

**PEO2 Serving society:** Graduates should be able to use medications and devices appropriately to achieve optimal therapeutic outcomes.

**PEO3 Promoting leadership and ethics:** Graduates should be able to demonstrate leadership and entrepreneurship qualities, as well as professional ethics and human values.

**PEO4 Lifelong learning :** Graduates should be able to absorb new technologies and continue learning throughout their lives.

**PEO5 Communicating effectively:** Graduates should be able to communicate well with other healthcare professionals.

**PEO6 Meeting industry needs:** Graduates should be able to meet the needs of the pharmaceutical industry and provide clinical services to the community.

**PEO7 Academic excellence:** Graduates should have knowledge of fundamental principles and their applications in pharmaceutical sciences and technology.



**PEO8 Technical competence:** Graduates should have strong fundamental concepts and high technical competence in pharmaceutical sciences.

**PEO9 Professional Competence:** Graduates will demonstrate the knowledge and skills necessary to practice pharmacy effectively in various healthcare settings, ensuring safe and effective medication use.

**PEO10 Patient-Centered Care:** Graduates will provide high-quality, patient-centered care, including medication management, counseling, and health promotion, to improve patient outcomes.

**PEO11 Inter-professional Collaboration:** Graduates will work collaboratively within interdisciplinary healthcare teams to optimize patient care and contribute to public health initiatives.

### **Programme Specific Objectives (PSO's)**

**PSO1 Pharmaceutical Care Skills:** Students will demonstrate the ability to assess patient medication needs, develop individualized care plans, and implement appropriate therapeutic interventions.

**PSO2 Drug Development and Management:** Students will gain knowledge in drug formulation, development processes, and the management of pharmaceutical products throughout their lifecycle.

**PSO3 Clinical Knowledge Application:** Students will apply pharmacological principles and clinical knowledge to evaluate and optimize drug therapy in diverse patient populations.

**PSO4 Regulatory and Compliance Understanding:** Students will understand the regulatory frameworks governing pharmacy practice, including drug approval processes, safety, and quality assurance.

**PSO5 Communication Proficiency:** Students will develop effective communication skills to counsel patients, collaborate with healthcare professionals, and convey complex information clearly.

**PSO6 Health Promotion and Disease Prevention:** Students will engage in public health initiatives, providing education on disease prevention and health promotion strategies.

**PSO7 Research and Evidence-Based Practice:** Students will engage in research activities and apply evidence-based practices to inform clinical decisions and improve patient outcomes.

**PSO8 Ethical Decision-Making:** Students will learn to navigate ethical dilemmas in pharmacy practice, demonstrating professional judgment and integrity.

### **Programme Outcome Objectives (POO's)**

**POO1 Clinical Competence:** Graduates will be able to conduct comprehensive medication reviews, assess patient health needs, and design effective therapeutic regimens.

**POO2 Pharmaceutical Knowledge:** Graduates will possess a thorough understanding of pharmacology, pharmacotherapy, drug interactions, and the mechanisms of drug action.

**POO3 Ethical Practice:** Graduates will demonstrate professionalism and ethical behavior in all aspects of pharmacy practice, including patient interactions and professional relationships.

**POO4 Communication Skills:** Graduates will effectively communicate with patients, caregivers, and healthcare team members, ensuring clarity and understanding of medication information.

**POO5 Critical Thinking and Problem Solving:** Graduates will apply critical thinking skills to analyze patient data, identify medication-related problems, and develop appropriate solutions.

**POO6 Research and Evidence-Based Practice:** Graduates will be able to conduct research, critically evaluate scientific literature, and apply evidence-based guidelines in clinical practice.

**POO7 Interprofessional Collaboration:** Graduates will work effectively within interdisciplinary teams to enhance patient care and contribute to overall healthcare delivery.

**POO8 Lifelong Learning:** Graduates will demonstrate a commitment to continuous professional development and lifelong learning in the rapidly evolving field of pharmacy.

**POO9 Public Health Awareness:** Graduates will engage in community health initiatives, promoting wellness and preventive care through education and outreach.

## **CHAPTER - II: SYLLABUS**

## **Semester I**

## **BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **Unit I**

**10 hours**

- **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

- **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

- **Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

#### **Unit II**

**10 hours**

- **Integumentary system**

Structure and functions of skin

- **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

- **Joints**

Structural and functional classification, types of joints movements and its articulation

**Unit III**

**10 hours**

- **Body fluids and blood**

- Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

- **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

**Unit IV**

**08 hours**

**Peripheral nervous system:**

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

- **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

**Unit V**

**07 hours**

- **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

## **BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

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

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

### **Recommended Books (Latest Editions)**

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

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books (Latest Editions)**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata



## BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

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

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

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

### Course Content:

#### UNIT-I

10 Hours

(a) **Pharmaceutical analysis**- Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

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

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

#### UNIT-II

10 Hours

- **Acid base titration:** Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- **Non aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

#### UNIT-III

10 Hours

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

## **UNIT-IV**

**08 Hours**

### **Redox titrations**

(a) Concepts of oxidation and reduction

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

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

## **UNIT-V**

**07 Hours**

### **• Electrochemical methods of analysis**

- **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
- **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

## **BP108P. PHARMACEUTICAL ANALYSIS (Practical)**

**4 Hours / Week**

### **I Limit Test of the following**

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

### **II Preparation and standardization of**

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

### **III Assay of the following compounds along with Standardization of Titrant**

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

### **IV Determination of Normality by electro-analytical methods**

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

### **Recommended Books: (Latest Editions)**

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

## **BP103T. PHARMACEUTICS- I (Theory)**

**45 Hours**

**Scope:** This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

### **Course Content:**

#### **UNIT – I**

**10 Hours**

- **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

#### **UNIT – II**

**10 Hours**

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

### UNIT – III

08 Hours

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

### UNIT – IV

08 Hours

- **Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

### UNIT – V

07 Hours

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms

**1 . Syrups**

- a) Syrup IP'66
- b) Compound syrup of Ferrous Phosphate BPC'68

**2. Elixirs**

- a) Piperazine citrate elixir
- b) Paracetamol pediatric elixir

**3.Linctus**

- a) Terpin Hydrate Linctus IP'66
- b) Iodine Throat Paint (Mandles Paint)

**4. Solutions**

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution
- c) Lugol's solution

**5. Suspensions**

- a) Calamine lotion
- b) Magnesium Hydroxide mixture
- c) Aluminium Hydroxide gel

**6. Emulsions**

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

**7. Powders and Granules**

- a) ORS powder (WHO)
- b) Effervescent granules
- c) Dusting powder
- d) Divided powders

**8. Suppositories**

- a) Glycero gelatin suppository
- b) Cocoa butter suppository
- c) Zinc Oxide suppository

**8. Semisolids**

- a) Sulphur ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel

**9. Gargles and Mouthwashes**

- a) Iodine gargle
- b) Chlorhexidine mouthwash

**Recommended Books: (Latest Editions)**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

## **BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT I**

**10 Hours**

- **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

**General methods of preparation,** assay for the compounds superscripted with **asterisk (\*)**, properties and medicinal uses of inorganic compounds belonging to the following classes

#### **UNIT II**

**10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- **Major extra and intracellular electrolytes:** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

#### **UNIT III**

**10 Hours**

- **Gastrointestinal agents**

**Acidifiers:** Ammonium chloride\* and Dil. HCl

**Antacid:** Ideal properties of antacids, combinations of antacids, Sodium



Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture

**Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

**Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

#### UNIT IV

08 Hours

- **Miscellaneous compounds**

**Expectorants:** Potassium iodide, Ammonium chloride\*.

**Emetics:** Copper sulphate\*, Sodium potassium tartarate

**Haematinics:** Ferrous sulphate\*, Ferrous gluconate

**Poison and Antidote:** Sodium thiosulphate\*, Activated charcoal, Sodium nitrite

**Astringents:** Zinc Sulphate, Potash Alum

#### UNIT V

07 Hours

- **Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of  $\alpha$ ,  $\beta$ ,  $\gamma$  radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.

## **BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)**

**4 Hours / Week**

### **I Limit tests for following ions**

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

### **II Identification test**

Magnesium hydroxide  
Ferrous sulphate  
Sodium bicarbonate  
Calcium gluconate  
Copper sulphate

### **III Test for purity**

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

### **IV Preparation of inorganic pharmaceuticals**

Boric acid  
Potash alum  
Ferrous sulphate

### **Recommended Books (Latest Editions)**

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

Pharmacopoeia

## **BP105T.COMMUNICATION SKILLS (Theory)**

**30 Hours**

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

### **Objectives:**

Upon completion of the course the student shall be able to

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

### **Course content:**

#### **UNIT – I**

**07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

#### **UNIT – II**

**07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

### UNIT – III

**07 Hours**

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

### UNIT – IV

**05 Hours**

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

### UNIT – V

**04 Hours**

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

## **BP111P.COMMUNICATION SKILLS (Practical)**

**2 Hours / week**

The following learning modules are to be conducted using wordsworth® English language lab software

### **Basic communication covering the following topics**

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

### **Pronunciations covering the following topics**

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

### **Advanced Learning**

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

**Recommended Books: (Latest Edition)**

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

## **BP 106RBT.REMEDIAL BIOLOGY (Theory)**

**30 Hours**

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

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

### **UNIT I**

**07 Hours**

#### **Living world:**

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

#### **Morphology of Flowering plants**

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

### **UNIT II**

**07 Hours**

#### **Body fluids and circulation**

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

#### **Digestion and Absorption**

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

#### **Breathing and respiration**

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

### **UNIT III**

**07 Hours**

#### **Excretory products and their elimination**

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

#### **Neural control and coordination**

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

#### **Chemical coordination and regulation**

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

#### **Human reproduction**

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

### **UNIT IV**

**05 Hours**

#### **Plants and mineral nutrition:**

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

#### **Photosynthesis**

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

### **UNIT V**

**04 Hours**

**Plant respiration:** Respiration, glycolysis, fermentation (anaerobic).

#### **Plant growth and development**

- Phases and rate of plant growth, Condition of growth, Introduction to plant growthregulators

#### **Cell - The unit of life**

- Structure and functions of cell and cell organelles. Cell division

#### **Tissues**

- Definition, types of tissues, location and functions.



**Text Books**

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

**Reference Books**

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

## **BP112RBP.REMEDIAL BIOLOGY (Practical)**

**30 Hours**

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

### **Reference Books**

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

## BP 106RMT.REMEDIAL MATHEMATICS (Theory)

**30 Hours**

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

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

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

### Course Content:

#### UNIT – I

**06 Hours**

- **Partial fraction**

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

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function:**

Real Valued function, Classification of real valued functions,

- **Limits and continuity :**

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

$$\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}, \quad \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1$$

#### UNIT –II

**06 Hours**

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

### UNIT – III

06 Hours

- **Calculus**

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

### UNIT – IV

06 Hours

- **Analytical Geometry**

**Introduction:** Signs of the Coordinates, Distance formula,

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

**Integration:**

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

### UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

### Recommended Books (Latest Edition)

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

## **Semester II**

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

**45 Hours**

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

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

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

### **Course Content:**

#### **Unit I**

**10 hours**

##### **● Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

#### **Unit II**

**06 hours**

##### **● Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, ( Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

### **Unit III**

- **Respiratory system**

**10 hours**

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

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

- **Urinary system**

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

### **Unit IV**

**10 hours**

- **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

### **Unit V**

**09 hours**

- **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

## **BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

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

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

### **Recommended Books (Latest Editions)**

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



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

**Reference Books:**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

## BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

**45 Hours**

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

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

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

### Course Content:

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

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

### UNIT-I

**07 Hours**

- **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

### UNIT-II 10 Hours

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

SP<sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes

E<sub>1</sub> and E<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E<sub>1</sub> versus E<sub>2</sub> reactions, Factors affecting E<sub>1</sub> and E<sub>2</sub> reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

### UNIT-III 10 Hours

- **Alkyl halides\***

SN<sub>1</sub> and SN<sub>2</sub> reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN<sub>1</sub> versus SN<sub>2</sub> reactions, Factors affecting SN<sub>1</sub> and SN<sub>2</sub> reactions

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

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

#### **UNIT-IV 10 Hours**

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

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

#### **UNIT-V**

**08 Hours**

- **Carboxylic acids\***

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

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

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

## **BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)**

**4 Hours / week**

1. Systematic qualitative analysis of unknown organic compounds like
  1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  3. Solubility test
  4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
  5. Melting point/Boiling point of organic compounds
  6. Identification of the unknown compound from the literature using melting point/ boiling point.
  7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
  8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

### **Recommended Books (Latest Editions)**

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

## **BP203 T. BIOCHEMISTRY (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT I**

**08 Hours**

- **Biomolecules**

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

- **Bioenergetics**

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

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

#### **UNIT II**

**10 Hours**

- **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

### **UNIT III**

**10 Hours**

- **Lipid metabolism**

β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

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

Catabolism of heme; hyperbilirubinemia and jaundice

#### **UNIT IV**

**10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

## UNIT V

07 Hours

- **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

### BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.



### **Recommended Books (Latest Editions)**

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

### **BP 204T.PATHOPHYSIOLOGY (THEORY)**

**45Hours**

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

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

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

### **Course content:**

#### **Unit I**

**10Hours**

- **Basic principles of Cell injury and Adaptation:**

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

- **Basic mechanism involved in the process of inflammation and repair:**

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

## Unit II

**10Hours**

- **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

- **Respiratory system:** Asthma, Chronic obstructive airways diseases.
- **Renal system:** Acute and chronic renal failure .

## Unit II

**10Hours**

- **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
- 

## Unit IV

**8 Hours**

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

## Unit V

**7 Hours**

- **Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis, Urinary tract infections
- **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea

## Recommended Books (Latest Editions)

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

#### **Recommended Journals**

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

## **BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)**

**30 Hrs (2 Hrs/Week)**

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

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

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

### **Course content:**

#### **UNIT – I**

**06 hours**

**Number system:** Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

**Concept of Information Systems and Software :** Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

#### **UNIT –II**

**06 hours**

**Web technologies:** Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

#### **UNIT – III**

**06 hours**

**Application of computers in Pharmacy** – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

#### **UNIT – IV**

**06 hours**

**Bioinformatics:** Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

#### **UNIT-V**

**06 hours**

**Computers as data analysis in Preclinical development:**  
Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs)

### **BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

### **Recommended books (Latest edition):**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

## **BP 206 T. ENVIRONMENTAL SCIENCES (Theory)**

**30 hours**

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

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

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

### **Course content:**

#### **Unit-I**

**10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

#### **Unit-II**

**10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

#### **Unit- III**

**10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment



## **SEMESTER III**

## BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

**45 Hours**

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

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

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

### Course Content:

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

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

### UNIT I

**10 Hours**

- **Benzene and its derivatives**

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

### UNIT II

**10 Hours**

- **Phenols\*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines\*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids\*** –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

### UNIT III

**10 Hours**

- **Fats and Oils**

- a. Fatty acids – reactions.

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

#### **UNIT IV**

**08 Hours**

- **Polynuclear hydrocarbons:**

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

#### **UNIT V**

**07 Hours**

- **Cyclo alkanes\***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

## **BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)**

**4 Hrs/week**

### **I Experiments involving laboratory techniques**

- Recrystallization
- Steam distillation

### **II Determination of following oil values (including standardization of reagents)**

- Acid value
- Saponification value
- Iodine value

### **III Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
- Cinnamic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

### **Recommended Books (Latest Editions)**

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

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

**BP302T. PHYSICAL PHARMACEUTICS-I (Theory)**

**45Hours**

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

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

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

**Course Content:**

**UNIT-I**

**10 Hours**

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

**UNIT-II**

**10Hours**

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

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

**UNIT-III**

**08 Hours**

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

#### **UNIT-IV**

**08Hours**

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

#### **UNIT-V**

**07 Hours**

**pH, buffers and Isotonic solutions:** Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

### **BP306P. PHYSICAL PHARMACEUTICS – I (Practical)**

**4 Hrs/week**

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

#### **Recommended Books: (Latest Editions)**

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

## **BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)**

**45Hours**

### **Scope:**

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

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

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

### **Course content:**

#### **Unit I**

**10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

#### **Unit II**

**10 Hours**

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

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

Evaluation of the efficiency of sterilization methods.



Equipments employed in large scale sterilization.

Sterility indicators.

### **Unit III**

**10 Hours**

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

Classification and mode of action of disinfectants

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

Evaluation of bactericidal & Bacteriostatic.

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

### **Unit IV**

**08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

### **Unit V**

**07Hours**

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

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

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

Application of cell cultures in pharmaceutical industry and research.

## **BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)**

**4 Hrs/week**

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

### **Recommended Books (Latest edition)**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> 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. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

## **BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)**

**45 Hours**

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

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

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

### **Course content:**

#### **UNIT-I**

**10 Hours**

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

#### **UNIT-II**

**10 Hours**

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

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

### UNIT- III

**08 Hours**

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

### UNIT-IV

**08 Hours**

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

### UNIT- V

**07 Hours**

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

**Recommended Books: (Latest Editions)**

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

## **BP308P - PHARMACEUTICAL ENGINEERING (Practical)**

**4 Hours/week**

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

## **SEMESTER IV**

## **BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)**

**45 Hours**

**Scope:** This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

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

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

### **Course Content:**

**Note: To emphasize on definition, types, mechanisms, examples, uses/applications**

#### **UNIT-I**

**10 Hours**

##### **Stereo isomerism**

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and a chiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

#### **UNIT-II**

**10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

#### **UNIT-III**

**10 Hours**



**Heterocyclic compounds:**

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

**UNIT-IV****8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

**UNIT-V****07 Hours****Reactions of synthetic importance**

Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

**Recommended Books (Latest Editions)**

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

## **BP402T. MEDICINAL CHEMISTRY – I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

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

### **UNIT- I**

**10 Hours**

#### **Introduction to Medicinal Chemistry**

#### **History and development of medicinal chemistry**

#### **Physicochemical properties in relation to biological action**

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

#### **Drug metabolism**

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

### **UNIT- II**

**10 Hours**

#### **Drugs acting on Autonomic Nervous System**

#### **Adrenergic Neurotransmitters:**

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

#### **Sympathomimetic agents: SAR of Sympathomimetic agents**

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

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

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

#### **Adrenergic Antagonists:**

**Alpha adrenergic blockers:** Tolazoline\*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers:** SAR of beta blockers, Propranolol\*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

### **UNIT-III**

**10 Hours**

#### **Cholinergic neurotransmitters:**

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

#### **Parasympathomimetic agents: SAR of Parasympathomimetic agents**

**Direct acting agents:** Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine.

**Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):** Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathione, Malathion.

**Cholinesterase reactivator:** Pralidoxime chloride.

#### **Cholinergic Blocking agents: SAR of cholinolytic agents**

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

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

### **UNIT- IV**

**08 Hours**

#### **Drugs acting on Central Nervous System**

### **A. Sedatives and Hypnotics:**

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

**Barbiturates:** SAR of barbiturates, Barbitol\*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

#### **Miscellaneous:**

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

### **B. Antipsychotics**

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

**Ring Analogues of Phenothiazines:** Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

**Fluorobutyrophenones:** Haloperidol, Droperidol, Risperidone.

**Beta amino ketones:** Molindone hydrochloride.

**Benzamides:** Sulpieride.

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

**Barbiturates:** Phenobarbitone, Methobarbital. **Hydantoins:**

Phenytoin\*, Mephentyoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide\* **Urea and**

**monoacylureas:** Phenacemide, Carbamazepine\*

**Benzodiazepines:** Clonazepam

**Miscellaneous:** Primidone, Valproic acid, Gabapentin, Felbamate

**UNIT – V**

**07 Hours**

**Drugs acting on Central Nervous System**

**General anesthetics:**

**Inhalation anesthetics:** Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

**Ultra short acting barbiturates:** Methohexital sodium\*, Thiopental sodium, Thiopental sodium.

**Dissociative anesthetics:** Ketamine hydrochloride.\*

**Narcotic and non-narcotic analgesics**

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

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

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

## **BP406P. MEDICINAL CHEMISTRY – I (Practical)**

**4 Hours/Week**

### **I Preparation of drugs/ intermediates**

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

### **II Assay of drugs**

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

### **III Determination of Partition coefficient for any two drugs**

#### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

## **BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)**

**45Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**07 Hours**

**Colloidal dispersions:** Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

#### **UNIT-II**

**10 Hours**

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

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

#### **UNIT-III**

**10 Hours**

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



#### **UNIT-IV**

**10Hours**

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

#### **UNIT-V**

**10 Hours**

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

## **BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)**

**3 Hrs/week**

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

### **Recommended Books: (Latest Editions)**

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

## **BP 404 T. PHARMACOLOGY-I (Theory)**

**45 Hrs**

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

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

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

### **Course Content:**

#### **UNIT-I**

**08 hours**

##### **1. General Pharmacology**

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists( competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

#### **UNIT-II**

**12 Hours**

##### **General Pharmacology**

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

**UNIT-III****10 Hours****2. Pharmacology of drugs acting on peripheral nervous system**

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

**UNIT-IV****08 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

**UNIT-V****07 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

## **BP 408 P.PHARMACOLOGY-I (Practical)**

**4Hrs/Week**

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

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

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

## **BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)**

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Introduction to Pharmacognosy:**

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

##### **Classification of drugs:**

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

##### **Quality control of Drugs of Natural Origin:**

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

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

#### **UNIT-II**

**10 Hours**

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

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

##### **Conservation of medicinal plants**

#### **UNIT-III**

**07 Hours**

##### **Plant tissue culture:**

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

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

#### **UNIT IV**

**10 Hours**

##### **Pharmacognosy in various systems of medicine:**

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

##### **Introduction to secondary metabolites:**

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

#### **UNIT V**

**08 Hours**

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

##### **Plant Products:**

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

##### **Primary metabolites:**

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

**Carbohydrates:** Acacia, Agar, Tragacanth, Honey

**Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

**Lipids(Waxes, fats, fixed oils) :** Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

##### **Marine Drugs:**

Novel medicinal agents from marine sources





**BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)****4 Hours/Week**

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

**Recommended Books: (Latest Editions)**

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

## **SEMESTER V**

## BP501T. MEDICINAL CHEMISTRY – II (Theory)

**45 Hours**

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

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

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

<b>Course Content:</b>
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**Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*)**

### UNIT- I

**10 Hours**

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

**H<sub>1</sub>-antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

**H<sub>2</sub>-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

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

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorethamine\*, Cyclophosphamide, Melfhalan,

Chlorambucil, Busulfan, Thiotepa

**Antimetabolites:** Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

**Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate

**Miscellaneous:** Cisplatin, Mitotane.

## UNIT – II

10 Hours

**Anti-anginal:**

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

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

**Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

**Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

## UNIT- III

10 Hours

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

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

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

**Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.



## UNIT- IV

08 Hours

### Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

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

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

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

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

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

## UNIT – V

07 Hours

### Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

### Local Anesthetics: SAR of Local anesthetics

**Benzoic Acid derivatives;** Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine.

**Amino Benzoic acid derivatives:** Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

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

**Miscellaneous:** Phenacaine, Dipreron, Dibucaine.\*

### Recommended Books (Latest Editions)

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





## BP 502 T. Industrial PharmacyI (Theory)

**45 Hours**

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

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

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

### Course content:

**3 hours/ week**

#### UNIT-I

**07 Hours**

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

**a. Physical properties:** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

**b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

#### UNIT-II

**10 Hours**

##### Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

**Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

### UNIT-III

08 Hours

#### Capsules:

- a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

**Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

### UNIT-IV

10 Hours

#### Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

**Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

### UNIT-V

10 Hours

**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

**Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

**Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

## **BP 506 P. Industrial PharmacyI (Practical)**

**4 Hours/week**

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

### **Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5<sup>th</sup>edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

## **BP503.T. PHARMACOLOGY-II (Theory)**

**45 Hours**

**Scope:** This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

**Objectives:** Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

### **Course Content:**

#### **UNIT-I**

**10hours**

##### **1. Pharmacology of drugs acting on cardio vascular system**

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

#### **UNIT-II**

**10hours**

##### **1. Pharmacology of drugs acting on cardio vascular system**

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

##### **2. Pharmacology of drugs acting on urinary system**

- a. Diuretics
- b. Anti-diuretics.

#### **UNIT-III**

**10hours**

##### **3. Autocoids and related drugs**

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

**UNIT-IV****08hours****5. Pharmacology of drugs acting on endocrine system**

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

**UNIT-V****07hours****5. Pharmacology of drugs acting on endocrine system**

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

**6. Bioassay**

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

## BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of  $PA_2$  value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of  $PD_2$  value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

*Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos*

### Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.



## **BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

**45Hours**

**Scope:** The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

**Objectives:** Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

### **Course Content:**

#### **UNIT-I**

**7 Hours**

##### **Metabolic pathways in higher plants and their determination**

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

#### **UNIT-II**

**14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

**Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium,

**Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta

**Steroids, Cardiac Glycosides & Triterpenoids:** Liquorice, Dioscorea, Digitalis

**Volatile oils:** Mentha, Clove, Cinnamon, Fennel, Coriander,

**Tannins:** Catechu, Pterocarpus

**Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

**Glycosides:** Senna, Aloes, Bitter Almond

**Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids

#### **UNIT-III**

**06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

#### **UNIT-IV**

**10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

#### **UNIT V**

**8 Hours**

##### **Basics of Phytochemistry**

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.



**BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**  
**4 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
  - a. Caffeine - from tea dust.
  - b. Diosgenin from Dioscorea
  - c. Atropine from Belladonna
  - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 2<sup>nd</sup> edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.



## **BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**45 Hours**

**Scope:** This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

**Objectives:** Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

#### **UNIT-II**

**10 Hours**

##### **Drugs and Cosmetics Act, 1940 and its rules 1945.**

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

#### **UNIT-III**

**10 Hours**

- **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

## Penalties

- **Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

## UNIT-IV

**08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

## UNIT-V

**07 Hours**

- **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

## Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

## **SEMESTER VI**

## BP601T. MEDICINAL CHEMISTRY – III (Theory)

**45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

**Objectives:** Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

### Course Content:

**Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (\*)**

### UNIT – I

**10 Hours**

#### Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

**β-Lactam antibiotics:** Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams

**Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

**Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

### UNIT – II

**10 Hours**

#### Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

**Macrolide:** Erythromycin Clarithromycin, Azithromycin.

**Miscellaneous:** Chloramphenicol\*, Clindamycin.

**Prodrugs:** Basic concepts and application of prodrugs design.

**Antimalarials:** Etiology of malaria.

**Quinolines:** SAR, Quinine sulphate, Chloroquine\*, Amodiaquine, Primaquine phosphate, Pamaquine\*, Quinacrine hydrochloride, Mefloquine.

**Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil.

**Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone.

### UNIT – III

**10 Hours**

#### **Anti-tubercular Agents**

**Synthetic anti tubercular agents:** Isoniazid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.\*

**Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

#### **Urinary tract anti-infective agents**

**Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

**Miscellaneous:** Furazolidine, Nitrofurantoin\*, Methanamine.

#### **Antiviral agents:**

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

### UNIT – IV

**08 Hours**

#### **Antifungal agents:**

**Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

**Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole\*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*.

**Anti-protozoal Agents:** Metronidazole\*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

**Anthelmintics:** Diethylcarbamazine citrate\*, Thiabendazole, Mebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.



### **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

**Folate reductase inhibitors:** Trimethoprim\*, Cotrimoxazole.

**Sulfones:** Dapsone\*.

## **UNIT – V**

**07 Hours**

### **Introduction to Drug Design**

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

**Combinatorial Chemistry:** Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

## **BP607P. MEDICINAL CHEMISTRY- III (Practical)**

**4 Hours / week**

### **I Preparation of drugs and intermediates**

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

### **II Assay of drugs**

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

### **III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique**

### **IV Drawing structures and reactions using chem draw®**

### **V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)**

### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

## **BP602 T. PHARMACOLOGY-III (Theory)**

**45 Hours**

**Scope:** This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

**Objectives:** Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

### **Course Content:**

#### **UNIT-I**

**10hours**

##### **1. Pharmacology of drugs acting on Respiratory system**

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

##### **2. Pharmacology of drugs acting on the Gastrointestinal Tract**

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

#### **UNIT-II**

**10hours**

##### **3. Chemotherapy**

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

#### **UNIT-III**

**10hours**

##### **3. Chemotherapy**

- a. Antitubercular agents
- b. Antileprotic agents

- c. Antifungal agents
- d. Antiviral drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

#### **UNIT-IV**

**08hours**

#### **3. Chemotherapy**

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

#### **4. Immunopharmacology**

- a. Immunostimulants
- b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

#### **UNIT-V**

**07hours**

#### **5. Principles of toxicology**

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

#### **6. Chronopharmacology**

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

### BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens ( rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology( student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

*\*Experiments are demonstrated by simulated experiments/videos*

#### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

**BP 603 T. HERBAL DRUG TECHNOLOGY****(Theory)****45 hours**

**Scope:** This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

**Objectives:** Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

**Course content:****UNIT-I****11 Hours****Herbs as raw materials**

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

**Biodynamic Agriculture**

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

**Indian Systems of Medicine**

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

**UNIT-II****7 Hours****Nutraceuticals**

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

**Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

**UNIT-III****10 Hours****Herbal Cosmetics**

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

**Herbal excipients:**

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

**Herbal formulations :**

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

**UNIT- IV**

**10 Hours**

**Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs  
Stability testing of herbal drugs.

**Patenting and Regulatory requirements of natural products:**

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

**Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

**UNIT-V**

**07 Hours**

**General Introduction to Herbal Industry**

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

**Schedule T – Good Manufacturing Practice of Indian systems of medicine**

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.



## **BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

**4 hours/ week**

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

### **Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

## BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

**Scope:** This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arising therein.

**Objectives:** Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

### Course Content:

#### UNIT-I

10 Hours

##### Introduction to Biopharmaceutics

**Absorption:** Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

#### UNIT- II

10 Hours

**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

**Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

#### UNIT- III

10 Hours

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters -  $K_E$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CL_R$ - definitions methods of eliminations, understanding of their significance and application

**UNIT- IV****08 Hours****Multicompartment models:** Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

**UNIT- V****07 Hours**

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity.  
c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

**Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition, USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Marcel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania



## **BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

**45 Hours**

### **Scope:**

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

**Objectives:** Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

### **Unit I**

**10 Hours**

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

### **Unit II**

**10 Hours**

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
  - i) Interferon
  - ii) Vaccines- hepatitis- B
  - iii) Hormones-Insulin.
- d) Brief introduction to PCR

### **Unit III**

**10 Hours**

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications
- g) Blood products and Plasma Substitutes.

### **Unit IV**

**08Hours**

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

### **Unit V**

**07 Hours**

- a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b) Large scale production fermenter design and its various controls.
- c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
- d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

### **Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitaker A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

## **BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)**

**45 Hours**

**Scope:** This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

**Objectives:** Upon completion of the course student shall be able to:

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

**Course content:**

### **UNIT – I**

**10 Hours**

**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP

**Total Quality Management (TQM):** Definition, elements, philosophies

**ICH Guidelines:** purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

**Quality by design (QbD):** Definition, overview, elements of QbD program, tools

**ISO 9000 & ISO14000:** Overview, Benefits, Elements, steps for registration

**NABL accreditation :** Principles and procedures

### **UNIT - II**

**10 Hours**

**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records.

**Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

**Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

### **UNIT – III**

**10 Hours**

**Quality Control:** Quality control test for containers, rubber closures and secondary packing



materials.

**Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

#### **UNIT – IV**

**08 Hours**

**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

**Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

#### **UNIT – V**

**07 Hours**

**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

**Warehousing:** Good warehousing practice, materials management

#### **Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

## **SEMESTER VII**

## **BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)**

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Objectives:** Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

### **Course Content:**

#### **UNIT –I**

**10 Hours**

##### **UV Visible spectroscopy**

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

##### **Fluorimetry**

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

#### **UNIT –II**

**10 Hours**

##### **IR spectroscopy**

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

**Flame Photometry**-Principle, interferences, instrumentation and applications

**Atomic absorption spectroscopy-** Principle, interferences, instrumentation and applications

**Nepheloturbidometry-** Principle, instrumentation and applications

### **UNIT –III**

**10 Hours**

**Introduction to chromatography**

**Adsorption and partition column chromatography-**Methodology, advantages, disadvantages and applications.

**Thin layer chromatography-** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

**Paper chromatography-**Introduction, methodology, development techniques, advantages, disadvantages and applications

**Electrophoresis–** Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

### **UNIT –IV**

**08 Hours**

**Gas chromatography -** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

**High performance liquid chromatography (HPLC)-**Introduction, theory, instrumentation, advantages and applications.

### **UNIT –V**

**07 Hours**

**Ion exchange chromatography-** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

**Gel chromatography-** Introduction, theory, instrumentation and applications

**Affinity chromatography-** Introduction, theory, instrumentation and applications

## **BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)**

**4 Hours/Week**

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

### **Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

## **BP 702 T. INDUSTRIAL PHARMACYII (Theory)**

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

**Objectives:** Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

### **Course Content:**

#### **UNIT-I**

**10 Hours**

**Pilot plant scale up techniques:** General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

#### **UNIT-II**

**10 Hours**

**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

#### **UNIT-III**

**10 Hours**

**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

**Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

**UNIT-IV****08 Hours**

**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

**UNIT-V****07 Hours**

**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

**Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7<sup>th</sup> April available at [http://en.wikipedia.org/wiki/Regulatory\\_Affairs](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)**

**45 Hours**

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

**Objectives:** Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

### **Unit I:**

**10 Hours**

#### **a) Hospital and its organization**

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

#### **b) Hospital pharmacy and its organization**

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

#### **c) Adverse drug reaction**

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting



drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

**d) Community Pharmacy**

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

**Unit II:**

**10 Hours**

**a) Drug distribution system in a hospital**

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

**b) Hospital formulary**

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

**c) Therapeutic drug monitoring**

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

**d) Medication adherence**

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

**e) Patient medication history interview**

Need for the patient medication history interview, medication interview forms.

**f) Community pharmacy management**

Financial, materials, staff, and infrastructure requirements.

**Unit III:**

**10 Hours**

**a) Pharmacy and therapeutic committee**

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

**b) information services**

**Drug**

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

**c) Patient counseling**

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

**d) Education and training program in the hospital**

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

**e) Prescribed medication order and communication skills**

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

**Unit IV**

**8 Hours**

**Budget preparation and implementation**

**a) 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.

**b) Over the counter (OTC) sales**

Introduction and sale of over the counter, and Rational use of common over the counter medications.

**Unit V**

**7 Hours**

**a) Drug store management and inventory control**

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

**b) Investigational use of drugs**

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

**c) Interpretation of Clinical Laboratory Tests**

Blood chemistry, hematology, and urinalysis

**Recommended Books (Latest Edition):**

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1<sup>st</sup> ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1<sup>st</sup> ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

**Journals:**

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

## **BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

**Objectives:** Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

### **Course content:**

#### **Unit-I**

**10 Hours**

**Controlled drug delivery systems:** Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

**Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

#### **Unit-II**

**10 Hours**

**Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

**Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

**Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implants and osmotic pump

#### **Unit-III**

**10 Hours**

**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

**Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

**Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

#### **Unit-IV**

**08 Hours**

**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

## **Unit-V**

**07 Hours**

**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

**Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

### **Recommended Books: (Latest Editions)**

1. Y W. Chien, Novel Drug Delivery Systems, 2<sup>nd</sup> edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

### **Journals**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

## **SEMESTER VIII**

## **BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)**

**45 Hours**

**Scope:** To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

**Objectives:** Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

### **Course content:**

#### **Unit-I**

**10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution

**Measures of central tendency:** Mean, Median, Mode- Pharmaceutical examples

**Measures of dispersion:** Dispersion, Range, standard deviation, Pharmaceutical problems

**Correlation:** Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

#### **Unit-II**

**10 Hours**

**Regression:** Curve fitting by the method of least squares, fitting the lines  $y = a + bx$  and  $x = a + by$ , Multiple regression, standard error of regression– Pharmaceutical Examples

**Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

**Parametric test:** t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

#### **Unit-III**

**10 Hours**

**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

**Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

**Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

#### **Unit-IV**

**8 Hours**

Blocking and confounding system for Two-level factorials

**Regression modeling:** Hypothesis testing in Simple and Multiple 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 to Industrial and Clinical trial approach

#### **Unit-V**

**7Hours**

**Design and Analysis of experiments:**

**Factorial Design:** Definition,  $2^2$ ,  $2^3$  design. Advantage of factorial design

**Response Surface methodology:** Central composite design, Historical design, Optimization Techniques

#### **Recommended Books (Latest edition):**

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery



## **BP 802T SOCIAL AND PREVENTIVE PHARMACY**

**Hours: 45**

### **Scope:**

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

### **Objectives:**

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

### **Course content:**

#### **Unit I:**

**10 Hours**

**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

**Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

**Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

**Hygiene and health:** personal hygiene and health care; avoidable habits

#### **Unit II:**

**10 Hours**

**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

#### **Unit III:**

**10 Hours**

**National health programs, its objectives, functioning and outcome of the following:** HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

**Unit IV:**

**08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

**Unit V:**

**07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

**Recommended Books (Latest edition):**

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2<sup>nd</sup> Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4<sup>th</sup> Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6<sup>th</sup> Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2<sup>nd</sup> Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21<sup>st</sup> Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

## **BP803ET. PHARMA MARKETING MANAGEMENT (Theory)**

**45 Hours**

### **Scope:**

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

**Course Objective:** The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

### **Unit I**

**10 Hours**

#### **Marketing:**

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

#### **Pharmaceutical market:**

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

### **Unit II**

**10 Hours**

#### **Product decision:**

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

### **Unit III**

**10 Hours**

#### **Promotion:**

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

**Unit IV****10 Hours****Pharmaceutical marketing channels:**

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

**Professional sales representative (PSR):**

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

**Unit V****10 Hours****Pricing:**

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

**Emerging concepts in marketing:**

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

**Recommended Books: (Latest Editions)**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.



## **BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

**45Hours**

**Scope:** This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

**Objectives:** Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

### **Course content:**

#### **Unit I**

**10Hours**

##### **New Drug Discovery and development**

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

#### **Unit II**

**10Hours**

##### **Regulatory Approval Process**

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

##### **Regulatory authorities and agencies**

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

#### **Unit III**

**10Hours**

##### **Registration of Indian drug product in overseas market**

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

#### **Unit IV**

**08Hours**

##### **Clinical trials**

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

#### **Unit V**

**07Hours**

##### **Regulatory Concepts**

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

##### **Recommended books (Latest edition):**

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5<sup>th</sup> edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

## BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

**Scope:** This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

### Objectives:

*At completion of this paper it is expected that students will be able to (know, do, and appreciate):*

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

## Course Content

### Unit I

10 Hours

#### Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

#### Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

#### Basic terminologies used in pharmacovigilance



- Terminologies of adverse medication related events
- Regulatory terminologies

## **Unit II**

**10 hours**

### **Drug and disease classification**

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

### **Drug dictionaries and coding in pharmacovigilance**

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

### **Information resources in pharmacovigilance**

- Basic drug information resources
- Specialised resources for ADRs

### **Establishing pharmacovigilance programme**

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

## **Unit III**

**10 Hours**

### **Vaccine safety surveillance**

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

### **Pharmacovigilance methods**

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

### **Communication in pharmacovigilance**

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

## Unit IV

8 Hours

### Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

### ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

## Unit V

7 hours

### Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

### Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

### CIOMS

- CIOMS Working Groups
- CIOMS Form

### CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

### Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology 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
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

## **BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)**

**Scope:** In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

**Objectives:** Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

### **Unit I**

**10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

### **Unit II**

**10 hours**

**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

### **Unit III**

**10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

### **Unit IV**

**08 hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

## **Unit V**

**07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

### **Recommended Books: (Latest Editions)**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

## BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

**45 Hours**

**Scope:** This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

**Objectives:** Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

### Course Content:

#### UNIT-I

**10 Hours**

##### **Introduction to Drug Discovery and Development**

Stages of drug discovery and development

##### **Lead discovery and Analog Based Drug Design**

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

**Analog Based Drug Design:** Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

#### UNIT-II

**10 Hours**

##### **Quantitative Structure Activity Relationship (QSAR)**

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

#### UNIT-III

**10 Hours**

##### **Molecular Modeling and virtual screening techniques**

**Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

**Molecular docking:** Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

**UNIT-IV****08 Hours****Informatics & Methods in drug design**

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

**UNIT-V****07 Hours**

**Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

**Recommended Books (Latest Editions)**

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.



## **BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)**

**45 Hours**

### **Scope:**

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

**Objectives:** Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

### **Course content:**

#### **Unit I**

**10Hours**

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: History and Summation.
- c) Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations – an Introduction and Reactions (Types)

#### **Unit II**

**10 Hours**

- a) DNA and the Flow of Molecular Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

#### **Unit III**

**10 Hours**

- a) Proteins: Defined **and** Amino Acids
- b) Protein Structure

- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

#### **Unit IV**

**08 Hours**

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

#### **Unit V**

**07 Hours**

- a) Cell Signals: Introduction
- b) Receptors for Cell Signals
- c) Signaling Pathways: Overview
- d) Misregulation of Signaling Pathways
- e) Protein-Kinases: Functioning

#### **Recommended Books (latest edition):**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

## **BP809ET. COSMETIC SCIENCE**

**(Theory)**

**45Hours**

### **UNIT I**

**10Hours**

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

**Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

**Skin:** Basic structure and function of skin.

**Hair:** Basic structure of hair. Hair growth cycle.

**Oral Cavity:** Common problem associated with teeth and gums.

### **UNIT II**

**10 Hours**

**Principles of formulation and building blocks of skin care products:**

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

**Antiperspirants & deodorants-** Actives & mechanism of action.

**Principles of formulation and building blocks of Hair care products:**

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

### **UNIT III**

**10 Hours**

Sun protection, Classification of Sunscreens and SPF.

**Role of herbs in cosmetics:**

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

**Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

### **UNIT IV**

**08 Hours.**

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

## **UNIT V**

**07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

### **References**

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## BP810 ET. PHARMACOLOGICAL SCREENING METHODS

**45 Hours**

**Scope:** This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

### Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Unit –I	08 Hours
<b>Laboratory Animals:</b> Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	10 Hours
<b>Preclinical screening models</b> a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. <b>b. Study of screening animal models for</b> Diuretics, nootropics, anti-Parkinson's, antiasthmatics, <b>Preclinical screening models:</b> for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

<b>Unit –III</b> <b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	
<b>Unit –IV</b> <b>Preclinical screening models:</b> for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
<b>Research methodology and Bio-statistics</b> 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	<b>05 Hours</b>

**Recommended Books (latest edition):**

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

## **BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES**

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

**Objectives:** Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

**Mass Spectrometry-** Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

#### **UNIT-II**

**10 Hours**

**Thermal Methods of Analysis:** Principles, instrumentation and applications of Thermo gravimetric 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.

#### **UNIT-III**

**10 Hours**

**Calibration and validation-**as per ICH and USFDA guidelines

##### **Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

**UNIT-IV**

**08 Hours**

**Radio immune assay:** Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

**Extraction techniques:** General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

**UNIT-V**

**07 Hours**

**Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.**

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein



## **BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

**No. of hours :3**

**Tutorial:1**

**Credit point:4**

### **Scope :**

This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

### **Objective:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

### **UNIT I**

**07 hours**

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

### **UNIT II**

**15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

- a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, leutin
- b) Sulfides: Diallyl sulfides, Allyl trisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin , Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f) Phyto estrogens : Isoflavones, daidzein, Geobustan, lignans
- g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

### **UNIT III**

**07 hours**

- a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

- b) Dietary fibres and complex carbohydrates as functional food ingredients..

#### **UNIT IV**

**10 hours**

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ - Lipoic acid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

#### **UNIT V**

**06 hours**

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

#### **References:**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
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 2<sup>nd</sup> Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 *Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

**Semester VIII – Elective course on Pharmaceutical Product Development No of**

**Hours: 3**

**Tutorial:1**

**Credit points:4**

**Unit-I**

**10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

**Unit-II**

**10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non - ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

**Unit-III**

**10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directly compressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products
- v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

**Unit-IV**

**08 Hours**

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

**Unit-V**

**07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.



**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, 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 kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman 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.