BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
B.Pharm. - Bachelor of Pharmacy
New Syllabus

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)

'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

Faculty of Pharmaceutical Sciences

Bachelor of Pharmacy

B.Pharm. (PCI Syllabus)

PROGRAMME STRUCTURE & SYLLABUS

CBCS

w.e.f. 2019-20

B.Pharm. CBCS 19-20

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)
'A' GRADE AWARDED BY GOVT OF INDIA
'A+' GRADE REACCREDITATION BY NAAC

FACULTY OF PHARMACEUTICAL SCIENCES

BACHELOR OF PHARMACY (B.PHARM.)

B. Pharm. (PCI Syllabus)

Choice Based Credit System

Programme Structure and Syllabus

w.e.f. 2019-20
B.Pharm. CBCS 19-20

Bharati Vidyapeeth (Deemed to be University), Pune

Bharati Vidyapeeth, the parent organization of this University is one of the largest educational organizations in the country. It has 180 educational units under its umbrella including 80 Colleges and Institutes of conventional and professional disciplines.

The Ministry of Human Resource Development, Government of India on the recommendations of the University Grants Commission accorded the status of "Deemed to be University" initially to a cluster of 12 units of Bharati Vidyapeeth. Subsequently, 17 additional colleges / institutes were brought within the ambit of Bharati Vidyapeeth (Deemed to be University), wide various notifications of the Government of India. Bharati Vidyapeeth (Deemed to be University), commenced its functioning on 26th April, 1996.

Constituent Units of Bharati Vidyapeeth (Deemed to be University)

1. BVDU Medical College, Pune.
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved, Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantrao Mohite College of Arts, Science & Commerce, Pune.
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.), Pune
9. BVDU Yashwantrao Chavan Institute of Social Science Studies & Research, Pune.
10. BVDU Centre for Research & Development in Pharmaceutical Sciences & Applied Chemistry, Pune
11. BVDU College of Physical Education, Pune.
12. BVDU Institute of Environment Education & Research, Pune
13. BVDU Institute of Management & Entrepreneurship Development, Pune
14. BVDU Poona College of Pharmacy, Pune
15. BVDU College of Engineering, Pune
16. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
17. BVDU Rajiv Gandhi Institute of Information Technology & Biotechnology, Pune
18. BVDU College of Architecture, Pune
19. BVDU Abhijit Kadam Institute of Management & Social Sciences, Solapur
20. BVDU Institute of Management, Kolhapur
21. BVDU Institute of Management & Rural Development administration, Sangli
22. BVDU Institute of Management & Research, New Delhi
23. BVDU Institute of Hotel Management & Catering Technology, Pune
24. BVDU Yashwantrao Mohite Institute of Management, Malakapur-Karad
25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

The status of university was given to a cluster of these colleges and institutes in appreciation of the high level of their academic excellence and for their potential for further growth.

During the last 20 years or so, the University has achieved higher pinnacles of academic excellence and has established its reputation to such an extent that it attracts students not only from various parts of India but also from abroad. According to a survey conducted by Association of Indian Universities, this University is one among the top ten Universities in the country preferred by the overseas students for admissions. At present, there are more than 850 overseas students from 47 countries on the rolls of constituent units of this University.

During the last 20 years, there has been tremendous academic expansion of the University. It now conducts in all 305 courses in its constituent units, of them 108 are Post Graduate, 45 are Under Graduate and 55 Diploma level courses. 12 Fellowship and 5 certificate courses. All the professional courses which the University conducts such as those of Medicine, Dentistry, Engineering etc., have approval of the respective statutory councils, viz., Medical Council of India, Dental Council of India, All India Council for Technical Education etc.

The University is a throbbing center of research activities and has launched Ph.D. programmes in 77 subjects and M.Phil in 3 subjects. It has also introduced quite few innovative academic programmes such as Masters in Clinical Optometry, M.Tech. in Nano Technology etc.

The University's performance and achievements were assessed by the "National Assessment and Accreditation Council" and it was reaccredited with a prestigious "A" grade in 2011. Some programmes of the constituent units such as College of Engineering at Pune, Management Institute in Delhi and others have also been accredited by "National Board of Accreditation". Three constituent units of Bharati Vidyapeeth (Deemed to be University), are also the recipients of ISO 9001-2001 certifications.

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)

POONA COLLGE OF PHARMACY, PUNE

Bharati Vidyapeeth's Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All India Council of Technical Education, New Delhi, Pharmacy Council of India, New Delhi and Bharati Vidyapeeth (Deemed to be University). Earlier the college was affiliated to University of Poona and Maharashtra University of Health Sciences. Now it is a constituent unit of Bharati Vidyapeeth (Deemed to be University). The College conducts B.Pharm, M.Pharm (in Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy and Quality Assurance Techniques). The college is housed in beautiful building and located in our bewitching teaching complex at Erandwane, Paud Road, Pune. The excellence which this college has achieved during these years in Pharmacy education is mainly due to its experienced and qualified teaching faculty and the infrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth (Deemed to be University), the syllabus of B.Pharm and M.Pharm Course was revised and upgraded with the help of eminent experts in the pharmacy and the same was approved by University Authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

VISION:

To be recognized as a premier pharmacy institution of academic excellence.

MISSION STATEMENT:

1) To produce competent pharmacists catering to the needs of Industry, Academia, Research and Society.
2) To create a centre of excellence for education and research in the field of Pharmaceutical Sciences.
3) To contribute our humble share to ensure the well-being and to reduce the suffering of mankind.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

1) To provide a comprehensive pharmaceutical education leading to B. Pharm. Degree.
2) To integrate pharmacy knowledge and skills with pharmaceutical research so as to increase inclination for higher studies and research.
3) To develop pharmacists to contribute effectively in the social health care system.
4) To provide hands on training through state of art infrastructure to meet challenges of pharmacy profession.
5) To inculcate leadership and entrepreneurship capabilities in future pharmacists.

PROGRAM OUTCOMES (POS)

On completion of the B. Pharm. program, a student will be able to:

1. **Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

2. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

3. **Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

4. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

5. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.

6. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

7. **Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

8. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

9. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

10. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

11. **Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

2.1 First year B. Pharm:

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall 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.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

7.2.Minimum credit requirements

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

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

8. Academic work

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

9. Course of study

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

Table-I: Course of study for semester I

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

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.
$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.
* Non University Examination (NUE)

Table-II: Course of study for semester II

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

*Non University Examination (NUE)

Table-III: Course of study for semester III

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

Table-IV: Course of study for semester IV

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

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial 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
	Total	**27**	**5**	**26**

Table-VI: Course of study for semester VI

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

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial 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
	Total	**28**	**5**	**24**

***** Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

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

Table-IX: Semester wise credits distribution

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

***** The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

$ Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course

10. Program Committee

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

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

11. Examinations/Assessments

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

11.1 End semester examinations

The End Semester Examinations for each theory and practical course through semesters 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	1hr.	25	75	3hr.	100
BP102T	Pharmaceutical Analysis I- Theory	10	15	1hr.	25	75	3hr.	100
BP103T	Pharmaceutic Inorganic Chemistry – Theory	10	15	1hr.	25	75	3hr.	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	5	15	1hr.	25	75	3hr.	100
BP105T	Communication Skills- Theory	5	10	1hr.	15	35	1.5hr.	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics- Theory	5	10	1hr.	15	35	1.5hr	50
BP107T	Human Anatomy and Physiology- Practical	5	10	4hr.	15	35	4hr.	50
BP108T	Pharmaceutical Analysis I- Practical	5	10	4hr.	15	35	4hr.	50
BP109T	Pharmaceutical I- Practical	5	10	4hr.	15	35	4hr.	50
BP110T	Pharmaceutical Inorganic chemistry- Practical	5	10	4hr.	15	35	4hr.	50
BP111T	Communication Skills- Practical	5	5	2hr.	10	15	2hr.	25
BP112RBP	Remedial Biology – Practical	5	5	2hr.	10	15	2hr.	25
	Total	**70/75$/80#**	**115/125$/130#**	**23/24$/26#hrs**	**185/200$/210#**	**490/525$/540#**	**31.5/33$/# hrs**	**675/725$/750#**

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

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

* Non University Examination (NUE)

Semester II

Course code	Name of the Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II- Theory	10	15	1 hr	25	75	3 hrs	100
BP202T	Pharmaceutical Organic Chemistry I - Theory	10	15	1 h	25	75	3 hrs	100
BP203T	Biochemistry – Theory	10	15	1 h	25	75	3 hrs	100
BP204T	Pathophysiology – Theory	10	15	1 h	25	75	3 hrs	100
BP205T	Computer Applications in Pharmacy _ theory	10	15	1 h	25	50	2 hrs	75
BP206T	Environmental Sciences- Theory	10	15	1 h	25	50	2 hrs	75
BP207T	Human Anatomy and Physiology II- Practical	5	10	4 h	15	35	4 hrs	50
BP208T	Pharmaceutical Organic Chemistry I _ - Practical	5	10	4 h	15	35	4 hrs	50
BP209T	Biochemistry Practical	5	10	4 h	15	35	4 hrs	50
BP210T	Computer Application in Pharmacy - Practical	5	10	2 h	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	1hrs	25	75	3hrs	100
BP302T	Physical Pharmaceutics I- Theory	10	15	1hrs	25	75	3hrs	100
BP303T	Pharmaceutics Microbiology-Theory	10	15	1hrs	25	75	3hrs	100
BP304T	Pharmaceutical Engineering Theory	10	15	1hrs	25	75	3hrs	100
BP305T	Pharmaceutical Organic Chemistry II- Practical	5	10	4hrs	15	35	4hrs	50
BP306T	Physical Pharmaceutics I- Practical	5	10	4hrs	15	35	4hrs	50
BP307T	Pharmaceutical Microbiology- Practical	5	10	4hrs	15	35	4hrs	50
BP308T	Pharmaceutical Engineering- Practical	5	10	4hrs	15	35	4hrs	50
	Total	**60**	**100**	**20**	**160**	**440**	**28 hrs**	**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	1hrs	25	75	3hrs	100
BP402T	Medical Chemistry I- theory	10	15	1hrs	25	75	3hrs	100
BP403T	Physical Pharmaceutics II- Theory	10	15	1hrs	25	75	3hrs	100
BP404T	Pharmacognosy I – Theory	10	15	1hrs	25	75	3hrs	100
BP405T	Pharmacology I – Theory	10	15	1hrs	25	75	3hrs	100
BP406T	Medicinal Chemistry I- Practical	5	10	4hrs	15	35	4hrs	50
BP407T	Physical Pharmaceutics II- Practial	5	10	4hrs	15	35	4hrs	50
BP408T	Pharmacology I- Practical	5	10	4hrs	15	35	4hrs	50
BP409T	Pharmacognosy I – Practical	5	10	4hrs	15	35	4hrs	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 hrs	25	75	3 hrs	100
BP502T	Industrial Pharmacy I- theory	10	15	1 hrs	25	75	3 hrs	100
BP503T	Pharmacology II- Theory	10	15	1 hrs	25	75	3 hrs	100
BP504T	Pharmacognosy II- Theory	10	15	1 hrs	25	75	3 hrs	100
BP505T	Pharmaceutical jurisprudence - Theory	10	15	1 hrs	25	75	3 hrs	100
BP506T	Industrial Pharmacy I- Practical	5	10	4 hrs	15	35	4 hrs	50
BP507T	Pharmacology II- Practical	5	10	4 hrs	15	35	4 hrs	50
BP508T	Pharmacognosy- II- Practical	5	10	4 hrs	15	35	4 hrs	50
	Total	**65**	**105**	**17hrs**	**170**	**480**	**27hrs**	**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 hrs	25	75	3 hrs	100
BP602T	Pharmacology III- Theory	10	15	1 hrs	25	75	3 hrs	100
BP603T	Hebbal Drug Technology- Theory	10	15	1 hrs	25	75	3 hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics- theory	15	15	1 hrs	25	75	3 hrs	100
BP605T	Pharmaceutical Biotechnology – Theory	15	15	1 hrs	25	75	3 hrs	100
BP606T	Quality ASSURANCE – THEORY	15	15	1 hrs	25	75	3 hrs	100
BP607T	Medicinal Chemistry III- Practical	5	10	4 hrs	15	33	4 hrs	50
BP608T	Pharmacology III- Practical	5	10	4 hrs	15	35	4 hrs	50
BP609T	Herbal Drug Technology – Practical	5	10	4 hrs	15	35	4 hrs	50
	Total	**75**	**120**	**18hrs**	**195**	**555**	**30hrs**	**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 hrs	25	75	3 hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 hrs	25	75	3 hrs	100
BP703T	Pharmacy Practice- Theory	10	15	1 hrs	25	75	3 hrs	100
BP704T	Novel Drug Delivery System-Theory	10	15	1 hrs	25	75	3 hrs	100
BP705P	Instrumental Methods of Analysis- Practical	5	10	4 hrs	15	35	4 hrs	50
BP706PS	Practice School*	25	-	-	25	125	5 hrs	150
	Total	**70**	**70**	**8hrs**	**140**	**460**	**21hrs**	**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 Hrs	25	75	3 Hrs	100
BP3802T	Social and Preventive Pharmacy – Theory	10	15	1 Hrs	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**
	TOTAL	**40**	**60**	**4 Hrs**	**100**	**450**	**16hrs**	**550**

11.2 Internal assessment: Continuous mode

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

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

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

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

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

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 gradein 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
For 50 marks paper

I. Multiple Choice Questions (MCQs)	=	20 x 1 = 20
OR Objective Type Questions (10 x 2)		OR 10 x 2 = 20
(Answer all the questions)	=	2 x 10 = 20
II. Long Answers (Answer 2 out of 3)		
III. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35
Total	**=**	**75 marks**
	=	---

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 fulfils 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

17.1. Letter grades and grade points allocations:

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

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

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

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

18.The Semester grade point average (SGPA)

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

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4 + C5G5}{C1 + C2 + C3 + C4 + C5}$$

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

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

19. Cumulative Grade Point Average (CGPA)

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

on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

where C1, C2, C3,. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….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

1. 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 subjects 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
Total	**75 Marks**

Evaluation of Presentation:

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

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

22.Industrial training (Desirable)

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

and certificate duly signed by the authority of training organization to the head of the institute.

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.

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

Course Outcomes

1. Explain the terminologies related to human anatomy and physiology.
2. Discuss the anatomy and physiology of various systems of the human body.
3. Identify bones, joints and study their anatomy and physiology.
4. Relate the synchronous working of organs and use of modern technologies for evaluating physiological functions.
5. Interpret the imbalance of homeostasis responsible for various diseases.
6. Outline environmental conditions implied in lifestyle disorders.

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) Content-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, hemopoeisis, 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 heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

P107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Course Outcomes:

1 Examine blood samples for hematological parameters and correlate with clinical conditions
2 Measure and interpret the blood pressure and heart rate by different techniques.
3 Identify bones and explain their anatomy and physiology.
4 Describe the histology of various tissues.
5 Determine blood group and explain its significance.
6 Communicate effectively the importance of hematological parameters and healthcare to the society.

Course Content

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

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 Outcomes:

1. Understand the classification of different analytical techniques useful in drug analysis
2. Integrate physicochemical and electrochemical properties of drugs with analytical methods
3. Comprehend the importance of potential errors and apply strategies for its reduction
4. Remember the principle, advantages, challenges and applications of electrochemical analysis
5. Describe principle and application of titrimetric methods
7 Choose the appropriate titrimetric/instrumental technique for evaluation of samples.

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)

5 Hours / Week

Course Outcomes:

1. Understand the significance of calibration in analytical chemistry and awareof safety measures
2. Identify inorganic impurities and discuss the principles of limit tests as per IP
3. Describe the principle involved in various electrochemical analytical methods for drug analysis
4. Prepare and standardize different reagents as per IP
5. Demonstrate analytical skills for evaluation of drugs by titrimetric methods
6. Observe, record and communicate experimental data

Course Content

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

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 Outcomes

8 Evaluate the prescription for rational drug therapy
9 Explain principles of modern dispensing practices
10 Recommend patients about pharmaceutical dosage forms
11 Compound and dispense dosage forms
12 Practice ethics in community pharmacy
13 Apply basic principles and calculations in formulation development

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.

UNIV – 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 dosages forms

BP109P. PHARMACEUTICS I (Practical)

3 Hours / week

Course Outcomes:

1 Interpret prescription
2 Apply skills in compounding and dispensing pharmaceutical dosage forms
3 Counsel the patients for appropriate use of medicines
4 Understand the fundamentals of dosage forms
5 Maintain patient medication records
6 Create patient counselling aids

Course Content

1. **Syrups**
   a) Syrup IP'66
   b) Compound syrup of Ferrous Phosphate BPC'68
2. **Elixirs**
   a) Piperazine citrate elixir
   b) Paracetamol paediatric 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) Aluminimum 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) Coca butter suppository
   c) Zinc Oxide suppository
9. **Semisolids**
   a) Sulphur ointment
   b) Non staining-iodine ointment with methyl salicylate
   c) Carbopal gel

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)

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 Outcomes

1. Describe the relevance and significance of inorganic chemistry with reference to pharmaceutical sciences
2. Refer official Pharmacopoeias to detect impurities.
3. Understand monographs of inorganic pharmaceuticals.
4. Review the official electrolytes intended for replacement therapy and maintaining acid-base balance.
5. Discuss and apply the physicochemical properties, assay, and uses of inorganic gastrointestinal agents.
6. Gain information about measurement of radioactivity and handling of radioactive pharmaceutical substances

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*, Aluminium 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 α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

Course Outcomes

1. Comprehend basic practical terms and concepts used inorganic chemistry.
2. Apply the monograph of pharmaceuticals from official compendia.
3. Prepare and determine purities of inorganic compounds.
4. Identify impurities in pharmaceutical compounds as per Indian Pharmacopoeia
5. Apply expertise intended for identification of official compounds
6. Compute, analyze and record data.

Course Content

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, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd 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

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

1. Understand the behavioural 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 Outcomes

1. Develop behavioural traits to function effectively in pharmaceutical operations.
2. Develop effective communication skill.
3. Organize and manage the team as a team player
4. Apply effective writing and listening skill at personal and professional level.
5. Communicate in interviews confidently.
6. Demonstrate entrepreneurship capabilities meticulously to succeed in today's competitive world.

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

Course Outcomes

1. Develop behavioral traits to function effectively in pharmaceutical operations.
2. Communicate confidently with a good understanding of people's skills.
3. Apply effective writing and listening skills at personal and professional level.
4. Illustrate presentation skills.
5. Communicate in interviews confidently.
6. Apply email etiquette in professional set up.

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

Course Content

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, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen.P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, 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, 2ndEdition, New arrivals –PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, 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, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

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

Course Outcomes

1. To apply the theory and application statistics in Pharmacy
2. To develop problem solving approach by applying statistical theories
3. To apply of calculus differentiation and analytical geometry in pharmaceutical statistical data analysis.
4. To understand basic statistical concepts such as partial fraction, logarithms, function, limit and
5. continuity and their application for problem solving.
6. To analyze matrices and determinant and their related equations.
7. To apply chemical kinetics and solving pharmacokinetics equations for given set of data

Course Content

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, Potista, 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 & Dicotyledonous.

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

Course Content

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

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 Outcomes

1. To apply the theory and application statistics in Pharmacy
2. To develop problem solving approach by applying statistical theories
3. To apply of calculus differentiation and analytical geometry in pharmaceutical statistical data analysis.
4. To understand basic statistical concepts such as partial fraction, logarithms, function, limit and continuity and their application for problem solving.
5. To analyze matrices and determinant and their related equations.
6. To apply chemical kinetics and solving pharmacokinetics equations for given set of data
7.

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 ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1,$

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 xn w.r.tx,where n is any rational number, Derivative of ex,, Derivative of loge x , Derivative of ax,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

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 Outcome:

1. Explain the structure and functions of various systems of the human body.
2 Describe the synchronous working of various organs and systems.
3 Outline modern technologies for evaluating physiological functions.
4 Understand the concept of imbalance of homeostasis in diseases.
5 Correlate the impact of social and environmental factors on body systems.
6 Comprehend the common disorders prevalent in the society.

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 **10 hours**

•Respiratory system

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

Course Outcomes:

1. Understand the role of special sense organs.
2. Explain the anatomy and physiology of various human systems with simulated models.
3. Interpret the physiological feedback mechanisms.
4. Describe the histology of various organs and tissues.
5. Determine the respiratory volumes and assess its implications in respiratory diseases.
6. Communicate effectively the importance of different family planning devices to the society.

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.

Course Content

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 brother's 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 USAText book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
4. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
5. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
6. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.

7. 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

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 Outcomes:

1 Write the structure and IUPAC name of the organic compound.
2 Understand method of preparation, reactions, kinetics, stereochemistry and stability of alkanes, alkenes and conjugated dienes.
3 Illustrate and differentiate nucleophilic substitution reactions.
4 Demonstrate method of preparation and reactions of carbonyl compounds.
5 Interpret acidity and basicity of different carboxylic acids and aliphatic amines.
6 Describe structure, uses and qualitative tests of different 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 **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*

SP3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP2 hybridization in alkenes

E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E1 verses E2 reactions, Factors affecting E1 and E2 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*

SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbonations.

SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions Structure and uses of ethyl chloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetra chloromethane 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)

3 Hours / week

Course Outcomes:

1. Recognize color/odor and detect the elements present in the organic compound.
2. Perform solubility test of different organic compounds.
3. Analyze organic compounds qualitatively having different functional groups.
4. Prepare solid derivatives of different organic compounds.
5 Identify organic compounds and their derivatives using melting and boiling point.
6 Construct molecular models.

Course Content

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.
9. Preparation of suitable solid derivatives from organic compounds
10. 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 Ahluwaliah/Chatwal.

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Objectives: Upon completion of course student shell 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 Outcomes

1. Paraphrase structure- function relationship of bio-molecules from living system.
2. Recognize the importance of metabolism and regulation of pathways with reference to homeostasis of key metabolites.
3. Identify the structural elements of carbohydrates, proteins and lipids along with their physiological role.
4. Summarize enzymes as biocatalyst
5. Understand bioenergetics in biochemical reaction.
6. Describe DNA manipulation, inheritance and recombinant DNA technology.

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 phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers level

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 (Phenyketonuria, Albinism, alkeptonuria, 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

Course Outcomes

1. Develop skills for handling laboratory instruments and biological samples.
2. Estimate proteins, sugars and Vitamins.
3. Isolate and characterize proteins.
4. Describe and evaluate of kinetic parameters and factors affecting enzymatic reaction..
5. Qualitative identification of carbohydrates and amino acids
6. Compute, analyze and record biochemical data.

Course Content

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

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 Outcomes

1. Understand the etiopathogenesis of diseases.
2. Correlate the pathological changes with clinical course and identify therapeutic targets.
3. Summarize the signs and symptoms of diseases.
4. Describe conventional and modern techniques for diagnosis of diseases.
5. Interpret the complications of diseases and their implications in society.
6. Communicate effectively the measures for prevention of diseases to the society.

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 &Alkalos is, 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 anaemia (Vit B12 and folic acid), sickle cell anaemia, thalassemia, hereditary acquired anaemia, haemophilia
- **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; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th 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; 12th 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; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd 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)

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 Outcomes:

1. Undestand applications of computer in pharmacy.
2. Describe the types of databases and number systems
3. Apply Information Systems and Softwares in planning and project management
4. Employ use of bioinformatics in vaccine discovery
5. Use various Web technologies
6. Analyze preclinical data using Computer

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 dada analysis(CDS), Laboratory Information Management System (LIMS) and Text Information Management System(TIMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

Course Outcomes

1. Apply use of MS WORD and MS Access
2. Create web page and documents
3. Design product information leaflet using software
4. Create patient database
5. Retrieve the information of a drug using online tools
6. Create and work with queries in MS access

Course Content

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

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 Outcomes

1. Understand basics of environment and its associated problems.
2. Summarise the ethical, cross-cultural, and historical context of environmental issues
3. Develop concern and awareness about environmental problems.
4. Evaluate and apply the tools to attain harmony with Nature.
5. Apply knowledge in environment protection and environment improvement.
7 Recommend solution for identified environmental problems.

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 Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson 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

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 Outcomes

1. Describe structure, orbital picture, resonance and different reactions of benzene.
2. Predict effect of substitution on the reactivity of benzene.
3. Interpret acidity and basicity of phenols and aromatic amines.
4. Understand reactions, significance and principle involved in the determination of fats and oils.
5. Design synthesis and predict reactions of polynuclear hydrocarbons.
6. Review the stability of cycloalkanes.

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.

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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)

3 Hrs/week

Course Outcomes

1. Illustrate laboratory techniques for purification of the compounds by recrystallization and steam distillation method.
2. Apply acid, saponification and iodine value for the determination of quality of fats and oils.
3. Describe reaction & mechanism involved in the synthesis of organic compounds.
4. Perform melting point determination to identify compound.
5. Review different organic reactions involved in the synthesis.
6. Record, compute and analyze the data.

Course Content

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-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic 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

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 nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Outcomes

1. Understand physicochemical properties of drugs and excipients.
2. Use modern analytical tools to assess physicochemical properties of drugs
3. Relate physicochemical properties of pharmaceuticals for formulation design.
4. Classify and analyze drug complexes.
5. Justify the role of stable formulations for effective therapeutic outcome.
6. Analyze and tackle problems encountered in formulation development.

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

Course Outcomes

1. Evaluate physicochemical properties of drug molecules using modern analytical tools.
2. Understand significance of physicochemical properties of pharmaceuticals formulation development
3. Estimate stability constant of complexes.
4. Justify use of buffers in pharmaceutical and biological systems.
5. Compute, analyze and record data.
6. Identify and tackle problems encountered in formulation development by working in a team.

Course Content

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 CCl4 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 Phramacy, by Gaurav Jain & Roop K. Khar

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

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 Outcomes

1. Apply techniques for identification of microorganisms.
2. Understand process of sterilization and disinfection
3. Explain aseptic conditions in pharmaceutical laboratories as per GLP
4. Describe microbiological standardization and sterility testing of pharmaceuticals.
5. Review cell culture technology in pharmacy.
6. Create social awareness regarding biohazards.

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 constrast 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

Course Outcomes

1. Use microscopes for pharmaceutical research.
2. Identify and isolate various microorganisms.
3. Apply sterilization and disinfection techniques in pharmacy.
4. Determine efficacy of antibiotics and disinfectants using microbial assays.
5. Implement ethical practices in microbial laboratory.
6. Compute, analyze and record data.

Course Content

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, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. 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

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 Outcomes

1. Understand and conceptualize significance of pharmaceutical unit operations.
2. Apply material handling techniques.
3. Describe unit processes involved in pharmaceutical manufacturing.
4. Employ approaches to prevent environmental pollution.
5. Design plant layout for optimum use of resources.
6. Recommend methods to minimize corrosion 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 – Mcabe 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 pharmaceutics- 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

Course Outcomes

1. Demonstrate pharmaceutical unit operations
2. Explain the functioning of pharmaceutical equipments.
3. Select and recommend appropriate pharmaceutical packaging materials.
4. Apply the concept of industrial safety.
5. Select cost effective process to quality products.
6. Comprehend the various safety precautions in Pharmaceutical industries.

Course Content

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

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 Outcomes

1. Understand the basics of stereo isomerism.
2. Outline synthesis and reactions of chiral molecules and heterocyclic compounds.
3. Comprehend geometric isomerism.
4. Name, classify and write reactions of heterocyclic compounds.
5. Identify medicinally useful organic compounds having heterocyclic rings.
6. Illustrate important named reactions used in organic synthesis.

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 ($NaBH_4$ and $LiAlH_4$), 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

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 Outcomes:

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 alkanes, alkenes and conjugated dienes.
3. Know the Structural Activity Relationship (SAR) of different class of drugs.
4. Write the chemical synthesis of some drugs.
5. Knowledge about the mechanism pathways of different class of medicinal compounds
6. Helps in correlating between pharmacology of a disease and its mitigation or cure.

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, Isofluorphate, 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

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants:

SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital.

Hydantoins: Phenytoin*, Mephenytoin, 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 barbitutrates: Methohexital sodium*, Thiamylal 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, Anilerdine 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, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

Course Outcomes:

1. Learn Synthesis of pharmaceutical compounds having heterocyclic ring with one or more heteroatom.
2. Determine the partition coefficient of drugs as one of the physico-chemical parameters of drug likeness.
3. Estimate different types of drugs by using quantitative methods of analysis.
4. Inculcate the experimental knowledge of chemical synthesis of some drugs/ intermediates.
5. To provide a broad exposure to students about various experimental techniques like reflux, vacuum filtration, melting point
6. Record, compute and analyze the data.

Course Content

I. Preparation of drugs/ intermediates

a. 1,3-pyrazole
b. 1,3-oxazole
c. Benzimidazole
d. Benztriazole
e. 2,3- diphenyl quinoxaline
f. Benzocaine
g. Phenytoin
h. Phenothiazine
i. Barbiturate

2. Assay of drugs

1 Chlorpromazine
2 Phenobarbitone
3 Atropine
4 Ibuprofen
5 Aspirin
6 Furosemide

3. 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

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 nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Outcomes

1. Understand physicochemical properties of drugs and excipients.
2. Use modern analytical tools to assess physicochemical properties of drugs
3. Relate physicochemical properties of pharmaceuticals for formulation design.
4. Apply principles of chemical kinetics in stability testing and estimation of shelf life of formulations.
5. Understand factors governing stability of finished pharmaceutical products.
6. Analyze and tackle problems encountered in formulation development.

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**

Micromere tics: 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

Course Outcome:

1. Evaluate physicochemical properties of drug molecules using modern analytical tools.
2. Understand significance of various physicochemical properties of drug molecules in formulation development.
3. Estimate chemical kinetic parameters.
4. Calculate shelf life of pharmaceuticals.
5. Compute, analyze and record data.
6. Identify and tackle problems encountered in formulation development by working in a team.

Course Content

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

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 Outcomes

1. Describe the fundamental concepts of pharmacology.
2. Explain the pharmacological basis of therapeutics.
3. Comprehend the concept of adverse effects and drug interactions.
4. Justify correlation of pharmacology with other bio medical sciences.
5. Apply the pharmacological knowledge in the prevention and treatment of various diseases.
6. Recommend to the society about measures to minimize adverse drug effects and drug interactions.

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.
a. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
b. Local anesthetic agents.
c. 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

Course Outcomes

1. Outline the basic concepts of experimental pharmacology.
2. Explain maintenance of laboratory animals as per CPCSEA guidelines.
3. Observe the effect of drugs using simulated experiments.
4. Design appropriate laboratory technique for preclinical studies.
5. Illustrate the importance of preclinical screening in drug discovery process.
6. Apply the experimental pharmacology concepts for environmental sustainability.

Course Content

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,.Churchil 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,

BP 405 T. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours.

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 Outcomes

1. Understand the concept of Pharmacognosy, drug classification.
2. Reviewing the evaluation techniques for the herbal drug.
3. Discuss Cultivation, Collection, Processing and storage of drugs of natural origin.
4. Explain the role of Pharmacognosy in various systems of medicine.
5. Comprehend the concept of plant tissue culture.
6. Explain about various primary, secondary metabolites, natura fibers and marine 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, leafconstants, 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

BP409 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

Course Outcomes:

1. Analyze and identify crude drugs based chemical tests.
2. Evaluating various leaf constants.
3. Experimenting the dimensions of starch grains.
4. Plan and execute Lycopodium spore method of evaluation.
5. Estimating dimensions of natural fibers.
6. Assessing various physicochemical properties of crude drugs.

Course Content

1. Analysis of crude drugs by chemical tests: (i)Tragaccanth (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 paliside 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, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th 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, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

Semester V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

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

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Outcomes

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.
5. Sketch the structure and name the drugs and their intermediates
6. Explain mechanism of action of various categories 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 (*)

UNIT- I **10 Hours**

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody
H1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium
H2-antagonists: Cimetidine*, Famotidine, Ranitidin.
Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:
Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa
Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine
Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin Plant
products: Etoposide, Vinblastin sulphate, Vincristin sulphate Miscellaneous: Cisplatin, Mitotane.

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, Lorcainide hydrochloride, Amiodarone, Sotalol.
Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol
Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel
Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

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: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics
Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.
Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.
Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.
Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.

6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. Industrial Pharmacy (Theory)

45 Hours

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 Outcomes

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
4. Review evaluation parameters of pharmaceutical dosage forms and cosmetics
5. Identify appropriate quality control equipment's for pharmaceuticals.
6. Select and recommend appropriate packaging for solid dosage form

Course content

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 pharmacy I (Practical)

4 Hours/week

Course Outcomes

1. Review of marketed drug products of various dosage forms.
2. Justify the composition, containers, labels, expiry period, economy, acceptance drug Products.
3. formulate solid, liquid, semisolid dosage forms and cosmetics preparations
4. Select appropriate manufacturing equipment's.
5. Evaluate quality of pharmaceuticals and cosmetics
6. Adapt Good Laboratory Practices

Course Content

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

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 Outcomes

1. Identify drug targets considering pathophysiology of diseases.
2. Correlate the molecular basis of drug action with clinical uses.
3. Understand the adverse effects and drug interactions.
4. Suggest appropriate drug therapy for diseases.
5. Compare efficacy, safety and cost-effectiveness of drug therapy.
6. Recommend measures for prevention and management of inflammatory and lifestyle diseases.

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**

2. 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

3. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10hours**

4. Autocoids and related drugs

a. Introduction to autacoids and classification
b. Histamine, 5-HT and their antagonists.
c. Prostaglandins, Thromboxanes and Leukotrienes.
d. Angiotensin, Bradykinin and Substance P.
e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs
g. Antirheumatic drugs

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.
e. Insulin, Oral Hypoglycemic agents and glucagon.
f. ACTH and corticosteroids.

UNIT-V **07hours**

6. Pharmacology of drugs acting on endocrine system

a. Androgens and Anabolic steroids.
b. Estrogens, progesterone and oral contraceptives.
c. Drugs acting on the uterus.

7. 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

Course Outcomes

1. Understand the importance of use of animals in drug discovery and development
2. Apply ethical principles in animal experimentation.
3. Outline the principles and applications of bioassay and demonstrate various receptor actions using isolated tissue preparation.
4. Justify the need of alternatives to animals.
5. Demonstrate computer simulated animal experiments.
6. Appreciate correlation of pharmacology with related medical sciences

Course Content

1. Introduction to in-vitro pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema 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, Churchil 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

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 Outcomes

1. Understand production of secondary metabolites in higher plants.
2. Reviewing the role of radioactive isotopes in the investigation of Biogenetic studies.
3. Comprehend the composition, chemistry and role of secondary metabolites.
4. Discuss Isolation, Identification and Analysis of Phytoconstituents.
5. Estimation, Industrial production, and utilization of phytoconstituents.
6. Explain methods of extraction and isolation.

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: Glycyrhetinic 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 Photochemistry

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

Course Outcomes

1. Analyze and identify crude drugs based on Morphology, histology and powder characteristics
2. Experimenting isolation & detection of active principles from crude drugs.
3. Experimenting separation of sugar by paper chromatography
4. Plan and execute TLC of herbal extract
5. Design Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Evaluate crude drugs by chemical tests

Course Content

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
   a. Caffeine - from tea dust.
   b. Diosgenin from Dioscorea
   c. Atropine from Belladonna
   d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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 Outcomes

1. Understand Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals
2. Explain the role of regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Apply and practice the code of ethics during the pharmaceutical practice
4. Comprehend various Indian Pharmaceutical Acts and Laws
5. Discuss the Right to Information Act for the benefit of society
6. Illustrate various Intelletual Property Rights.

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 D efinition, 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

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 Outcomes

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.
5. Understand the principles of drug design and QSAR.
6. Explain the principles of combinatorial chemistry and microwave assisted drug synthesis
7.

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, Cepholosporins, 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, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, 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, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**
Antifungal agents:
Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.
Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.
Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.
Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones
Historical development, chemistry, classification and SAR of Sulfonamides:
Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.
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, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.
Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis of combinatorial.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

Course Outcomes

1. Apply principles of organic chemistry for synthesis of intermediates and drugs.
2. Apply principles of quantitative analysis of drugs
3. Determine physicochemical parameters like partition coefficient, MR and dissociation constant
4. Apply microwave assisted techniques for synthesis of drug and drug intermediates
5. Sketch the structures and reactions using softwares'
6. Compute, analyze and record the observations

Course Content

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

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 poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Course Outcomes

1. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. Illustrate the clinical uses of drugs.
3. Analyze the adverse effects and drug interactions with measures to minimize them.
4. Appreciate correlation of pharmacology with related medical sciences.
5. Sensibilise the society about use of nasal decongestants and pumps used for asthma
6. Comprehend the principles of toxicologyand treatment of various poisoning

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 **10 hours**

3. Chemotherapy

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

UNIT-III **10 hours**

4. Chemotherapy

a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e. Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

UNIT-IV **08 hours**

5. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

a. m. Chemotherapy of malignancy.

4. Immunopharmacology
   a. Immunostimulants
   b. Immunosuppressant

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

UNIT-V **07hours**

6. Principles of toxicology
   a. Definition and basic knowledge of acute, subacute and chronic toxicity.
   b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
   c. General principles of treatment of poisoning
   d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

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

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

Course Outcomes

1. Understand the importance of animal experimentation in drug discovery and development.
2. Understand the ex- vivo experiments
3. Analyze the effect of drugs on GIT
4. Appreciate correlation of toxicology in drug discovery
5. Justify the need of alternatives to animals
6. Demonstrate computer simulated animal experiments.

Course Content

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, Churchil 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. Vallabh Prakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chrono pharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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 Outcomes

1. Understand the concept of herbal raw material its cultivation, processing and product development
2. Describe Biodynamic Agricultural practices
3. Summarize the concept of Indian Systems of Medicine
4. Exemplify Patenting, Regulatory requirements of natural products and herbal drug industry
5. Explain about herbal cosmetics, excipients, formulations and herb drug interactions.
6. Discuss WHO and ICH guidelines for evaluation of herbal drugs

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: Alfa alfa, 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, Ginko biloba, 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

Course Outcomes

1 Experimenting Phytochemical screening of crude drugs Analyze Interpret Experimenting
2 Develop and evaluate herbal cosmetics.
3 Determination of the alcohol content of Asava and Arishta
4 Formulate herbal formulations and their standardization and evaluate the excipients of natural origin.
5 Analyze monographs of herbal drugs from recent Pharmacopoeia
6 Experimenting aldehyde content, phenol content and total alkaloid.

Course Content

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

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 Outcomes

1. Understand the basic concepts and significance in biopharmaceutics
2. Describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. Apply the concepts of bioavailability and bioequivalence of drug products.
4. Articulate pharmacokinetic parameters, their significance & applications.
5. Design Bioavailability-Bioequivalence study protocol for New Drug Application and Abbriveated New Drug Application
6. Review the role of biopharmaceutics in drug development.

Course Content:

UNIT-I **10Hours**

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10Hours**

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 - KE, t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application

UNIT- IV **08 Hours**

Multicompetent models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

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 Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By 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 Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington’s Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

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

Course Outcomes

1. Recall types, characteristics and origin of DNA, RNAs and genetic code.
2. Illustrate techniques involved in DNA manipulation
3. Demonstrate recombinant DNA technology and its applications in pharmacy
4. Review antigen-antibody reactions and immune responses
5. Explain enzyme immobilization techniques and fermentation process
6. Inculcate biotechnological aptitude and values required for self-motivated, lifelong learning and professional development.

Course Content

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 Substituties.

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 - penicillin, 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, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606 T PHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

1 understand the cGMP aspects in a pharmaceutical industry
2 appreciate the importance of documentation
3 understand the scope of quality certifications applicable to pharmaceutical industries
4 understand the responsibilities of QA & QC departments

Course Outcomes

1 Understand the concept of Quality control, Quality assurance and cGMP in a pharmaceutical industry
2 Understand the principles and procedures of NABL accreditation
3 Explain the concept of QbD, ISO standardization and Quality Management System
4 Apply good documentation practices and good laboratory practices in pharmaceutical
5 industry
6 Implement knowledge in validation and calibration of pharma equipment and instruments
7 Practice ethics and inculcate human values in pharma sector

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.

Equipment 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, 2nd 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

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 Outcomes

1. Comprehend the basic concepts of UV visible spectroscopy and IR spectroscopy
2. Understand and apply the chromatographic separation for analysis of drugs.
3. Describe the basics of Flourimetry, Flame photometry, atomic absorption and nepheloturbidimetric techniques and their applications
4. Explain instrumentation and their functions of spectroscopic and chromatographic instruments
5. Elaborate the protocols for quantitative and qualitative analysis of drugs using various analytical instruments.
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

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

Course Outcomes

1. Perform suitable analytical technique to assess purity and safety of pharmaceuticals
2. Design protocol for quantitative analysis of drugs and formulations
3. Handle selected analytical instruments
4. Demonstrate HPLC and Gas chromatography
5. Apply problem solving approach in pharmaceutical analysis
6. Compute, analyse and record data

Course Content

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

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 Outcomes

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. Recognize the approval process and regulatory requirements for drug products.
5. Understand and able to apply principles of quality management systems.
6. Know organization structure and responsibilities of Indian regulatory agencies.

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

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

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

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Course Outcomes

1. Describe the stores management and inventory control
2. Recognise and explain roles and responsibilities of hospital pharmacist
3. Prepare relevant drug or medicine information and counsel the patients
4. Solve and manage Adverse Drug Reactions
5. Formulate evidence-based drug information for better practices to be followed by physicians.
6. Justify and appraise quality assurance of pharmaceutical care services

Course Content

Unit I **10 Hours**

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

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**

a) Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

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, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

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

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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 Outcomes

1. Apply different approaches for development of novel drug delivery systems.
2. Explore the criteria for selection of drugs and polymers for development of novel drug delivery systems.
3. Understand controlled and sustained drug delivery systems along with approaches for their development
4. Evaluate various Novel drug delivery systems including transdermal, nasopulmonary, targeted and gastroretentive drug delivery system.
5. Analyse the formulation and evaluation parameters of various novel drug delivery systems.
6. Remember the need, design and concept of customized sustained and controlled release dosage forms.

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 implantsand osmotic pump

Unit-III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

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

Journals

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

Semester VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

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 Outcomes

1. Know the operation of M.S. Excel, SPSS, R and MINITAB
2. Understand the concept of DoE (Design of Experiment)
3. Know the various statistical techniques to solve statistical problems
4. Appreciate statistical techniques in solving the problems.
5. Develop biostatistical aptitude and values required for self-motivated, lifelong learning and professional development.

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 - problemsSample, 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 regressionmodels Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical

Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 22, 23design. 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. NewYork.
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

Objectives:

After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated 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 Outcomes

1. To Identify current issues related to health and
2. Pharmaceutical problems within the country and worldwide.
3. Recognize Social causes and concept of diseases
4. Prepare relevant drug or medicine information and counsel the patients
5. Categorize ailments and provide appropriate management
6. Formulate alternative ways of solving problems related to health and pharmaceutical issues
7. Appraise critical way of thinking based on current healthcare development.

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

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Course Objective:

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

Course Outcomes

1. Understand the concept of marketing.
2. Apply the concept of product management in pharmaceutical industry.
3. Assess and design sales promotion technique for a product.
4. Recommend appropriate pricing strategy and pharmaceutical marketing channel.
5. Recognize role and responsibility of professional sales representative.
6. Review the DPCO and NNPA guidelines.

Course Content

Unit I **10 Hours**

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behaviour; industrial buying behaviour.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market ;Role of market research.

Unit II **10 Hours**

Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and 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

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, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

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 Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Course Content

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest 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

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, Hammet's substituent constant and Tafts 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 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

Objectives: Upon completion of the subject student shall be able to;

1. Summarize cell and molecular biology history.
2. Summarize cellular functioning and composition.
3. Describe the chemical foundations of cell biology.
4. Summarize the DNA properties of cell biology.
5. Describe protein structure and function.
6. Describe cellular membrane structure and function.
7. Describe basic molecular genetic mechanisms.
8. 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, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

Course Content

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 cosmecuticals. Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo. Hair oils.
Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.
Role of herbs in cosmetics:
Skin Care: Aloe and turmeric Hair care: Henna and amla.
Oral care: Neem and clove
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin- cream and toothpaste.

UNIT IV **08 Hours.**

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

UNIT 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, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

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

Course Content

Unit –I **08 Hours**

Laboratory Animals:

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strainsof animals. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Unit –II **10 Hours**

Preclinical screening models

a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

b. Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's, antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative andhypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

Unit –III

Preclinical screening models: for ANS activity, sympathomimetic, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

Unit –IV

Preclinical screening models: for CVS activity- antihypertensives,diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

Research methodology and Bio-statistics **05 Hours**

Selection of research topic, review of literature, research hypothesisand study design

Pre-clinical data analysis and interpretation using Students ‘t’ test and One-way ANOVA. Graphical representation of data

Recommended Books (Latest Editions)

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

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 Outcomes

1. Comprehend the basic concepts of NMR spectroscopy, Mass spectrometry, Thermal analytical methods and X ray diffraction techniques.
2. Explain instrumentation and their functions of NMR spectroscopy and Mass spectrometry thermal methods and X-ray diffraction
3. Understand the principle and methods of extraction, Radioimmunoassay and hyphenated techniques
4. Describe procedures of calibration of different analytical instruments and validation of analytical methods following ICH and USFDA guidelines
5. Develop problem solving skills in basic interpretation aspects of analytical techniques
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

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 immune 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

Objective

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.

Course Content

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- α and β-Carotene, Lycopene, Xanthophylls, leutin
b) Sulfides: Diallyl sulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

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, α- Lipoic acid, melatonin
c) Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
d) 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: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 Tutorial:1 Credit points:4

Course Content

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.

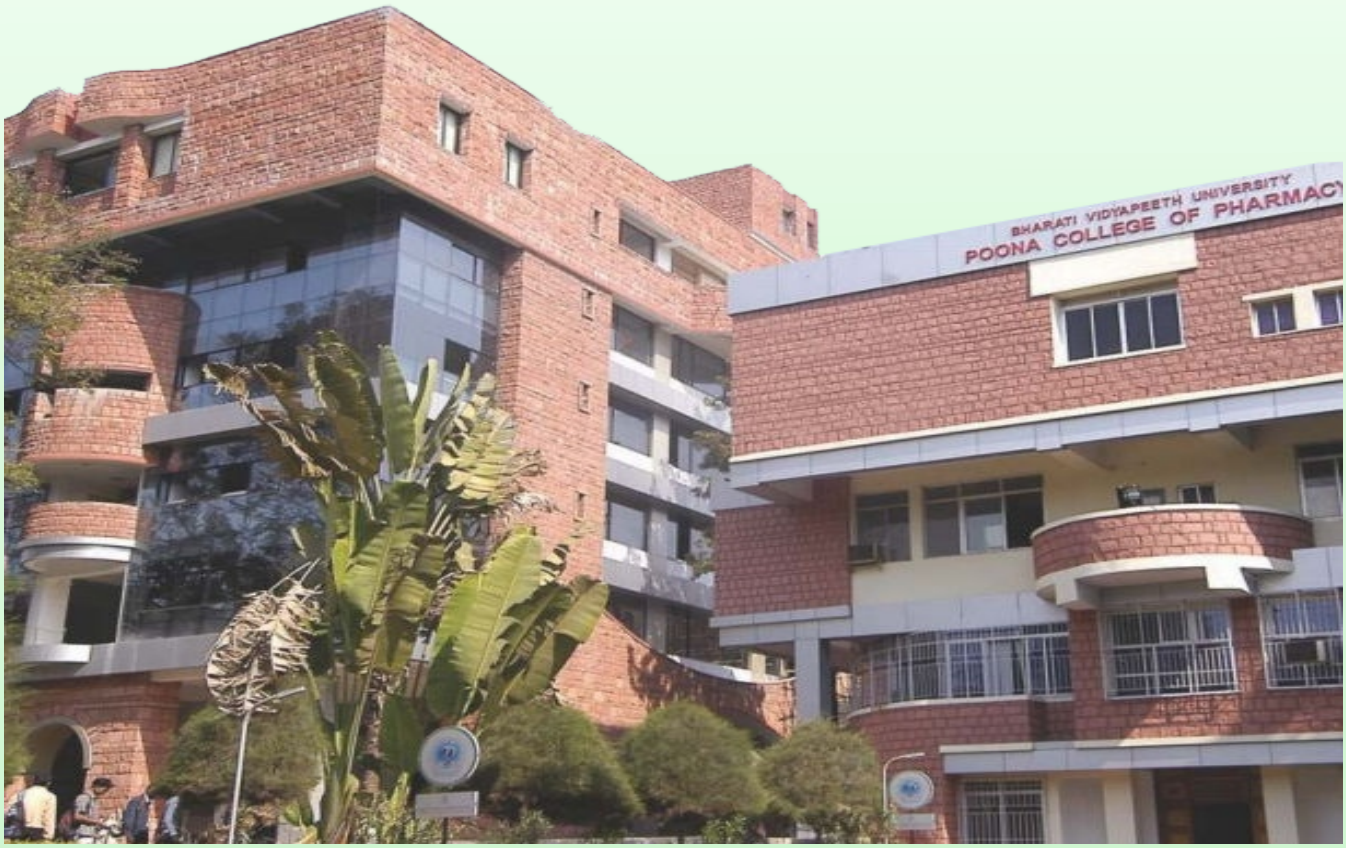
Unit-V **07 Hours**

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, CharlesBon; 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 andLeon 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 andJoseph 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 andH.A. Libermann.
13. Advanced Review Articles related to the topics.



Bharati Vidyapeeth
(Deemed to be University) Pune, India
Poona College of Pharmacy
Erandwane, Pune - 411 038
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BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
B.Pharm. - Bachelor of Pharmacy
Old Syllabus

BHARATI VIDYAPEETH UNIVERSITY,

A GRADE AWARDED BY GOVT. OF INDIA
GRADE REACCREDITATION BY NAAC

Faculty of Pharmaceutical sciences

Bachelor of Pharmacy

B.Pharm. Semester Pattern

CHOICE BASED CREDIT SYSTEM

COURSE STRUCTURE AND SYLLABUS

w.e.f. 2015 - 16

B.Pharm. CBCS 2015 - 16

BHARATI VIDYAPEETH UNIVERSITY

Faculty of Pharmaceutical sciences
Bachelor of Pharmacy (B.Pharm.)

GUIDELINES FOR

CHOICE BASED CREDIT SYSTEM

Course Structure and Syllabus

w.e.f. 2015-16
B.Pharm. CBCS 2015-16
GUIDELINES FOR CHOICE-BASED CREDIT AND GRADING SYSTEM

Bharati Vidyapeeth Deemed University, Pune

Bharati Vidyapeeth, the parent organization of this University is one of the largest educational organizations in the country. It has 180 educational units under its umbrella including 80 Colleges and Institutes of conventional and professional disciplines..

The Ministry of Human Resource Development, Government of India on the recommendations of the University Grants Commission accorded the status of "Deemed to be University" initially to a cluster of 12 units of Bharati Vidyapeeth. Subsequently, 17 additional colleges / institutes were brought within the ambit of Bharati Vidyapeeth University wide various notifications of the Government of India. Bharati Vidyapeeth Deemed University commenced its functioning on 26th April, 1996.

Constituent Units of Bharati Vidyapeeth Deemed University

1. BVDU Medical College, Pune.
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved, Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantrao Mohite College of Arts, Science & Commerce, Pune.
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.), Pune
9. BVDU Yashwantrao Chavan Institute of Social Science Studies & Research, Pune.
10. BVDU Centre for Research & Development in Pharmaceutical Sciences & Applied Chemistry, Pune
11. BVDU College of Physical Education, Pune.
12. BVDU Institute of Environment Education & Research, Pune
13. BVDU Institute of Management & Entrepreneurship Development, Pune
14. BVDU Poona College of Pharmacy, Pune
15. BVDU College of Engineering, Pune
16. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
17. BVDU Rajiv Gandhi Institute of Information Technology & Biotechnology, Pune
18. BVDU College of Architecture, Pune
19. BVDU Abhijit Kadam Institute of Management & Social Sciences, Solapur
20. BVDU Institute of Management, Kolhapur

21. BVDU Institute of Management & Rural Development administration, Sangli
22. BVDU Institute of Management & Research, New Delhi
23. BVDU Institute of Hotel Management & Catering Technology, Pune
24. BVDU Yashwantrao Mohite Institute of Management, Malakapur-Karad
25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

The status of University was given to a cluster of these colleges and institutes in appreciation of the high level of their academic excellence and for their potential for further growth.

During the last 20 years or so, the University has achieved higher pinnacles of academic excellence and has established its reputation to such an extent that it attracts students not only from various parts of India but also from abroad. According to a survey conducted by Association of Indian Universities, this University is one among the top ten Universities in the country preferred by the overseas students for admissions. At present, there are more than 850 overseas students from 47 countries on the rolls of constituent units of this University.

During the last 20 years, there has been tremendous academic expansion of the University. It now conducts in all 305 courses in its constituent units, of them 108 are Post Graduate, 45 are Under Graduate and 55 Diploma level courses. 12 Fellowship and 5 certificate courses. All the professional courses which the University conducts such as those of Medicine, Dentistry, Engineering etc., have approval of the respective statutory councils, viz., Medical Council of India, Dental Council of India, All India Council for Technical Education etc.

The University is a throbbing center of research activities and has launched Ph.D. programmes in 77 subjects and M.Phil in 3 subjects. It has also introduced quite few innovative academic programmes such as Masters in Clinical Optometry, M.Tech. in Nano Technology etc.

The University's performance and achievements were assessed by the "National Assessment and Accreditation Council" and it was reaccredited with a prestigious "A" grade in 2011. Some programmes of the constituent units such as College of Engineering at Pune, Management Institute in Delhi and others have also been accredited by "National Board of Accreditation". Three constituent units of Bharati Vidyapeeth Deemed University are also the recipients of ISO 9001-2001 certifications.

BHARATI VIDYAPEETH UNIVERSITY
POONA COLLGE OF PHARMACY, PUNE

Bharati Vidyapeeth's Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All India Council of Technical Education, New Delhi, Pharmacy Council of India, New Delhi and Board of Technical Exam Govt. of Maharashtra. Earlier the college was affiliated to University of Poona and Maharashtra University of Health Sciences. Now it is a constituent unit of Bharati Vidyapeeth Deemed University. The College conducts B.Pharm, M.Pharm (in Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy and Quality Assurance Techniques). The college is housed in beautiful building and located in our bewitching teaching complex at Erandwane, Paud Road, Pune. The excellence which this college has achieved during these years in Pharmacy education is mainly due to its experienced and qualified teaching faculty and the infrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth Deemed University, the syllabus of B.Pharm and M.Pharm Course was revised and upgraded with the help of eminent experts in the pharmacy and the same was approved by University Authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

VISION :

To be recognized as a premier pharmacy institution of academic excellence.

MISSION STATEMENT :

1) To produce competent pharmacists catering to the needs of Industry, Academia, Research and Society.
2) To create a centre of excellence for education and research in the field of pharmac utical sciences.
3) To contribute our humble share to ensure the well being and to reduce the suffering of mankind.

Programme Educational Objectives (PEO)

1) To provide a comprehensive pharmaceutical education leading to B. Pharm. Degree.

2) To integrate pharmacy knowledge and skills with pharmaceutical research so as to increase inclination for higher studies and research.

3) To develop pharmacists to contribute effectively in the social health care system.

4) To provide hands on training through state of art infrastructure to meet challenges of pharmacy profession.

5) To inculcate leadership and entrepreneurship capabilities in future pharmacists.

Program Outcomes (POs)

On completion of the B. Pharm. program, a student will be able to:

1. Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving.
2. Describe the synthesis, formulation, analysis and pharmacological aspects of drugs and pharmaceuticals.
3. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.
4. Observe record, analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical products and practices.
5. Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
6. Demonstrate the ability to plan and implement professional activities.
7. Act efficiently as a leader in the diverse areas of the profession.
8. Write, interpret and communicate effectively and scientifically.
9. Apply the knowledge and skills gained through education to gain recognition in professional circle and society.
10. Partnering with other health care communities to provide innovative solutions.
11. Create awareness in society about the effective and safe use of medicines.
12. Demonstrate eco-friendly products and processes to maintain public health.
13. Imbibe ethical practices and moral values in personal and professional endeavors.
14. Tackle future challenges through lifelong learning.

Introduction :

The university Grants Commission (UGC), the National Assessment and Accreditation (NAAC), the Distance Education Council, the National Knowledge Commission (NKC) and even Ministry for Human Resource Developments (MHRD) have been recommending for improving quality and effectiveness of higher education provisions in the country. Ministry of Higher and Technical Education , Govt. of Maharashtra have also been stressing on the need to develop Choice Based Credit and Grading System (CBCS) in tune with global trends. Bharati Vidyappeth University is one of the few universities that have adopted CBCS system for Post-Graduation w.e.f 2012-13. Therefore, it becomes necessary to adopt CBCS at undergraduate studies.

A credit system is a systematic way of describing an educational programme by attaching credits to its components, the components can be lectures, practicals, seminars, project work etc. Credits assigned for a single course reflects the number of hours it would take for an average learner to complete a single course successfully.

Advantages of the Credit System :

- Represents a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching.
- Helps to record course work and to document learner workload realistically. Since all activities are taken into account - not only the time learners spend in lectures or seminars but also the time they need for individual learning and the preparation of examinations etc.
- Segments learning experience into calibrated units, which can be accumulated in order to gain an academic award.
- Helps self-paced learning. Learners may undertake as many credits as they can cope with.
- Affords more flexibility to the learners allowing them to choose inter-disciplinary courses, programmes, etc.
- Respects 'Learner Autonomy'. Allows learners to choose according to their own learning needs, interests and aptitudes.
- Makes education more broad-based. One can take credits by combining unique combinations.
- Facilitates learner mobility. Offers the opportunity to study at different times and in different places. Credits earned at one institution can be transferred to another.
- Is beneficial for achieving more transparency and compatibility between different educational structures.

2.0 L-T-P Structure :

The Lecture-Tutorial- Practical (L-T-P) structure focuses on learner-centric teaching. Lecture describes conventional classroom teaching sessions, Tutorial sessions makes the

learner to absorb effectively the contents delivered in the lecture classes and Practical provides opportunities to apply and understand the concepts covered in theory and develop experimental skills.

There is distribution of learning hours for these components could be as follows :

L : 3 hours/week, amounting to 3 credits of lectures/semester by a learner for the course, for which the learner has to appear for a written examination.

T : 3 hours/semester, by a learner for the course , for which the learner has to solve assignments/ class tests or discuss/ present the course content. The three tutorials will be held at the end of 13th, 27th and 41st lecture.

P : 3 hours/week, amounting to 1.5 credit of learning/semester by a learner in the laboratory, for which the learner has to perform practical, write practical book and give viva examinations.

3. Additional Credits :

Additional credits are assigned by the University to the learner for his/her activities as mentioned below :

Table 1: Additional Credits

Sr. No.	Type of Activity	Nature of Involvement by the Learner
1	Publication	Publishing research paper/poster/ review article in International Journal/ National Journal/ International Conference/ National Conference/State-level Conference
2	Co-curricular Activity	i) Participation in conference/ Exhibition / Contest held at state / national / international level ii) Participation in professional/ISTE/ Entrepreneur Development / IIPC/ Technical event / health care related contest held at university/ state / national / international level iii) Industrial tour (More than 3 days)
3	Extra-curricular Activity	Participation in sp orts / cultural event / contests held at interuniversity / state / national / international levels
4	Social Activity	Participation in any social activity such as blood donation, attending NSS camp, Health promotion and care camp, literacy -drive camp etc. for the betterment of common men.

Additional credits are assigned for publication, co-curricular activities, extra-curricular activities and social activities. Maximum credits for research activities are 6, and maximum credits for co-curricular, extra curricular and social activities are 4. Maximum Number of Credits under these activities are not more than 10. But these credits are over and above 220 credits of the programme and hence they are not counted in the calculation of the CGPA of the learner.

The learner has to submit the respective documents/ proof to the Project Guide or activity in-charge, to become eligible for getting the credits as mentioned above. The institutional committee will scrutinize the documents and will accordingly take the decision for awarding the credits.

Table 2: Criteria for award of credits for Research Publications*

Sr.No	Type of the Publication	Credits Awarded
1	International Journal	02
2	National Journal	01
3	International Conference	02
4	National Conference	01
5	State Conference	01

***Maximum Number of Credits Awarded: 6**

The additional credits as given in the above table are exclusively allotted as per his performance/work in the research publications. These credits are not a part of course structure. These additional credits will appear in the mark sheet of final examination wherever applicable.

Additional marks for Co-curricular/ Extra-Curricular / Social Activities will be as per University rules

4. STRUCTURE AND SYLLABUS

Ordinance Including Choice Based Credit System (CBCS) Scheme and Syllabi regulating the Bachelor of Pharmacy (B. Pharm.) Degree Course (Semester Pattern) effective from Academic Year (2015-2016):

The following criteria are applicable to all the candidates for continuation in the course.

A candidate to be eligible for the degree will be required to pass examination as under:

First Year B. Pharm.		:	Semester – I and Semester – II
Second Year B. Pharm.		:	Semester – III and Semester – IV
Third Year B. Pharm.		:	Semester – V and Semester –V
Fourth Year B. Pharm.		:	Semester – VII and Semester –VIII
1	Course Title	:	Bachelor of Pharmacy
2	Abbreviation	:	B. Pharm.
3	Type of Course	:	Four year degree course consisting of eight semesters and of 220 credits.
4	Pattern	:	Semester
5	No. of Years & Semester	:	Four year eight semesters duration with two semesters per year
6	Nomenclature of Semesters	:	• Semester I and Semester II First Year B. Pharm. • Semester III and Semester IV Second Year B. Pharm. • Semester V and Semester VI Third Year B. Pharm. • Semester VII and Semester VIII Fourth Year B. Pharm.
7	Award of the Degree	:	Degree will be awarded for those completing a minimum of 220 credits as per the rules and regulations given subsequently.
8	Duration of Semester	:	Each semester will be of 15 weeks duration for class room, teaching / lecture. Examination for that semester will be held during or after the 16th week from the commencement of the semester.

9 Entry Levels into the course, eligibility criteria, admission authority and Procedures :

Entry levels into the course will be at the beginning of the Semester – I or at the beginning of the Semester – III

9.1 Eligibility Criteria for Admission at the entry level at Semester – I into the Course.

In order to secure admission to Semester – I of the Four Year Degree Course in Pharmacy, the candidate should fulfill the following eligibility criteria; Passed 10 + 2 with English, Physics, Chemistry and either Mathematics / Biology / Biotechnology / other vocational courses and secured minimum 45% marks (40% in case of reserved category)

OR

Must have passed Diploma in Pharmacy as per ER.1991 or its equivalent examination by Board of Technical Education or equivalent examination with not less than 45% of marks in the aggregate of all subjects taken together at the Final Year Examination.

As described in admission brochure for admission to the first semester of B. Pharm. in the particular academic year.

9.2 Eligibility Criteria for Direct Admission at the entry level of Semester – III (i.e. the First Semester of Second year B. Pharm.) into the Course;

The candidate who has passed the final examination leading to the Diploma in Pharmacy conducted by the Board of Technical Education, Maharashtra State or equivalent examination from the institute approved by the Pharmacy Council of India and with a minimum 45% marks (40% for reserve categories) at part – II examination for the Diploma in Pharmacy Course) as per ER-1991 (i.e. Post H.S.C. two year Diploma Course) or eligibility described in admission brochure for direct admission to the second year (Semester III) B. Pharm. in particular academic year be held eligible for admission to Semester – III

OR

As described in admission brochure for admission to the direct admission to second year B. Pharm. in the particular academic year.

9.3 Reservation: Seats are reserved for backward class and NRI candidates as per the guidelines of Government of Maharashtra and as described in admission brochure for admission to the B. Pharm. in the particular academic year.

9.4. Admission authority and procedure at the entry levels into the course. As per the directives of Government of Maharashtra / Director of Technical Education and national level entrance examination conducted by Bharati Vidyapeeth University prevailing at the time of admission. The following criteria are applicable to all the

candidates for continuation in the course. A candidate to be eligible for the Degree will be required to pass examinations, as under:

First Year B. Pharm.	Semester - I & Semester - II
Second Year B. Pharm.	Semester - III & Semester - IV
Third Year B. Pharm.	Semester - V & Semester - VI
Fourth Year B. Pharm.	Semester - VII & Semester - VIII

10 Grant of Terms :

No candidate will be admitted to any examination unless he / she keeps term at a College affiliated to the University, and produces testimonials of the same from the Principal of the College.

Satisfactory attendance at the Theory and Practical classes as prescribed i.e. 75% of the theory as well as practical for each subject separately and should have successfully appeared for the sessional examination held for each of the subject separately for theory and practical.

A student whose attendance is less than 75% in all the courses putting together in any semester will not be permitted to attend the end-semester examination. He/She has to repeat the semester subsequently.

11.0 CREDIT BASED SYSTEM :

The studies and examinations of the B. Pharm. course shall be on the basis of Marks cum Credit System but semester – wise and final evaluation shall be by grading system.

11.1 The course content of the individual subjects (theory and practical) is expressed in terms of a specified number of credits. The number of credits assigned to a subject depends on the number of contact hours per week.

11.2 In general, credits are assigned to the subjects based on the following contact hours per week semester.

One Credit for each Lecture hour/week.

One and half Credit for three hours of practical/week

Five credits for Project at eighth semester.

Eleven credits for practical training.

11.3 The curriculum of B. Pharm. Programme is designed to have a total of 220 credits for the award of B. Pharm. degree. A student is to have successfully completed a particular semester's programme of study when he / she earns all the credits of that semester i.e. he / she has no 'F' grade in any subject of that semester.

12.0 MEDIUM OF INSTRUCTION :

The medium of instruction (including examinations and project reports) shall be English.

13.0 REGISTRATION :

Every student has to register himself / herself for each semester individually at the time specified by the College / University.

14.0 Scheme of Examination: CONNTINUOUS ASSESSMENT AND EXAMINATIONS

14.1 The assessment of the student's performance in each course will be based on continuous internal evaluation and semester-end examination. The marks for each of the component of assessment and Scheme of examination for B. Pharm. are as given in Table 3.

Table 3: Assessment Procedure

Sr. No.	Component of assessment	Marks allotted	Type of Assessment	Scheme of Examination
0	Theory	40	Internal Assessment * **(IA)**	(i) Two mid semester examinations shall be conducted for15marks each. (ii)10 marks are allotted for assignments.
		60	University Examinations* **(UE)**	The semester-end examination in theory subjects will be for a maximum of 60 marks.
	Total	100		
2	Practical	40	Internal Assessment * **(IA)**	(i) 10 marks are allotted for record work, day to day performance and viva-voce of the student in each lab. throughout the semester. (ii)One examination for a maximum of 30 marks shal l be conducted at the middle of the semester.
		60	University Examinations* **(UE)**	The semester-end practical examination will be for a maximum of 60 marks.
	Total	100		

*BVU shall appoint examiners for conduct of the Semester end examination.

15.0 REAPPEARANCE :

A student who has secured 'F' Grade in any Theory course / Practical of any semester shall have to reappear for the semester end examination of that Theory course/Practical.

16.0 Standard of Passing :

For all courses, both UE and IA constitute separate heads of passing. In order to pass in such courses and to earn the assigned credits, the learner must obtain a minimum grade point of 5.0 (40% marks) at UE and also a minimum grade point of 5.0 (40% marks) at IA.

If a student fails in IA, the Student passes in the course if he / she obtains a minimum of 25% in IA and GPA for the course is at least 6.0 (50% in aggregate). The GPA for a course will be calculated only if the leaner passes at the UE.

A student who fails at UE in a course has to reappear only at UE as a backlog candidate and clear the head of passing. Similarly, a student who fails in a course at IA has to reappear only at IA as a backlog candidate and clear the head of passing.

The 10 Point scale Grades and Grade Points according to the following Table 4:

Table 4: Ten Point scale Grades and Grade Points

Range of Marks (Out of 100)	Grade	Grade Point
80 ≤ Marks ≤ 100	O	10
70 ≤ Marks ≤ 80	A+	9
60 ≤ Marks ≤ 70	A	8
55 ≤ Marks ≤ 60	B+	7
50 ≤ Marks ≤ 55	B	6
40 ≤ Marks ≤ 50	C	5
Marks < 40	D	0

The performance at UE and IA will be combined to obtain the Grade Point Average (GPA) for the course. The weights for performance at UE and IA shall respectively be 60% and 40%.

GPA is calculated by adding the UE marks out of 60 and IA marks out of 40. The total marks out of 100 are converted to grade point, which will be the GPA.

17.0 Formula to calculate Grade Points (GP) :

Suppose that *'Max'* is the maximum marks assigned for an examination or evaluation based on which GP will be computed. In order to determine the GP, Set $x = Max / 10$ (since we have adapted 10 point system). Then GP is calculated by the formulas shown in Table 5:

Table 5: Calculation of Grade Points (GP)

Range of Marks at the evaluation	Formula for the Grade Point
$8x \leq$ Marks $\leq 10x$	10
$5.5x \leq$ Marks $\leq 8x$	Truncate (Marks/x) + 2
$4x \leq$ Marks $\leq 5.5x$	Truncate (Marks/x) + 1

Two kinds of performance indicators, namely, the Semester Grade Point Average (SGPA) and the Cumulative Grade Point Average (CGPA) shall be computed at the end of each term. The SGPA measures the cumulative performance of a learner in all courses in a particular semester, while the CGPA measures the cumulative performance in all courses since his/her enrolment. The CGPA of learner when he/she completes the programme is the final result of the learner.

The SGPA is calculated by the formula $\frac{\Sigma C_k X GP_k}{\Sigma C_k}$, where

C_k is the credit-value assigned to a course and GP_k is the GPA obtained by the learner in the course. In the above, the sum is taken over all the courses that the learner has undertaken for the study during the semester, including those in which he / she might have failed or those for which he /she remained absent. The SGPA shall be calculated up to two decimal place accuracy.

The CGPA is calculated by the formula $CGPA = \frac{\Sigma C_k X GP_k}{\Sigma C_k}$, where

C_k is the credit-value assigned to a course and GP_k is the GPA obtained by the learner in the course. In the above, the sum is taken over all the courses that the learner has undertaken for the study from the time of his / her enrolment and also the during the semester for which CGPA is calculated, including those in which he / she might have failed or those for which he /she remained absent. The CGPA shall be calculated up to two decimal place accuracy.

Table 6 : The Formula to compute equivalent percentage marks for specified CGPA

% Marks (CGPA) =	10 X CGPA - 10	if 5.00 ≤ CGPA ≤ 6.00
	5 X CGPA - 20	if 6.00 ≤ CGPA ≤ 8.00
	10 X CGPA - 20	if 8.00 ≤ CGPA ≤ 9.00
	20 X CGPA - 110	if 9.00 ≤ CGPA ≤ 9.50
	40 X CGPA - 300	if 9.50 ≤ CGPA ≤ 10.00

18.0 Award of Honours:

A student who has completed the minimum credits specified for the programme shall be declared to have passed in the programme. The final result will be in terms of letter grade only and is based on the CGPA of all courses studied and passed. The Criteria for the award of honours are given in Table 7:

Table 7: Criteria for the award of honours

Range of CGPA	Final Grade	Performance Descriptor	Equivalent Range of Marks (%)
9.50 ≤ CGPA ≤ 10.00	O	Outstanding	80 ≤ Marks ≤ 100
9.00 ≤ CGPA ≤ 9.49	A+	Excellent	70 ≤ Marks ≤ 80
8.00 ≤ CGPA ≤8.99	A	Very Good	60 ≤ Marks ≤ 70
7.00 ≤ CGPA ≤ 7.99	B+	Good	55 ≤ Marks ≤ 60
6.00 ≤ CGPA ≤ 6.99	B	Average	50 ≤ Marks ≤ 55
5.00 ≤ CGPA ≤ 5.99	C	Satisfactory	40 ≤ Marks ≤ 50
CGPA Below 5.00	F	Fail	Marks below 40

The requirement of CGPA for a student to be declared to have passed on successful completion of the B.Pharm. programme and for the declaration of the class is as shown in Table 8.

Table 8: CGPA required for award of class

Distinction	9.0 and above
First class	8.0 to 8.99
Higher Second class	7.0 to 7.99
Second class	6.0 to 6.99
Pass	5.0 to 5.99

19.0 Eligibilty for the award of the B.Pharm. degree :

19.1 Duration of the programme

A student is ordinarily expected to complete the B.Pharm. Programme in eight semesters of four years. However a student may complete the programme in not more than six years including the study period.

19.2 However the above regulation may be relaxed by the Vice-Chancellor in individual cases for cogent and sufficient reasons.

19.3 A student shall be eligible for the award of the B.Pharm degree if he/she fulfill all the following conditions.

a) Registered and successfully completed all the courses.

b) Successfully acquired the minimum required credits as specified in the curriculum within the stipulated time.

c) Has no dues to the Institute, hostels, Libraries etc, and

d) No disciplinary action is pending against him/her.

19.4 The degree shall be awarded after approval by the Academic Council.

RULES :

1. With regard to the conduct of the end-semester examination in any of the practical courses of the programme, the University shall appoint one examiner from the institute in addition to an external examiner in the said subject.

2. In respect of all theory examinations, the paper setting of end semester examination shall be done by an internal and external paper setter.

3. The theory papers of end-semester examination will be evaluated by two examiners, internal and external.

4. Panel of examiners of evaluation for each course is to be prepared by the Board of Studies and approved by the Academic Council.

5. The examiner for evaluation should possess post-graduate qualification and a minimum of five years UG teaching/industrial experience.

6. A.T.K.T.

A candidate failing in Semester I, III, V & VII shall be promoted to next higher semester i.e. II, IV, VI and VIII irrespective of the number of subject heads in which he/she is failing.

A candidate failing in more than three theory and more than two practical heads of University Examination (UE) of semester – I & II taken together will not be promoted to semester-III

A candidate failing in more than three theory and more than two practical heads of University Examination (UE) of semester III& IV taken together will not be promoted to semester-V unless a student passes in all the subjects of sem I & II

A candidate failing in more than three theory and two practical heads of University Examination (UE) of semester – V & VI taken together will not be promoted to semester-VII unless a student passes in all the subjects of sem III & IV

7. Criteria for admitting the candidate for examinations irrespective of regular or supplementary examinations:

Candidate must have been admitted to the respective Semester as per the criteria for continuation into the respective semesters given in B.Pharm. and has kept the term for the Semester for which he is examined. The candidate must submit prescribed application form along with fees. Candidates must appear for the examination in the place and time as decided by the admitting Institute /the University as the case may be.

8. Clarifications:

Candidate who has ATKT will appear for examinations in only those subject heads in which the candidate has failed.

9. Time Schedule:

The internal assessment shall be normally conducted after completion of at least two thirds of instruction weeks in the Semester.

Any candidates remaining absent for the sessional examination for any reason what so ever will be treated as not appeared for the sessional examination. However a committee constituted by the Principal may allow the candidate for appearing in the re-sessional examination subject to the conditions as specified by the committee, otherwise no separate examination will be conducted.

The institute conducting the course must submit the internal assessment marks of the respective semester to the Controller of Examination before the commencement of theory or practical examination whichever is later.

10. Practical Training:

Every candidate shall be required to work for at least four weeks in a Pharmaceutical Industry or Govt. Hospital or research and development organization or public testing laboratory after the Semester V of the course study, and shall submit satisfactory report of such work to the head of the institute. The student will eligible to obtain 11 credits after successful completion of the practical training.

11. Improvement of Class:

A student will be allowed to improve his/her class at B.Pharm degree as per University rules

12. Validity of Term:

A term once granted shall be valid for four attempts.

13. Environmental Sciences:

As per the decision of the Supreme Court and directives of the U.G.C., every student has to pass in the subject of Environmental Sciences during the course of the study of B.Pharm. as per university rules.

Table 9: Course Structure for B. Pharm.

B.Pharm	Semester	Course Title	Hr/Wk	Hr/Wk	Credits	Credits	Hr/sem	Total Credits
First Year	I		L	P	L	P	T	
1.1.1	1	Pharmaceutical Chemistry-I (Inorganic)	3	3	3	1.5	3	4.50
1.1.2	2	Pharmaceutical Chemistry - II (Organic)	3	3	3	1.5	3	4.50
1.1.3	3	Modern Dispensing Pharmacy	3	3	3	1.5	3	4.50
1.1.4	4	Human Anatomy and Physiology- I	3	3	3	1.5	3	4.50
1.1.5	5	Pharmaceutical Engineering - I	3	-	3	-	3	3.00
1.1.6	6	Pharmaceutical Statistics	3	-	3	-	3	3.00
1.1.7	7	Computer Application	-	3	-	1.5	-	1.50
			18	**15**	**18**	**7.5**	**18**	**25.50**
First Year	II							
1.2.1	1	Pharmaceutical Chemistry-III (Inorganic)	3	3	3	1.5	3	4.50
1.2.2	2	Pharmaceutical Chemistry–IV (Organic)	3	3	3	1.5	3	4.50
1.2.3	3	Pharmaceutical Biochemistry-I	3	3	3	1.5	3	4.50
1.2.4	4	Pharmaceutical Engineering -II	3	3	3	1.5	3	4.50
1.2.5	5	Community Pharmacy and Hospital Pharmacy	3	3	3	1.5	3	4.50
1.2.6	6	Human Anatomy and Physiology- II	3	3	3	1.5	3	4.50
			18	**18**	**18**	**9.0**	**18**	**27.0**
Total Credits of Sem I & II								**52.50**

Second Year	III							
2.1.1	1	Pharmaceutical Chemistry – V (Organic)	3	3	3	1.5	3	4.50
2.1.2	2	Pharmaceutical Biochemistry-II	3	3	3	1.5	3	4.50
2.1.3	3	Pharmaceutical Analysis -I	3	3	3	1.5	3	4.50
2.1.4	4	Physical Pharmacy-I	3	3	3	1.5	3	4.50
2.1.5	5	Pharmaceutical Microbiology –I	3	3	3	1.5	3	4.50
2.1.6	6	Pathophysiology	3	-	3	-	3	3.00
			18	**15**	**18**	**7.5**	**18**	**25.50**
Second Year	IV							
2.2.1	1	Pharmaceutical Chemistry – VI (Organic)	3	3	3	1.5	3	4.50
2.2.2	2	Pharmaceutical Microbiology –II	3	3	3	1.5	3	4.50
2.2.3	3	Pharmaceutical Analysis -II	3	3	3	1.5	3	4.50
2.2.4	4	Physical Pharmacy-II	3	3	3	1.5	3	4.50
2.2.5	5	Pharmacognosy - I	3	3	3	1.5	3	4.50
2.2.6	6	Pharmacology-I	3	-	3	-	3	3.00
			18	**15**	**18**	**7.5**	**18**	**25.5**
Total Credits of Sem III & IV								**51.00**

Third Year	Semester	Course Title	Hr/ Wk	Hr/Wk	Credits	Credits	Hr/ sem	Total Credits
	V		L	P	L	P	T	
3.1.1	1	Medicinal Chemistry-I	3	3	3	1.5	3	4.50
3.1.2	2	Pharmaceutical Analysis-III	3	3	3	1.5	3	4.50
3.1.3	3	Pharmaceutical Technology-I	3	3	3	1.5	3	4.50
3.1.4	4	Pharmacology-II	3	3	3	1.5	3	4.50
3.1.5	5	Pharmacognosy-II	3	3	3	1.5	3	4.50
3.1.6	6	Pharmaceutical Jurisprudence	3	-	3	-	3	3.00
			18	**15**	**18**	**7.5**	**18**	**25.50**
Third Year	VI							
3.2.1	1	Medicinal Chemistry-II	3	3	3	1.5	3	4.50
3.2.2.	2	Pharmaceutical Analysis-IV	3	3	3	1.5	3	4.50
3.2.3	3	Pharmaceutical Technology-II	3	3	3	1.5	3	4.50
3.2.4	4	Pharmacognosy-III	3	3	3	1.5	3	4.50
3.2.5	5	Pharmaceutical Biotechnology	3	3	3	1.5	3	4.50
3.2.6	6	Pharmacology-III	3	-	3	-	3	3.00
			18	**15**	**18**	**7.5**	**18**	**25.5**
Total Credits of Sem V & VI								**51.00**

Final Year	VII							
4.1.1	1	Medicinal Chemistry-III	3	3	3	1.5	3	4.50
4.1.2	2	Pharmaceutical Technology-III	3	3	3	1.5	3	4.50
4.1.3	3	Biopharmaceutics and Pharmacokinetics	3	3	3	1.5	3	4.50
4.1.4	4	Pharmacognosy-IV	3	3	3	1.5	3	4.50
4.1.5	5	Pharmaceutical Analysis-V	3	-	3	-	3	3.00
4.1.6	6	Clinical Pharmacy	3	-	3	-	3	3.00
	7	Soft Skills	-	3	-	1.5	-	1.5
			18	**15**	**18**	**7.5**	**18**	**25.5**
Final Year	VIII							
4.2.1	1	Medicinal Chemistry-IV	3	3	3	1.5	3	4.50
4.2.2	2	Pharmaceutical Analysis-VI	3	3	3	1.5	3	4.50
4.2.3	3	Pharmaceutical Technology-IV	3	3	3	1.5	3	4.50
4.2.4	4	Pharmacology-IV	3	3	3	1.5	3	4.50
4.2.5	5	Pharmaceutical management	3	-	3	-	3	3.00
4.2.6	6	Elective	3	-	3	-	3	3.00
	7	Project	-	3	-	5.0	-	5.00
			18	**15**	**18**	**11.0**	**18**	**29**
Total Credits of Sem VII & VIII								**54.5**
		Industrial Training of four weeks any time after completion of Second Year and before completion of Fourth Year of B.Pharm.			**11.00**			**11.00**
								220

Table 10: Scheme of examination for B. Pharm.

Note: Semester Question paper should contain two sections viz., SECTION I on the topics covered in UNIT 1 and UNIT 2, and SECTION II on the topics covered under UNIT 3 and UNIT 4.

B. Pharm	Semester	Course Title	Theory				Practical			
First Year	I		Mid Sem test	Assign ment	End Sem	Total marks	Mid Sem test	Assign ment	End Sem	Total marks
	1.1.1	Pharmaceutical Chemistry- I (Inorganic)	30	10	60	100	30	10	60	100
	1.1.2	Pharmaceutical Chemistry -II (Organic)	30	10	60	100	30	10	60	100
	1.1.3	Modern Dispensing Pharmacy	30	10	60	100	30	10	60	100
	1.1.4	Human Anatomy and Physiology- I	30	10	60	100	30	10	60	100
	1.1.5	Pharmaceutical Engineering - I	30	10	60	100	-	-	-	-
	1.1.6	Pharmaceutical Statistics	30	10	60	100	-	-	-	-
	1.1.7	Computer Application	-	-	-	-	30	10	60	100
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**
First Year	II									
	1.2.1	Pharmaceutical Chemistry- III (Inorganic)	30	10	60	100	30	10	60	100
	1.2.2	Pharmaceutical Chemistry –IV (Organic)	30	10	60	100	30	10	60	100
	1.2.3	Pharmaceutical Biochemistry-I	30	10	60	100	30	10	60	100
	1.2.4	Pharmaceutical Engineering -II	30	10	60	100	30	10	60	100
	1.2.5	Community Pharmacy and Hospital Pharmacy	30	10	60	100	30	10	60	100
	1.2.6	Human Anatomy and Physiology- II	30	10	60	100	30	10	60	100
		Total	**180**	**60**	**360**	**600**	**180**	**60**	**360**	**600**
Second Year	III									
	2.1.1	Pharmaceutical Chemistry –V (Organic)	30	10	60	100	30	10	60	100
	2.1.2	Pharmaceutical Biochemistry-II	30	10	60	100	30	10	60	100
	2.1.3	Pharmaceutical Analysis -I	30	10	60	100	30	10	60	100
	2.1.4	Physical Pharmacy-I	30	10	60	100	30	10	60	100
	2.1.5	Pharmaceutical Microbiology –I	30	10	60	100	30	10	60	100
	2.1.6	Pathophysiology	30	10	60	100	-	-	-	-
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**

Second Year	IV									
	2.2.1	Pharmaceutical Chemistry –VI (Organic)	30	10	60	100	30	10	60	100
	2.2.2	Pharmaceutical Microbiology –II	30	10	60	100	30	10	60	100
	2.2.3	Pharmaceutical Analysis -II	30	10	60	100	30	10	60	100
	2.2.4	Physical Pharmacy-II	30	10	60	100	30	10	60	100
	2.2.5	Pharmacognosy- I	30	10	60	100	30	10	60	100
	2.2.6	Pharmacology-I	30	10	60	100	-	-	-	-
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**
Third Year	**V**									
	3.1.1	Medicinal Chemistry-I	30	10	60	100	30	10	60	100
	3.1.2	Pharmaceutical Analysis-III	30	10	60	100	30	10	60	100
	3.1.3	Pharmaceutical Technology-I	30	10	60	100	30	10	60	100
	3.1.4	Pharmacology-II	30	10	60	100	30	10	60	100
	3.1.5	Pharmacognosy-II	30	10	60	100	30	10	60	100
	3.1.6	Pharmaceutical Jurisprudence	30	10	60	100	-	-	-	-
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**
Third Year	VI									
	3.2.1	Medicinal Chemistry-II	30	10	60	100	30	10	60	100
	3.2.2	Pharmaceutical Analysis-IV	30	10	60	100	30	10	60	100
	3.2.3	Pharmaceutical Technology-II	30	10	60	100	30	10	60	100
	3.2.4	Pharmacognosy-III	30	10	60	100	30	10	60	100
	3.2.5	Pharmaceutical Biotechnology	30	10	60	100	30	10	60	100
	3.2.6	Pharmacology-III	30	10	60	100	-	-	-	-
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**
Final Year	VII									
	4.1.1	Medicinal Chemistry-III	30	10	60	100	30	10	60	100
	4.1.2	Pharmaceutical Analysis-V	30	10	60	100	-	-	-	-
	4.1.3	Pharmaceutical Technology-III	30	10	60	100	30	10	60	100
	4.1.4	Biopharmaceutics and Pharmacokinetics	30	10	60	100	30	10	60	100
	4.1.5	Pharmacognosy-IV	30	10	60	100	30	10	60	100
	4.1.6	Clinical Pharmacy	30	10	60	100	-	-	-	-
	4.1.7	Soft Skills	-	-	-	-	30	10	60	100
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**
Final Year	VIII									
	4.2.1	Medicinal Chemistry-IV	30	10	60	100	30	10	60	100
	4.2.2	Pharmaceutical Analysis-VI	30	10	60	100	30	10	60	100
	4.2.3	Pharmaceutical Technology-IV	30	10	60	100	30	10	60	100
	4.2.4	Pharmacology-IV	30	10	60	100	30	10	60	100
	4.2.5	Pharmaceutical management	30	10	60	100	-	-	-	-
	4.2.6	Elective	30	10	60	100	-	-	-	-
	4.2.7	Project	-	-	-	-	40	-	60	100
		Total	**180**	**60**	**360**	**600**	**150**	**50**	**300**	**500**

SEMESTER-I

1.1.1 PHARMACEUTICAL CHEMISTRY -I (INORGANIC)

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To study the principles of inorganic chemistry with reference to inorganic pharmaceuticals

2 To elucidate importance of impurities in pharmaceuticals and acquire skills to detect and control them by official standards

3 To demonstrate significance of contents of monographs of important inorganic pharmaceuticals with reference to treatment of diseases

Course Outcomes :

At the end of the course students shall be able to

1 Understand the relevance and significance of inorganic chemistry with reference to pharmaceutical sciences

2 Develop competency for official standard methods to detect and control impurities

3 Acquire knowledge of complete profiles of important inorganic pharmaceuticals

Unit- 1

1 Pharmacopoeia and monograph :

Different pharmacopoeia and contents of official monograph in Indian Pharmacopoeia (IP) **03 h**

2 Purity of pharmaceuticals :

Sources of impurities and factors affecting purity of Pharmaceuticals, limit tests for chloride, sulphate, iron, arsenic, lead, heavy metals and official tests of purity (Excluding Assays) **08 h**

Unit-2

For all official compounds it is expected to study physicochemical properties, assays, uses and storage conditions

3 Electrolytes :

Major extra and intracellular electrolytes and ions: chloride, phosphate, bicarbonate, Na, K, Ca, Mg and their physiological role and disorders caused by their imbalance.

Electrolytes used for replacement therapy, Physiological acid base balance, Electrolytes used in acid-base therapy, Electrolyte combination therapy.

Sodium chloride injection, Ringer solution, Lactated ringer injection, Sodium acetate, Potassium bicarbonate , Sodium lactate, Sodium citrate **10 h**

Unit-3

4 Antacids :

General introduction, definition, classification, mechanism of action, acid neutralizing capacity, properties of ideal antacid.

Sodium bicarbonate, Aluminum hydroxide, Calcium carbonate, Magnesium hydroxide, Magnesium carbonate **06 h**

5 Protective and adsorbents :

General introduction, definition, classification, mechanism of action, properties of ideal protective and adsorbent. Bismuth subcarbonate, Bismuth subgallate, Kaolin, Pectin, Activated charcoal **04 h**

6 Cathartics :

General introduction, definition, classification, mechanism of action.

Sodium phosphate, Magnesium sulphate **03 h**

Unit-4

7 Essential and trace elements :

Absorption, distribution, physiological role and deficiency symptoms of Fe, Cu, Zn, Mn, S, I. Ferrous sulfate, Ferrous fumarate, Ferric ammonium citrate, Strong and weak iodine solution, Potassium iodide, Zinc sulphate **08 h**

Recommended Books :

1 J.H.Block, E.B. Roche, T.O. Soine,, C.O.Wilson: Inorganic, Medicinal and Pharmaceutical Chemistry (Verghese Puhblication)

2 C.A.Dicher: Modern Inorganic Pharmaceutical Chemistry

3 Bentley & Drivers text-book of Pharmaceutical Chemistry, 8th edition (ELBS London.)

4 Beckett and Stenlake Pratical Pharmaceutical Chemistry Vol. I (C.B.S.)

5 A. I. Vogel (Long man), Quantitative in organic analysis, 4th edition

6 Indian Pharmacopoeia

7 Remington's Pharmaceutical Sciences (Mack Publishing Co.)

8 G. R. Chatwal, Pharmaceutical Chemistry-Inorganic, (Himalaya Publishing House)

1.1.1 PHARMACEUTICAL CHEMISTRY-I (INORGANIC)

Practical (3 Hrs/Week)

Course Objectives :

1 To study monographs of important inorganic substances

2 To develop skills for performing official tests for purity and assays

3 To demonstrate principles of qualitative analysis of inorganic compounds

Course Outcomes :

At the end of the course students shall be able to

1 Conceptualize significance of official standards for drug substances and pharmaceutical aids

2 Apply the skills of qualitative analysis to unknown samples

3 Develop mathematical approach to calculate quantitative parameters for synthesized compounds

4 Identify impurities from pharmaceutical substances

5 Compute and quantitate purity of inorganic pharmaceuticals

Experiments:

1 Identification test (any five)

i) Sodium bicarbonate
ii) Bismuth subcarbonate
iii) Aluminium hydroxide gel(dried)
iv) Calcium carbonate
v) Ferrous sulphate
vi) Ferric ammonium citrate
vii) Magnesium sulphate
viii) Sodium acetate

2 Limit test (any four)

i) Limit test for Chloride
ii) Limit test for Sulphate
iii) Limit test for Iron
iv) Limit test for Heavy metals
v) Limit test for Lead

3 Qualitative analysis of given samples (any five)

Recommended Books :

1 Indian Pharmacopoeia

2 Bentley & Drivers Text-Book of Pharmaceutical Chemistry, 8th Edition (Oxford University Press)

3 A.I. Vogel : Quantitative Inorganic Analysis - (Longman), 4th edition

4 Remington's Pharmaceutical Sciences (Mack Publishing CO.)

5 Cotton & Wilkinson, Advanced Inorganic Chemistry, 18th edition, (Willey Eastern Ltd, Delhi)

6 Beckett and Stenlake Vol. I (CBS Publishers & Distributors Delhi-32.)

7 G. R. Chatwal, Pharmaceutical Chemistry-Inorganic (Himalaya Publishing House)

8 K. R. Mahadik, Practical Hand book of Pharmaceutical Organic and Inorganic Chemistry (Nirali Publication)

1.1.2 PHARMACEUTICAL CHEMISTRY - II (ORGANIC)

(Theory) (3Hrs/Week) (42 lectures)

Course Objectives :

1 To imbibe the foundation of organic chemistry.

2 To demonstrate logical approach to reaction mechanisms.

3 To ascertain knowledge of official nomenclature, properties, methods of preparation, reactions of various functional groups and their applications.

4 To inculcate basic concepts of stereochemistry.

Course Outcomes :

At the end of the course students shall be able to

1 Understand concepts of fundamentals of organic reactions and IUPAC nomenclature.

2 Elucidate reaction mechanisms through problem based approach.

3 Conceptualize the basic concepts of stereochemistry.

Unit- 1

1 Structure of organic molecule

a) Atomic orbital

b) Hybridization

c) Sigma and Pi bonds

d) Intermolecular forces and related properties [polarity of bonds, M. P., B. P., Solubility.]

e) Acids and bases : Lowry Bronsted and Lewis theories **05 h**

2 Factors affecting electron availability in a molecule

a) Inductive effects and its applications

b) Resonance effects and its applications

c) Hyper conjugation and its applications

d) Steric effects **06 h**

Unit-2

3 **IUPAC nomenclature** of organic compounds belonging to following classes : alkanes, alkenes, amines, phenols, alcohols, esters, aldehydes, ketones, carboxylic acids and cycloalkanes **02 h**

4 **Nucleophilic substitution reactions** at saturated carbon and aryl carbon atom.

S_N1, S_N2 and S_Ni reactions with their kinetics, mechanism, stereochemistry and orientation.

Factors affecting nucleophilic substitution reactions

i) Effect of solvent ii) Effect of structure

iii) Effect of nucleophile iv) Effect of leaving group

Application of these in preparation and reactions of alkyl halides, alcohols, epoxides. **08 h**

Unit-3

5 Stereochemistry

Introduction to Isomerism, Classification, Structural isomerism and Stereoisomerism (Geometrical isomerism, Optical isomerism) **05 h**

6 Reaction mechanism

a) Types of reagent

b) Types of reaction intermediates

c) Types of mechanism

d) Collision and transition state theories **08 h**

Unit-4

7 Aromatic electrophilic substitution

a. Electrophilic attack on benzene.

b. Nitration, halogenations, sulphonation, Friedal craft alkylation and acylation, diazo coupling.

c. Orientation in mono-substituted benzene. **08 h**

Recommended Books :

1 Morrison and Boyd, Organic Chemistry (Prentice Hall of India (P) Ltd.)

2 I.L. Finar, Organic Chemistry, The Fundamentals of Chemistry (Longmann UK).

3 T. W. Graham Solomans Fundamentals of Organic Chemistry (John Wiley and Sons. Inc. USA).

4 Cram and Hammond, Pine and Hendrickson, Organic Chemistry, (McGraw Hill USA)

5 Jerry and March, Advanced Organic Chemistry (Wiely Eastern Ltd. New Delhi).

6 Sachin Kumar Ghosh, General Organic Chemistry, (New Central Book Agency Calcutta).

7 Marye Anne, Fox James, K.Whitesell, Organic Chemistry, Jones and Bartlet.

1.1.2 PHARMACEUTICAL CHEMISTRY- II (ORGANIC)

(Practical) (3 Hrs/Week)

Course Objectives :

1 To create awareness about safety measures and Good Laboratory Practices.

2 To develop skill for identification of unknown organic compounds and its application in synthetic chemistry

3 To train for basic laboratory techniques.

Course Outcomes :

At the end of the course students shall be able to

1 Imbibe the safety measures and inculcate Good Laboratory Practices.

2 Apply analytical tools for identification of organic compounds.

3 Master important laboratory techniques.

4 Record, compute and analyze the data.

Experiments :

1 Introduction to general safety and laboratory techniques.

2 Identification of organic compounds belonging to the following classes by systemic qualitative analysis, including preparation of suitable derivatives [Minimum 14 compounds]

Phenols, amines, amides, carboxylic acids, aldehydes, ketones, esters, nitro compounds, hydrocarbons, alcohols.

Recommended Books :

1 A.I.Vogel : A Text Book of Practical Organic Chemistry, 4th Edition.

2 H.T.Cloke : Hand book of Organic Analysis (Qualitative and Quantitative), (Arnold- Heinemann).

3 Shriner, Hermann, Morris, Curtin and Fuson : The Systematic Identification of Organic Compounds, (Wiley & Sons,Inc)

1.1.3 MODERN DISPENSING PHARMACY

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To acquaint about pharmacy practice.
2. To impart knowledge of prescription handling and dispensing practice.
3. To introduce to pharmaceutical dosage forms.

Course Outcomes :

At the end of the course students shall be able to

1. Evaluate prescription for correctness.
2. Apply principles of modern dispensing practices.
3. Give instructions to patient about pharmaceutical dosage forms.

Unit-1

1. **Developmental changes in pharmacy profession and pharmacopoeia :**
   Historical background and development of profession of pharmacy, Pharmacy practices regulation 2015 and pharmaceutical industry in brief. History & features of Indian Pharmacopoeia. **01h**

2. **Pharmacist as health care provider :**
   Role and responsibilities of community pharmacist in health care, barriers and challenges. **02h**

3. **Prescription :**
   Definition, Parts, Errors in prescription writing, Incompatabilities **04h**

4. **Concept of Good Dispensing Practice :**
   Basic elements, handling of prescription, errors in dispensing, documentation, patient instruction aids-PIL, PMR and pictograms, introduction to use of drug indices like CIMS, Drugs Today. **04h**

Unit-2

5. **Pharmaceutical calculation :**
   Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc. **03h**

6. **Posology :**
   Definition, Factors affecting dose selection. Calculation of children and infant doses. **03h**

7. **Storage and Stability :**
   Signs of degradation of drug product, Storage conditions, meaning of expiry date and its relation with storage condition. **02h**

Unit-3

8. Introduction to dosage forms :
Classification and definitions, Advisory labels. **02h**

9. Various dosage forms and its dispensing :
Definition and classification, merits/demerits, additives (just role of individual additive with examples), dispensing with instructions of following dosage forms :

10. Oral liquids and oral topical dosage forms :
Mixtures/ liquids, syrup, elixirs, linctuses, suspensions, emulsions, mouthwash, gargle, throat / gum paint. **03h**

11. Powders and granules :
Bulk powder and granules, divided powder and dose divisions, ORS, dry syrups, tooth powder **02h**

12. Tablets and capsules :
Types of tablets and capsules with their applications, dispensing of these including from bulk packs **02h**

13. Topical formulations :
Ointment, cream, gels, pastes, liniment, lotion, topical spray, collidions, dusting powders. **02h**

Unit- 4

14. Eye drops and ointments, Ear and nasal drops, nasal spray **02h**

15. Rectal/vaginal formulations :
Suppository, pessaries, enema and semisolids for rectal and vaginal administration **02h**

16. Injections :
Types of injections as per route of administration and volume. Precautions during handling, storage. **02h**

17. Surgical aids :
Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages. **02h**

18. NDDS :
Principle, application and patient instruction for SR tablets, inhalers, transdermal patch and Insulin injection **02h**

19. Galenicals :
Principle, application and storage of various galenical or related ayurvedic medicines like Asawa, Arista, liquid extracts, dry extracts, etc. **02h**

Recommended Books :

1. A.J.Winfield, RM.E. Richards: Pharmacy practice (J.B.Lippincott Company).
2. Cooper and Gunns; Dispensing for Pharmaceutical Students,12th edition. (C.B.S. Delhi).

3. Atmaram Pawar; Modern Dispensing Pharmacy (Career Publications).
4. H.C. Ansel, N.G.Poporich. L.V. Allen; Pharmaceutical dosage forms and Drug Delivery systems (Williams and Wilkins).
5. Remington: The Science and Practice of Pharmacy (Mack Publishing Company).
6. M.J.Stocklosa, H.C.Ansel; Pharmaceutical Calculation (K.M.Varghese Company).
7. B.M.Mithal; Pharmaceutical Formulation (Vallabh Prakashan).

1.1.3 MODERN DISPENSING PHARMACY

(Practical) (3 Hrs/Week)

Course Objectives :

1. To acquaint with prescription handling
2. To develop skills in compounding and dispensing of pharmaceutical dosage forms
3. To learn appropriate use of medicines

Course Outcomes :

At the end of the course students shall be able to

1. Evaluate prescription
2. Apply skills in compounding and dispensing of pharmaceutical dosage forms
3. Instruct the patients for appropriate use of medicines

Practical: 3 Hrs/Week

List of Experiments :

Compounding, dispensing label, documentation in PMR and PIL and patient instruction / counselling note/ precautions, indications and contraindications, names of currently available proprietary products with its company and general description.

1. Evaluation of 2 prescriptions per student.

2. Demonstration to prepare PMR, PIL and Pictrograms.

3. Oral liquids and oral topical liquids (any 5)

a. Simple Syrup I.P
b. Vasaka Syrup
c. Paracetamol elixir BPC
d. Simple Linctus BPC
e. Magnesium Hydroxide mixture BP
f. Liquid paraffin emulsion IP
g. Zinc sulphate and Zinc Chloride Mouthwash BPC.
h. Tannic Acid Glycerin Paint INF

4. Two examples of dispensing of marketed products :

Expectorant, Analgesic - antipyretic or any other.

5. Powder (any 3)

a. ORS formula (WHO)
b. Isapgul granules
c. Tooth powder
d. Divided powder for dose division with calculations.
e. Dispensing of marketed dry syrup.

6. Tablet and capsule (any 2)

a) Dispensing of tablet/ capsule from bulk pack.
b) Dispensing of marketed tablet / capsule for adult patient and paediatric patient: conventional tablet, dispersible tablet, sublingual tablet, coated tablet

7. Topical Products (any 2)

a. Methyl salicylate ointment BPC
b. Cetrimide cream BPC
c. Dispensing of a topical liquid/spray, gel.

8. Eye drops, Ear Drops, Nasal drops/spray :
Dispensing of marketed products.

9. Rectal/Vaginal products : (any 3)

a. Soap glycerine / medicated cocoa butter suppository.
b. Soap enema.
c. Dispensing of a marketed suppository and a pessary.
d. Dispensing of rectal and vaginal semisolid medicine.

10. Small volume and a large volume parenteral: Dispensing

11. Galenical product :

a. Carminative mixture/ Gripe water.
b. Dispensing of a galenical product.

12. Assignment :

a. Assignment should be based on literature survey, presentation, market survey or current trends in prescription / therapy.

Recommended Books :

1. A.J.Winfield, RM.E. Richarods: Pharmacy practice (J.B.Lippincott Company).
2. Cooper and Gunns; Dispensing for Pharmaceutical Students,12th edition(C.B.S. Delhi)
3. Atmaram Pawar ; Modern Dispensing Pharmacy (Career Publications).
4. Remington: The Science and Practice of Pharmacy (Mack Publishing Company).

1.1.4 HUMAN ANATOMY AND PHYSIOLOGY - I

(Theory) (3Hrs/Week) (42 lectures)

Course Objectives :

1 To introduce scientific terminologies with respect to human body.

2 To decide structural organization and functions of human body.

3 To exemplify the mechanisms of synchronous working of organs.

4 To impart knowledge of the physiological basis of disorders in human body.

Course Outcomes :

At the end of the course students shall be able to

1 Understand the terminologies related to human anatomy and physiology.

2 Identify and describe the structure and functions of various systems of the human body.

3 Realize synchronous working of various organs.

4 Appreciate the concept of imbalance of homeostasis with respect to diseases

Unit- 1

1 Basic terminologies used in anatomy and physiology. 02 h
Directional terms, planes of the body, body cavities, Scope of anatomy and physiology.

2 **Cell Physiology :**
Structure of cell, its components- Their structure and functions, movement of materials across plasma membrane, homeostasis. **04 h**

3 Elementary tissues of human body :
Epithelial, connective, muscular, and nervous tissues-their subtypes and characteristics. **04 h**

Unit-2

4 Cardiovascular system :
Blood vessels-anatomy of heart, conduction system of heart, cardiac cycle and heart sounds, blood vessels and circulation (pulmonary coronary, systemic and portal), ECG, Blood pressure (Maintenance and regulation), disorders of cardiovascular system (definitions only) **07 h**

5 Lymphatic system :
Lymph (Formation, composition, functions, circulation), lymph node (structure and functions), spleen and its functions, disorders of lymphatic system (definitions only) **04 h**

Unit-3

6 The Blood :

composition and functions of blood, RBC, WBC, Platelets, Haemopoiesis, blood groups, mechanism of clotting, anemia, disorders of blood (definitions only) **08 h**

Unit-4

7 Respiratory system :

Anatomy of respiratory organs and their functions, mechanism and regulation of respiration, physiology of respiration, transport of gases, respiratory volumes, methods of artificial respiration, Cough and sneezing reflex and disorders of respiratory system. (definitions only) **07 h**

8 Digestive system :

Anatomy and physiology of organs of digestive system, secretions and functions of salivary glands, stomach, liver, pancreas, small intestine, large intestine, role of enzymes in digestion and absorption of food, disorders of digestive system (definitions only) **06 h**

Recommended Books :

1 Chatterjee, C.C., Human Physiology (Medical Allied Agency, Kolkata).

2 Chaudhari S K. Concise Medical Physiology (New Central Book Agency (P) Ltd., Calcutta).

3 Ganong, W.F., Review of Medical Physiology. (Prentice-Hall International, London).

4 Guyton, A.C., Textbook of Medical Physiology. (W. B. Saunders Co., Philadelphia, USA).

5 Jain, A.K., Textbook of Physiology. (Avichal Publishing Co., New Delhi).

6 Singh, I., BD Chaurasia's Human Anatomy. CBS Publisher and Distributors, New Delhi).

7 Tortora, G.J. and Grabowski, S.R., 2005. Principals of Anatomy and Physiology. (Harper Collins College Publishers, New York).

8 Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. (McGraw-Hill Publishing Co., USA).

9 Wagh, A. and Grant, A., Ross and Wilson's Anatomy and Physiology in Health and Illness. (Churchill-Livingstone, London).

10 West, J.B., Best and Taylor's Physiological Basis of Medical Practice. (Williams and Wilkins, Baltimore, USA).

11 Worwick, R. and Williams, P., (Gray's Anatomy. Longman, London).

1.1.4 HUMAN ANATOMY AND PHYSIOLOGY - I

(Practical) (3 Hrs/Week)

Course Objectives :

1 To develop skills for determining hematological parameters.
2 To understand the structure and identification of human skeletal system.
3 To acquaint with the internal structure of various organs.
4 To learn common techniques of assessing cardiovascular functions.

Course Outcomes :

At the end of the course students shall be able to

1 Examine blood samples for hematological parameters and correlate with clinical conditions.
2 Identify bones and their structure.
3 Acquaint with the histology of various tissue sections.
4 Gain expertise in measurement of blood pressure

Experiments :

1 Determination of Haemoglobin content of blood
2 Determination of RBC count of blood
3 Determination of blood groups
4 Recording of Blood pressure of normal volunteer
5 Osteology-Study of appendicular skeleton
6 Osteology -Study of axial skeleton
7 Study of Joints
8 Study of following systems with the help of models and charts
   a) Cardiovascular system
   b) Lymphatic system
   c) Respiratory system
   d) Digestive System

Recommended Books :

1 Chaudhari, A.R., Textbook of Practical Physiology. (Paras Publishers, New Delhi).
2 Chaudhari, A.R., Viva in Physiology. (Paras Publishers, New Delhi).
3 Chaurasia, B.D., Human Osteology. (CBS Publisher and Distributors, New Delhi).
4 Goyal, R.K., Patel, N.M. and Shah, S.A., Practical Anatomy, Physiology and Biochemistry. (B. S. Shah Prakashan, Ahmedabad).
5 Ranade, V.G., Joshi, P.N. and Pradhan, S., Textbook of Practical Physiology. (Pune Vidyarthi Griha Prakashan, Pune).
6 Singh, I., BD Chaurasia's Human Anatomy. (CBS Publisher and Distributors, New Delhi).
7 Singh, I., Textbook of Human Osteology.(Jaypee Brothers Medical Publishers, New Delhi).

1.1.5 PHARMACEUTICAL ENGINEERING – I

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To provide general understanding of pharmaceutical unit operations

2 To provide information on selection and functioning of equipments used in pharmaceutical industry.

3 To apprise the students about industrial safety and hazards.

Course Outcomes :

At the end of the course students shall be able to

1 Understand the process of manufacturing of pharmaceuticals

2 Select appropriate equipments for manufacturing of pharmaceuticals

3 Understand importance of industrial safety

Unit- 1

1 Size Reduction :

Significance, Theory, mechanism and energy requirement of size reduction, Equipment: hammer, tumbling, fluid energy, roller, end and edge runner and cutter mill, Cryogenic Screw Feed Conveyor. Open and closed circuit milling. **07 h**

2 Size Separation :

Significance, Sieves, sieve bend, effectiveness of screens, and factors affecting screening. **03 h**

Unit-2

3 Extraction :

Theory of solid-liquid and liquid – liquid extraction, application of triangular diagrams. Extractors. **04 h**

4 Flow of fluids :

Fluid statics: Pressure, manometers and pressure gauge. Fluid dynamics: Mechanism of fluid flow, measurement of fluid flow, fluid flow through pipe, energy losses in fluid flow, fluid past immersed body, fluid flow through packed beds. **07 h**

Unit-3

5 Integrated automated production lines :

Automated Process Control Systems: Process variables, temperature, pressure and vacuum, their measurements **03 h**

6 Mixing :

Significance, Liquid mixing : Mechanisms, mechanically agitated vessel, jet, high shear and pipe mixers, power requirement, deaeration and defoaming of mixtures. Mixing equipment for mixing of solids with liquid Z-blade, planetary, high speed

mixers. Mixing of solids: mechanisms, degree of mixing, rate of mixing, tumbler and ribbon mixer. **08 h**

Unit-4

7 Filtration :

Significance, Mechanisms, types of filtration, clarification, filter media, theory of filtration, filter aids, filter press, rotary drum, leaf and membrane filters. Centrifugal filtration, Ultrafiltration, reverse osmosis, and Air filtration, bag filters, electrostatic precipitators, wet scrubbers and principle and design of HEPA filter. **07 h**

8 Industrial Hazards and Safety Precautions :

Mechanical, Chemical, Electrical, fire and dust hazards. **03 h**

Recommended Books :

1 W. McCabe, J.C. Smith, P. Harriot; Unit operations of chemical engineering ; (McGraw Hill).

2 W.L.Badger and J.T. Banchero, Introduction to chemical engineering, (McGraw Hill

3 M.S. Peters, K.D. Timmerhaus; Plant design and economics for chemical engineers; (McGraw Hill).

4 E. Ganderton; Pharmaceutical Unit Operations

5 Perry's Handbook of Chemical Engineering; (Mc-Graw Hill).

6 A. R. Paradkar, Pharmaceutical Engineering, (Nirali Prakashan).

7 Atmaram Pawar, Pharmaceutics II, (Nirali Prakashan).

1.1.6 PHARMACEUTICAL STATISTICS

(Theory) (3Hrs/Week) (42 lectures)

Course Objectives :

1 To familiarize with experimental designs.

2 To analyze data statistically.

3 To present data graphically and interpret the results.

4 To develop independent thinking ability in students through problem solving approach.

Course Outcomes :

At the end of the course students shall be able to

1 Apply appropriate study design for given data.

2 Plot graphs of given data and interpret the results.

Unit- 1

Collection and organization of Data :

Statistical data, Types of variables, Primary and secondary data, Tabulation of data, Measures of central tendency, Computation of A. Mean, Mode, Median. Measures of Dispersion, Computation of Variance, Standard Deviation and coefficient of variation, Graphical representation of data, Histogram, Ogives ,Frequency Polygon and Pie chart, Mean error, Accuracy and Precision. **11h**

Unit-2

Probability and Bi-variate data :

Concepts of probability and Standard probability distribution. Binomial, Poisson and Normal distribution, Computation of Probability using these distributions. Bi-variate data, Linear correlation, regression and their significance, Scatter diagram, Karl Pearson's correlation coefficient, Spearman's rank correlation coefficient, Regression Equations, Principle of Least Square. **10h**

Unit-3

Sampling Theory :

Population and sample, Random selection, sampling methods Hypothesis, Level of significance, Critical area, Type I/II errors, Factors to determine sample size, Experimental designs, Completely randomized, Randomized block, Latin Square Designs, Parallel and Cross over designs, Introduction to Statistical Quality Control. Small sample test

a) Based on T distribution

b) Based on F distribution

c) Based on chi-square distribution **10h**

Unit-4

Tests of Significance :

Significance of Means, Significance of Proportions, Chi Square tests for Goodness of Fit and Independence of Attributes. Introduction to Sign and Rank Tests (Non-parametric tests), Analysis of variance (ANOVA) **11h**

Recommended Books :

1 Bolten S. Pharmaceutical Statistics: Practical and Clinical Applications. (Marcel Dekker), ISBN: 0824772180

2 Shah Y. I., Paradkar A. R., Dhaygude M. G. Biostatistics and Computer Sciences. (Nirali Prakashan). Second Edition

3 Cox D. R., Donnelly C. A. Principles of Applied Statistics. (Cambridge University Press), ISBN: 9781107644458

4 Rao A. B. Business Statistics. (Himalaya Publishing House).

5 Pagano. Principles of Biostatistics. (Cengage Learning); 02 edition , ISBN- 978-8131502112

1.1.7 COMPUTER APPLICATIONS

(Practical) (3 Hrs/Week)

Course Objectives :

1 To make student well verse with the basic components of computer.

2 To perform fundamental operating system functions

3 To familiarize students with the use of Internet and electronic communication system.

4 To manipulate, present, analyze and retrieve data using computer.

Course Outcomes :

At the end of the course students shall be able to

1 Gain expertise in use of internet and electronic communication system.

2 Present the available data in graphical or pictorial manner.

3 Analyze the data by use of software.

Student should understand following :

a. Information Technology: Software application, browsers, Word processors, Spreadsheets, database, management systems, presentation graphics, software suits.

b. System software: System software, operating systems, utilities, device drivers, language translators.

c. System Unit: System Unit, electronic data and instructions, system board, microprocessor, memory, system clock, bus lines, parts and cables.

d. Input and output : Input devices, output devices and combining input and output devices (storage devices)

e. Connectivity: Communication channels, communication devices, data transmission, networks and their architecture, network types.

Compulsory Practical Assignments :

a) To prepare multimedia presentation on any topic related to pharmacy.

b) To use statistics function in Microsoft Excel for calculation of various parameters (Minimum two examples)

c) To use graph function for data presentation (At least 3 types of graphs).

d) To retrieve data from medical databases and websites for various purposes

e) To design a database for patient information.

f) To design labels for pharmaceutical preparation.

Recommended Books :

1 Timothy J. O'Leary & Linda J.o' Leary, Computing Essentials.

2 Stanford Bolton Marcel Dekker Publication, "Pharmaceutical Biostatistics" .

3 Andrew S. Robson, Pharmaceutical & Medicines Information Management Principles and Practice, (Elsevier Health Sciences).

SEMESTER- II

PHARMACEUTICAL CHEMISTRY-III (INORGANIC)

(Theory) (3 Hrs/week) (42 lectures)

Course Objectives :

1 To study the principles of inorganic chemistry with reference to inorganic pharmaceuticals

2 To elucidate importance of impurities in pharmaceuticals and acquire skills to detect and control them by official standards

3 To demonstrate significance of contents of monographs of important inorganic pharmaceuticals with reference to treatment of diseases

Course Outcomes :

At the end of the course students shall be able to

1 Understand the relevance and significance of inorganic chemistry with reference to pharmaceutical sciences

2 Develop competency for official standard methods to detect and control impurities

3 Acquire knowledge of complete profiles of important inorganic pharmaceuticals

Unit-1

For all official compounds it is expected to study physicochemical properties, assays, uses and storage conditions

1 Topical agents:

General introduction, classification and mechanism of action **02 h**

a) Protectives: Introduction, mode of action and uses.
Talc, Zinc Oxide, Titanium dioxide **03 h**

b) Antimicrobial agents: Introduction, classification and mode of action.
Hydrogen peroxide, Povidone-iodine, Tincture iodine and Potassium permanganate **04 h**

c) Astringents: Introduction and mode of action.
Boric acid, Alum **02 h**

Unit-2

2 Pharmaceutical aids :

General introduction, acid-base theories, buffers: theory, mechanism and pharmaceutical buffer systems, antioxidants **04 h**

3 Water :

Water as a universal pharmaceutical vehicle. Hardness of water, methods to remove hardness of water, different official waters and official control tests for water **06 h**

Unit-3

4 Expectorants, emetics and antidotes :

General introduction, classification and mechanism of action. Ammonium chloride, Copper sulphate, Sodium nitrite and Sodium thiosulphate. **08 h**

5 Dental Products :

General introduction, classification, dentrifices and mechanism of action. Sodium fluoride, Sodium monofluoro phosphate, Dibasic calcium phosphate, Zinc chloride **04 h**

Unit-4

6 Inhahalnts and respiratory stimulants :

Definition, official gases-properties and uses of O_2, CO_2, N_2, N_2O, He, Ammonia and their compounds. **05 h**

7 Inorganic radiopharmaceuticals :

Nuclear reaction, Radiation dosimetry, principle of measurement of radioactivity, therapeutic and diagnostic applications of radiopharmaceuticals and radio-opaque contrast media. Barium Sulphate **04 h**

Recommended Books :

1 J.H.Block, E.B. Roche, T.O. Soine,, C.O.Wilson: Inorganic, Medicinal and Pharmaceutical Chemistry (Verghese Puhblication)

2 C.A.Dicher: Modern Inorganic Pharmaceutical Chemistry

3 Bentley & Drivers text-book of Pharmaceutical Chemistry, 8th edition (ELBS London.)

4 Beckett and Stenlake Pratical Pharmaceutical Chemistry Vol. I (C.B.S.)

5 A. I. Vogel (Long man), Quantitative in organic analysis, 4th edition

6 Indian Pharmacopoeia

7 Remington's Pharmaceutical Sciences (Mack Publishing Co.)

8 G. R. Chatwal, Pharmaceutical Chemistry-Inorganic, (Himalaya Publishing House)

1.2.1 PHARMACEUTICAL CHEMISTRY-III (INORGANIC)

Practical (3 Hrs/Week)

Course Objectives :

1 To study monographs of important inorganic substances

2 To develop skills for performing official tests for purity and assays

3 To demonstrate principles of qualitative analysis of inorganic binary mixtures

Course Outcomes :

At the end of the course students shall be able to

1 Conceptualize significance of official standards for drug substances and pharmaceutical aids

2 Apply the skills of qualitative analysis to unknown samples

3 Develop mathematical approach to calculate quantitative parameters for synthesized compounds

4 Identify impurities from pharmaceutical substances

5 Compute and quantitate purity of inorganic pharmaceuticals

Experiments :

1. Preparation of Inorganic compounds (any Five)

i) Copper sulphate

ii) Boric acid

iii) Ammonium chloride

iv) Zinc oxide

v) Alum

vi) Barium sulpahte

vii) Dibasic calcium phosphate

viii) Magnesium sulphate

2. Assays of compounds from syllabus (any five)

3. Qualitative analysis of given samples (any four)

Recommended Books :

1 Indian Pharmacopoeia

2 Bentley & Drivers Text-Book of Pharmaceutical Chemistry, 8th Edition (Oxford University Press)

3 A.I. Vogel : Quantitative Inorganic Analysis - (Longman), 4th edition

4 Remington's Pharmaceutical Sciences (Mack Publishing CO.)

5 Cotton & Wilkinson, Advanced Inorganic Chemistry, 18th edition, (Willey Eastern Ltd, Delhi)

6 Beckett and Stenlake Vol. I (CBS Publishers & Distributors Delhi-32.)

7 G. R. Chatwal, Pharmaceutical Chemistry-Inorganic (Himalaya Publishing House)

8 K. R. Mahadik, Practical Hand book of Pharmaceutical Organic and Inorganic Chemistry (Nirali Publication)

1.2.2 PHARMACEUTICAL CHEMISTRY-IV (ORGANIC)

(Theory) (3 Hrs/week) (42 lectures)

Course Objectives :

1 To imbibe the foundation of organic chemistry.

2 To demonstrate logical approach to reaction mechanisms.

3 To ascertain knowledge of official nomenclature, properties, methods of preparation, reactions of various functional groups & their applications

Course Outcomes :

At the end of the course students shall be able to

1 Understand fundamentals of organic reactions and IUPAC nomenclature.

2 Elucidate reaction mechanisms through problem based approach.

Unit-1

1 Electrophilic addition to C-C multiple bonds :

a) Addition of hydrogens, halogens and hydroboration reaction.

b) Addition of hydrogen halide and orientation of addition, Markovnikov and Antimarkovnikov additions

c) Other addition reaction to olefins

i) Hydration ii) Hydroxylation

iii) Hydrogenation iv) Ozonolysis

v) Oxymercuration and deoxymercuration **10 h**

Unit-2

2 Nucleophilic addition to C=O

a) IUPAC nomenclature and methods of preparation of aldehydes and ketones.

b) Reactions of aldehydes and ketones, addition of water, alcohols, thiols, hydrogen cyanide, sodium bisulphite, derivatives of ammonia.

c) Nucleophilic additions, Aldol condensation, Knoevengel condensation, Dieckmann condensation, Reformatski reaction, Cannizaro reaction and Michael condensation. **12 h**

Unit-3

3 Elimination reactions

a) Elimination reaction

b) E1, E2 and E1 (cb) Mechanism

c) Orientation in E1 and E2 reactions (Saytzeff and Hofmann elimination)

d) Elimination versus substitution **05 h**

4 General chemistry :

IUPAC nomenclature, methods of preparation, reactions of amines and their applications. **05 h**

Unit-4

5 General chemistry :

IUPAC nomenclature, methods of preparation and reactions of

a) Phenols

b) Carboxylic acids and their applications **10 h**

Recommended Books :

1 Morrison and Boyd, Organic Chemistry, (Prentice Hall of India (P) Ltd.)

2 Pine, Organic Chemistry" (McGraw Hill, Interantional)

3 Jerry March, Advanced Organic Chemistry (Reaction Mechanism and Structure) (Willey Eastern Ltd.)

4 Sachin Kumar Ghosh, General Organic Chemistry (New Central Book Agency, Calcutta.)

5 T.W. Graham, Fundamental of Organic Chemistry (Wiley, International, New York.)

6 John McMeurrym, Organic Chemistry, Fifth Edn, (Asian Books Pv. Ltd)

PHARMACEUTICAL CHEMISTRY- IV (ORGANIC)

(Practical) (3 Hrs/Week)

Course Objectives :

1 To create awareness about safety measures and Good Laboratory Practices.

2 To develop skills for identification of unknown organic compounds and its application in synthetic chemistry

3 To train for basic laboratory techniques.

Course Outcomes :

At the end of the course students shall be able to

1 Imbibe the safety measures and inculcate Good Laboratory Practices.

2 Apply analytical tools for identification of organic compounds.

3 Master important laboratory techniques.

4 Record, compute and analyze the data.

Experiments :

1 To purify given organic compound by recrystalisation. (Two compounds)

2 Distillation (Demonstration experiment).

3 Qualitative analysis of binary mixtures (Minimum 12 mixtures)

a) Solid solid mixtures

b) Liquid solid mixtures

Recommended Books :

1 Longmann, A Text Book of Practical Organic Chemistry Vogel .

2 Orient Longmann , UK, Practical Organic Chemistry F. G. Mann and Sounders.

3 Gray D. Chrisston, Analytical Chemistry, (University of Washington) 4th Edition.

4 ShrinerHermann, Morril, Curtin and FusonThe Systematic Identification of Organic Coumpounds (8th Edition, Wiley).

1.2.3 PHARMACEUTICAL BIOCHEMISTRY - I

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To highlight and correlate chemistry of life process with different biomolecules and their simplicity to perform complex functions of living systems.

2 To demonstrate biochemical basis of interaction of drugs with biocatalysts & receptors.

3 To reinforce the topics in anatomy and physiology in understanding the subject.

Course Outcomes :

At the end of the course students shall be able to

1 Exemplify structure- function relationship of biomolecules from living system.

2 Conceptualize importance of metabolism and regulation of pathways with reference to homeostasis of key metabolites.

3 Understand the concepts of bio-separation techniques.

Unit-1

1. Introduction to biochemistry: Highlights of prokaryotic and eukaryotic cell metabolism. Scope of the subject in pharmaceutical sciences, biochemical morphology. **02 h**

2. Principle methods and techniques used in biochemistry. Impact of biochemical study on nutrition, preventive medicine and drug interactions. Methods of separation and purification of biomolecules. Precipitation techniques, chromatographic methods: gel filtration, ion-exchange and affinity–chromatography; Electrophoresis. **06 h**

Unit-2

Biomolecules :

Introduction to molecular organization of biological system and to study biomolecules.

3. Proteins :

Introduction, functional classification. Amino acids: Classification, Physicochemical properties, optical activity, reaction with ninhydrin, formaldehyde, R- group amino acids. Essential, non- essential amino acids, deficiency. Structure: Peptide bond, end group analysis. α– Helix, β – sheet structure. Tertiary, Quaternary structure, medicinally important amino acids, peptides and proteins. **05 h**

4. Carbohydrates :

Polysaccharides used in pharmaceuticals, complex carbohydrates, study of structure of starch, agarose, glycogen, pectin, inulin. Modified polysaccharides and their pharmaceutical applications. **04 h**

5. Lipids :

Definition, classification, functions, types of fatty acids and its biological role. **04 h**

Unit-3

6. Biomembrane :

Biochemistry of extracellular and intracellular communication structure and function,concept of artificial memebrane and liposome, fluid mosaic model of membrane.

Transport hypothesis: Active and passive, facilitated transport, Na^+, K^+, H^+ pumps. Glucose transport, excitable membrane, Ping –Pong mechanism, concept of co-transport. Ion channels: Voltage gated channels and aquaporines. Specialized membrane functions transmission of nerve impulse, endocytosis, exocytosis and iseases associated with membranes, mutation affecting membranes. **11 h**

Unit-4

7. Enzymes :

Introduction, Classifications, (according to the reaction of catalysis and sources) Structure of enzymes, Co- factor, active sites, Michaelis-Menten kinetics, Km, Vmax, Double reciprocal plot, effect of active substrates, pH, ionic strength, temperature on rate of enzymes catalyzed reactions. Enzyme specificity, measuring enzyme activity, isoenzymes and allosteric enzymes.

Enzyme inhibition. (Competitive, Non- competitive, irreversible inhibitions, allosteric inhibition, feedback inhibition), Concept of antimetabolites. Manufacturing of medicinal compounds by enzymatic reactions, Penicillin-acylase for the production of 6-Aminopenicillanic acid (6-APA), Therapeutic uses of enzymes. **10 h**

Recommended Books :

1 Albert Lehninger, Principles of Biochemistry (CBS Publishers and distributors, Pvt Ltd. Delhi.)

2 R.K.Murray, D.K.Granner, P.A.Mayes, Harpers Biochemistry (Practical Hall international Inc.).

3 R.K.Murray, D A Bender, K M Botham, P J Kennelly, V W Rodwell, P A Weil, Harpers Illustrated Biochemistry (McGrawHill Publisher, Edition 28)

4 Handbook of Bioseparations. Edited by Satindir Ahuja, Academic Press (ISBN 0-12-045540-4)

5 Amit Kessel and nir Ben-Tal CRC press,Taylor and Francis Group, Introduction to Protein (structure,function, and motion) (A Chapman and Hall Book (ISBN 978-1-4398-1071-2)

6 International Seventh Edtion W.H. Freeman and Co. New York, Biochemistry Jeremy M. Berg, John L. Tymoczko,Lubert Stryer.

1.2.3 PHARMACEUTICAL BIOCHEMISTRY-I
(Practical) (3 Hours/Week)

Course Objectives :

1 To study properties of important biomolecules such as proteins, amino acids, vitamins.

2 To study various biochemical techniques such as precipitation, centrifugation, incubation, enzyme & colorimetric assays.

3 To estimate marker or indicator metabolites from blood and urine for diagnosis of diseases.

Course Outcomes :

At the end of the course students shall be able to

1 Develop skill for handling of laboratory instruments and biological samples.

2 Estimate biomolecules for diagnosis of diseases.

3 Inculcate the separation technique for biomolecules and their characterization.

4 Compute the data and record the observations.

Experiments :

1 Introduction to colorimeter.

2 Estimation of Vitamin-C

3 Estimation of amino acid by formal titration

4 Estimation of dextrose by hypoiodate method

5 Determination of acid value of oil

6 Separation of albumin and globulin from egg white

7 Amino acid identification by colour reactions (6 samples)

8 Separation of amino acid by paper chromatography

9 Isolation of protein

10 Characterization by electrophoresis (Proteins and Nucleic acids).

11 Colorimetric estimation of protein by Biuret method

12 Colorimetric estimation of amino acid

13 Use of computer technology to understand three dimensional structure of proteins, Study of protein structure from library of available protein structure

Recommended Books :

1 David T. Plummer, An Introduction to Practical Biochemistry (Tata Mc Graw Hill Publishing Company, Ltd., New Delhi).

2 Harold Varley, Practical Clinical biochemistry (CBS Publishers and distributors, Delhi)

3 Handbook of Bioseparations. Edited by Satindir Ahuja, Academic Press (ISBN0-12-045540-4)

4 Mary Lee, Basic Skills in Interpreting Laboratory Data. Fourth Edition , (American Society of Health- System).

1.2.4 PHARMACEUTICAL ENGINEERING II

(Theory) (3Hrs/Week) (42 lectures)

Course Objectives :

1 To provide general understanding of pharmaceutical unit operations

2 To provide information on selection and functioning of equipments used in pharmaceutical industry.

3 To apprise the students about pharmaceutical packaging materials.

Course Outcomes :

At the end of the course students shall be able to

1 Understand the process of manufacturing of pharmaceuticals

2 Select appropriate equipments for manufacturing of pharmaceuticals

3 Select appropriate pharmaceutical packaging.

Unit-1

1 Heat Transfer :

Significance, mechanisms, heat transfer between fluid and solid boundary, heat transfer to boiling liquids, and condensing vapors. Heat exchangers: types and applications, steam traps. **07 h**

2 Evaporation :

Significance, Theory, Evaporators: pan, tubular, wiped film and centrifugal rotary evaporators. Vapor recompression and scale formation. **03 h**

Unit-2

3 Distillation :

Significance, Vapor – liquid equilibrium, boiling point diagram, Distillation of miscible systems, equilibrium distillation, differential distillation, rectification, fractionating column, heat and material balance, factors influencing plate efficiency, molecular distillation, separation of azeotropes, distillation of immiscible system. **07 h**

4 Drying:

Significance, Mechanism, theory of drying. Factors affecting drying, equipment: tray dryers, fluidized bed dryer, spray dryer, freeze dryer, flash dryer, drum dryer, Infra red drying, radiofrequency drying, Moisture content: significance, measurement. **04 h**

Unit-3

4 Crystallization:

Significance, Crystal form, theories of supersaturation, nucleation, crystal growth, classification of crystallizers, tank Swenson Walker, vacuum, circulating magma, DTB and growth type crystallizer. Caking of crystals. **06 h**

5 Advances in Particle Engineering:

Principle, techniques and applications for various Techniques of Granulation: Extrusion, Pelletisation, Fluidized bed granulation, Roller compactor. Melt and Antisolvent crystallization, Spray drying and congealing, co-crystallization **05 h**

Unit-4

6 Materials for construction and packaging of pharmaceuticals:

Significance, protection from hazards, types of containers and closures, Materials of construction and their selection, drug container interactions. **04 h**

7 Dehumidification and Humidity Control:

Basic concepts and definition, wet bulb and adiabatic saturation temperatures, Hygrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidification, air conditioners **06 h**

Recommended Books :

1 W. McCabe, J.C. Smith, P. Harriot; Unit operations of chemical engineering(McGraw Hill).

2 W.L. Badger and J.T. Banchero, Introduction to Chemical engineering,(McGraw Hill).

3 M.S. Peters, K.D. Timmerhaus; Plant design and economics for chemical engineers; (McGraw Hill).

4 E. Ganderton; Pharmaceutical Unit Operating (Academic Press)

5 Perry's Handbook of Chemical Engineering (McGraw Hill).

6 A. R. Paradkar, Pharmaceutical Engineering, (Nirali Prakashan).

7 Atmaram Pawar, Introduction to Pharmaceutics, (Career Publication).

8 Atmaram Pawar, Pharmaceutics RAPIdex, Pharmaceutics II, (Nirali Prakashan).

1.2.4 PHARMACEUTICAL ENGINEERING-II

(Practical) (3 Hours/Week)

Course Objectives :

1 To provide understanding of pharmaceutical unit operations

2 To provide hands on experience on equipments used in pharmaceutical industry.

3 To make aware about pharmaceutical packaging materials.

Course Outcomes :

At the end of the course students shall be able to

1 Understand unit operations in manufacturing of pharmaceuticals

2 Select appropriate equipments for manufacturing of pharmaceuticals

3 Understand selection of appropriate pharmaceutical packaging material

Experiments :

1 Determination of average particle size of given sample of powder and construction of size distribution frequency plot.

2 Study the effect of various factors affecting filtration rate (2 experiments).

3 Study the effect of speed of revolution on sedimentation rate of suspension by centrifugation.

4 Determination of drying rate of given sample using hot air oven.

5 Study the technique of crystallization for the purification of impure substance.

6 Demonstration of basic technique by simple distillation.

7 Determination of mixing efficiency of propeller blade when introduced in different positions.

8 Determination of density and specific gravity of given sample.

9 Demonstration of spray drying, extrusion-spheronisation of a given sample. (2 experiments)

10 Assignments on collection of containers and closures on basis of types of containers and packaging materials. (2 assignments)

11 To study mechanical strength of granules.

Recommended Books :

1 D M Sakarkar, Laboratory Manual for pharmaceutical engineering,(Nirali Prakashan

2 W.L.Badger and J.T. Banchero, Introduction to chemical engineering, (McGraw Hill

3 M.S. Peters, K.D. Timmerhaus; Plant design and economics for chemical engineers; (McGraw Hill).

4 E. Ganderton; Pharmaceutical Unit Operations.

5 Perry's Handbook of Chemical Engineering; (Mc-Graw Hill).

6 A. R. Paradkar, Pharmaceutical Engineering, (Nirali Prakashan).

7 Atmaram Pawar, Introduction to Pharmaceutics, (Career Publication).

1.2.5 COMMUNITY PHARMACY & HOSPITAL PHARMACY

(Theory) (3hrs/Week) (42 lectures)

Course Objectives :

1. To acquaint about community and hospital pharmacy practice
2. To provide patient education and counseling
3. To inculcate pharmaceutical ethics
4. To familiarize with drug inventory and distribution in hospital

Course Outcomes:

At the end of the course students shall be able to

1. Apply the knowledge in establishment of community and hospital pharmacy
2. Counsel the patients, respond to symptoms of minor ailments and provide health screening services.
3. Follow ethical practices in rational drug therapy
4. Apply knowledge in inventory and drug distribution in hospital setup

Unit-1

1. Community Pharmacy management :

a. Concept of Good Pharmacy Practice.
b. Selection of site, Space layout & design.
c. Staff, Materials- Coding & stocking
d. Legal requirements & code of ethics.
e. Maintenance of various registers.
f. Use of Computers: Business & Health care software. **6 h**

2. Health Education :

a. WHO Definition of health and health promotion (Yoga, exercise and diet). care for children, pregnant and breast feeding women and geriatric patients.
b. Overview, etiology and preventive measures for common communicable diseases - Tuberculosis, Hepatitis, Typhoid, Malaria and AIDS.
c. Family planning – Role of Pharmacist **6 h**

Unit-2

3. Health screening services :

Definition, importance, methods for screening of blood pressure/ blood sugar/ lung function and Cholesterol testing. **2 h**

4. OTC Medication :

Definition, OTC medication list and Counseling

Responding to symptoms of minor ailments Pain, GI disturbances (Nausea, vomiting, Dyspepsia, Diarrhea, Constipation), Pyrexia, Ophthalmic symptoms & worm infestations. Hazards of self medication **3 h**

5. Patient counseling :

Definition, Outcomes, various stages, barriers and role of Pharmacist **2 h**

6. Patient Medication Adherence :

Definition, Factors affecting medication adherence & role of Pharmacist in improving medication adherence. **2 h**

Unit-3

7. Hospital Pharmacy – Organization & Management :

Definition, Scope, Types of Hospitals, Space and Layout of Hospital Pharmacy. Pharmacy procedure manuals, Roles & responsibilities of Hospital Pharmacist. **3 h**

8. Hospital drug policy :

Pharmacy and Therapeutic committee (PTC), Hospital formulary, Infection control committee (Antibiotic policy) **3 h**

9. Purchase & Inventory Control :

Procurement & warehousing of drugs and pharmaceuticals, Inventory control: Definition, methods of inventory control, ABC (always better control), VED (vital, essential and desirable), EOQ (economic order quantity), Lead time, safety stock. **4 h**

Unit-4

10. Drug distribution in the hospital :

- Individual prescription method
- Floor stock method
- Unit dose drug distribution method
- Distribution of Narcotic and other controlled substances **4 h**

11. Central sterile supply Department (CSSD) :

- Location, Layout , Management & role of Pharmacist in CSSD **2 h**

12. Role of Pharmacists in Intravenous admixtures and nuclear pharmacy 2 h

13. Generic drugs and Introduction to Drug Price Control Order 1 h

14. Pharmaceutical Ethics 1 h

Recommended Books :

1. Ravikumar and Miglani, Pharmacy Practice, (Career Publications)
2. Parthsarathi, Nahata, Clinical Pharmacy Practice, (Orient Longman)
3. Atmaram Pawar, Handbook for Community Pharmacists, (Career Publications)
4. Tipnis and Bajaj Clinical Pharmacy, (Career Publications)
5. W.E. Hassan; Hospital Pharmacy; (Lee and Febiger).
6. Atwood and Florence; Hospital Pharmacy (Blackwell Scientific Publication)
7. Merchant and Qadry; Hospital Pharmacy (B.S. Shah Prakashan Ahmedabad)

1.2.5 COMMUNITY PHARMACY & HOSPITAL PHARMACY (PRACTICAL) (3 Hrs./Week)

Course Objectives :

1. To acquaint about common ailment
2. To familiarize hospital organization, layout and functioning
3. To impart skills of primary health screening services

Course Outcomes :

At the end of the course students shall be able to

1. Respond professionally in treatment of common ailments
2. Apply inventory techniques in hospital set up
3. Practice health screening services

Experiments :

1. Evaluation of 2 prescriptions per student: Legal aspects, elegancy and medication errors. (2 Practicals)
2. Preparation of Patient information leaflet, pictograms and other patient counseling aids for marketed OTC medications – emphasis should be given on common ailments like Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, Diarrhea, Constipation), Pyrexia, Ophthalmic symptoms & Worm infestations. (6 Practicals)
3. List of sound alike and look alike (SALA) medicines with its precautions and safety.
4. Inventory control: Practicing different inventory control methods. (2 Practicals)
5. Practical knowledge on devices for measuring (3 Practicals)

Blood Pressure, Blood Glucose, Cholesterol, Asthma and chronic obstructive pulmonary disease (COPD) (Inhalers- MDI)

6. Report on hospital visit – Inventory and drug distribution in hospital

7 Assignment :

Health Promotion: (PPT) Counseling aids, process activity for cessation of tobacco, smoking, alcohol, etc.

Recommended books :

1. Ravikumar and Miglani, Pharmacy Practice, (Career Publications)
2. Parthsarathi, Nahata, Clinical Pharmacy Practice, (Orient Longman)
3. Atmaram Pawar, Handbook for Community Pharmacists, (Career Publications)
4. Tipnis and Bajaj Clinical Pharmacy, (Career Publications)
5. W.E. Hassan; Hospital Pharmacy (Lee and Febiger)
6. Atwood and Florence; Hospital Pharmacy (Blackwell Scientific Publication)
7. Merchant and Qadry; Hospital Pharmacy (B.S. Shah Prakashan Ahmedabad)

1.2.6 HUMAN ANATOMY AND PHYSIOLOGY-II

(Theory) (3hrs/Week) (42 lectures)

Course Objectives-

1 To introduce scientific terminologies with respect to human body.

2 To convey structural organization and functions of human body.

3 To exemplify the mechanisms of synchronous working of organs.

4 To impart knowledge of the physiological basis of disorders in human body.

Course Outcomes :

At the end of the course students shall be able to

1 Understand the terminologies related to human anatomy and physiology.

2 Identify and describe the structure and functions of various systems of the human body.

3 Realize synchronous working of various organs.

4 Appreciate the concept of imbalance of homeostasis with respect to diseases.

Unit-1

1 Urinary system :

Anatomy and physiology of parts of urinary system, structure of nephron, formation of urine, Renin-angiotensin system, Balance (acid base, electrolyte and water), renal clearance tests and physiology of micturition, disorders of urinary system (definitions only) **06 h**

2 Muscular system :

Characteristics and functions of skeletal muscle, neuromuscular junction, physiology of skeletal muscle contraction, disorders of muscular system (definitions only) **04 h**

Unit-2

3 Endocrine system :

Anatomy and physiological role of hormones of pituitary gland, adrenal gland, thyroid gland, parathyroid gland, pancreas, gonads (testis and ovary), disorders of endocrine system (definitions only) **06 h**

4 Sense organs :

Anatomy and physiology of ear and eye, disorders of eye and ear (definitions only) **04 h**

5 Integumentary system:

Structure and functions of skin, thermoregulation **03 h**

Unit-3

6 Central Nervous system :

Classification of nervous system, Anatomy and physiology of parts of brain (cerebellum, pons, medulla oblongata, thalamus, hypothalamus, and functional areas of cerebrum), extra pyramidal system, limbic system, Spinal cord (Structure and reflexes), cranial nerves (Names and functions) **07 h**

7 Peripheral nervous system (sympathetic and parasympathetic) :

Fundamentals of neurotransmitters, Anatomy, physiology and divisions of ANS. Motor and sensory pathways ,Somatic nervous system. **03 h**

Unit-4

8 Reproductive system :

Anatomy and physiology of male and female reproductive systems, physiology of menstruation, spermatogenesis and oogenesis, disorders of reproductive system (definitions only) **06 h**

9 Sports physiology :

Muscles in exercise, respiration in exercise, CVS in exercise, body heat in exercise, body fluid and salts in exercise **03 h**

Recommended Books :

1 Chatterjee, C.C., Human Physiology. (Medical Allied Agency, Kolkata).

2 Chaudhari S K. Concise Medical Physiology. (New Central Book Agency (P) Ltd., Calcutta).

3 Ganong, W.F., 2005. Review of Medical Physiology. (Prentice-Hall International, London)

4 Guyton, A.C., Textbook of Medical Physiology. (W. B. Saunders Co., Philadelphia, USA).

5 Jain, A.K., Textbook of Physiology. (Avichal Publishing Co., New Delhi).

6 Singh, I., BD Chaurasia's Human Anatomy. (CBS Publisher and Distributors, New Delhi).

7 Tortora, G.J. and Grabowski, S.R., 2005. Principals of Anatomy and Physiology. (Harper Collins College Publishers, New York).

8 Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. (McGraw-Hill Publishing Co., USA).

9 Wagh, A. and Grant, A., Ross and Wilson's Anatomy and Physiology in Health and Illness. (Churchill-Livingstone, London).

10 West, J.B., Best and Taylor's Physiological Basis of Medical Practice. (Williams and Wilkins, Baltimore, USA).

11 Worwick, R. and Williams, P., Gray's Anatomy. (Longman, London).

1.2.6 HUMAN ANATOMY AND PHYSIOLOGY-II

(Practical) (3 Hrs./Week)

Course Objectives :

1 To develop skills for determining hematological parameters.

2 To acquaint with the internal structure of various organs

3 To learn common techniques of assessing respiratory functions.

Course Outcomes :

At the end of the course students shall be able to

1 Examine blood samples for hematological parameters and correlate with clinical conditions.

2 Acquaint with the histology of various tissue sections.

3 Gain expertise in measurement of respiratory functions.

Experiments :

1 Determination of Total WBC count of blood

2 Determination of Differential WBC count of blood

3 Determination of Bleeding time

4 Determination of Clotting time

5 Recording of ECG of healthy volunteer

6 Determination of respiratory volumes

Study of following systems with the help of models and charts

a. Urinary system

b. Endocrine system

c. Reproductive system

d. Nervous system

e. Sense organs (Eye, Ear, Skin)

7 Histology- Study of permanent slides of organs and tissues

8 Study of different family planning devices

Recommended Books :

1 Chaudhari, A.R., Textbook of Practical Physiology. (Paras Publishers, New Delhi).

2 Chaudhari, A.R., Viva in Physiology. (Paras Publishers, New Delhi).

3 DiFiore-Mariano, S.H., Atlas of Human Histology. (Lea and Fabiger, Philadelphia).

4 Garg, K., Bahel, I. and Kaul, M., A Textbook of Hiostology. (CBS Publishers and Distributors, New Delhi).

5 Ranade, V.G., Joshi, P.N. and Pradhan, S., Textbook of Practical Physiology. (Pune Vidyarthi Griha Prakashan, Pune).

6 Singh, I., BD Chaurasia's Human Anatomy. (CBS Publisher and Distributors, New Delhi).

7 Goyal, R.K., Patel, N.M. and Shah, S.A., Practical Anatomy, Physiology and Biochemistry (B. S. Shah Prakashan, Ahmedabad).

8 Singh, I., Textbook of Human Histology. (Jaypee brothers Medcial Publishers, New Delhi)

SEMESTER III

PHARMACEUTICAL CHEMISTRY-V (ORGANIC)

(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1 To imbibe the foundation of organic chemistry.

2 To demonstrate logical approach to reaction mechanisms.

3 To integrate principles of stereochemistry with chiral drugs to create awareness of stereochemical purity.

Course Outcome :

At the end of the course students shall be able to

1 Understand the fundamentals of various organic reactions.

2 Understand the mechanism of different types of reactions.

3 Understand the significance of stereochemistry in biological action and knowledge of chiral drugs.

Unit-1

1 Stereochemistry :

Optical activity and chirality, symmetry, asymmetry and dissymmetry, configuration of optical isomers, Diastereomerism. Resolution of Recemic modifications. Geometrical isomerism, E & Z nomenclature, determination of configuration of geometric isomers. Fisher projections, Relative and absolute (R & S nomenclatures). Conformational isomerism, Newman and Sawhorse Projections. Conformational isomerism in ethane and n-butane, conformations of cyclohexane, monoalkyl and dialkyl cyclohexanes.

Significance of stereochemistry in biological action. **10 h**

Unit-2

2 Free radicals :

Introduction to free radicals, types and preparation of free radicals, stable free radicals, radical ions, radical coupling reactions, substitution at saturated carbons, addition to olefins, and aromatic substitution. Quenching of free radicals. **06 h**

3 Name reactions :

Mechanism, orientation and stereochemistry of: Mannich reactions, Malonic ester synthesis, Perkin reaction, Schmidt's reaction, Gabriel Synthesis, Gattermann Synthesis, Kolbe Synthesis, Chichibabin reaction, Reimer–Tiemann reaction. **05 h**

Unit-3

4 Molecular rearrangement reactions :

Rearrangement of electron deficient systems, migration to carbon, oxygen, and nitrogen. Mechanism, orientation and stereochemistry of Bayer-Villiger and Dakin oxidations, Wagner, Merewin rearrangements, Wolf and related rearrangements, Pinacol- pinacolone rearrangement. Beckman, Curtius, Lossen, Hofmann and Schmidt rearrangements. **11 h**

Unit-4

5 Molecular rearrangement reactions :

Rearrangements of electron rich system including mechanism, kinetics, orientations and stereochemistry of Wittig, Sommelet, Favorskii, Neber and Benzilic acid rearrangements. Migration to double and triple bonds. Cope rearrangement to aromatic nucleus including mechanism of Fries and Claisen rearrangements. **10 h**

Recommended Books :

1 E.L. Eliet, Stereochemistry of Carbon Compounds (Tata McGraw Hill Publishing Co. Ltd., New Delhi).

2 Nasipuri, Stereochemistry (Wiley Eastern Ltd.,) 1st Edition.

3 J. March, Mechanism and Structures in Organic Chemistry, (Wiley) Eastern Edition) 2nd Edition.

4 J. March, Advanced Organic Chemistry, J. March, (Wiley) Eastern Edition) 2nd Edition.

5 Norman, Principles of Organic Chemistry (Chapman & Hall).

6 Morrison Boyd, Organic Chemistry (Prentice Hall of India (P) Ltd., New Delhi.

7 Joule and Smith, Heterocyclic Chemistry (E.L.B.S., London).

8 Fieser and Fieser, Organic Chemistry, (Asia Publishing House).

9. Jie Jack Li, Name Reactions, (Springar Publications).

2.1.1 PHARMACEUTICAL CHEMISTRY (ORGANIC) - V (Practical) (3 Hrs/Week)

Course Objectives :

1 To train for basic synthetic techniques.

2 To develop skills for analysis of fats, oils and functional groups.

Course Outcomes :

At the end of the course students shall be able to

1 Utilise chemical properties of organic compounds for their synthesis.

2 Master important synthetic techniques and safety measures in handling of chemicals.

3 Apply analytical tools to check purity of organic compounds.

4 Record, compute and analyse the data.

Experiments :

1 Analysis of fats and oils

a) Saponification value

b) Acid value

c) Peroxide value

d) Iodine value

2 Synthesis of ten organic compounds

Recommended Books :

1 A.I. Vogel, A Text Book of Practical Organic Chemistry, 4th Edition.

2 H. T. Cloke, Hand Book of Organic Analysis (Qualitative & Quantitative), (Arnold- Heinemann).

2.1.2 PHARMACEUTICAL BIOCHEMISTRY-II

(Theory) (3 Hrs/Week) (42 lectures)

Course objective :

1 To demonstrate biochemical basis of interaction of drugs with biocatalysts & receptors.

2 To create knowledge base for molecular genetics, nutrition & role of diet in treatment of diseases.

3 To study principles of bioassays for application to toxicity studies & diagnosis of genetic disorders.

4 To reinforce the topics in anatomy and physiology in understanding the subject.

Course outcome :

At the end of course the student shall be able to

1 Exemplify structure- function relationship of biomolecules from living system.

2 Conceptualize importance of metabolism and regulation of pathways with reference to homeostasis of key metabolites.

3 Understand the process of diagnosis of diseases.

4 Understand the flow of genetic information, manipulation of gene to treat diseases.

Unit-1

01 Bioenergetics :

Biological oxidation concept of free energy, standard free energy, high energy compounds, ATP, phosphorylation. **4 h**

02 Carborhydrate metabolism :

Anaerobic pathways of glucose metabolism, two phases of glycolysis. Alcohol fermentation, gluconeogenesis, citric acid cycle, electron transport chain, oxidative phosphorylation. Metabolism of glycogen, pentose phosphate pathways: Significance and role in RBC, homeostasis of blood sugar. Diseases of carbohydrate metabolism: diabetes mellitus, lactose intolerance, fructose intolerance, glycogen storage disease. **6 h**

Unit-2

03 Lipid metabolism :

Oxidation of fatty acids, formation of ketone bodies, biosynthesis of fattyacids and cholesterol, lipid transport and storage, HDLP, LDLP, clinical significance. **3 h**

04 Protein metabolism :

Protein metabolism: Importance of protein in diet. Digestion of proteins, oxidative degradation of amino acids, Transamination, urea formation. Genetic disorders of amino acid metabolism. Physiologically important substances from amino acids histamine, serotonine, dopamine. **4 h**

05 Nutrition :

Digestion and absorption, Energy balance, over and under nutrition,energy requirement, basal metabolic rate (BMR), Kwashiorker and Marasmus, free radicals and antioxidants. Recommended dietary allowances (RDA), Concept of neutraceuticals. **2 h**

06 Vitamins :

Structure and biochemical functions of fat soluble and water soluble vitamins deficiency manifestations. **2 h**

Unit-3

07 Nucleic acids :

Chemical composition of genetic material: nucleosides, nucleotides, structure, biochemical functions, replication, flow of genetic information, transcription, translation, genetic code, gene expression, disorder, recombinant DNA. Mutation molecular basis, point, frame shift mutations. **8 h**

08 Mineral metabolism :

Fluid balance, electrolyte balance, acid base balance, biochemical role of Sodium, Potassium, Chloride, Calcium, Phosphorus, Iron, Magnesium, Zinc, Iodine. **3 h**

Unit-4

09 Clinical biochemistry :

Liver functions tests, Kidney function tests, Immmunochemical methods of diagnosis ELISA and diagnostic PCR. **10 h**

Recommended Books :

01 Albert Lehninger, Principles of Biochemistry (CBS Publishers and distributors, Pvt. Ltd. Delhi).

02 Jeremy M. Berg, John L. Tymoczko,Lubert Stryer, Biochemistry, (International Seventh Edition W.H. Freeman and Co. New York)

03 R.K. Murray, D.K. Granner, P. A. Mayes, Harpers Biochemistry (Practical Hall international Inc.)

04 J.D. Watson, Molecular Biology (The Benjamin/Cummings Company Inc.)

05 Handbook of Bioseparations, Edited by Satindir Ahuja, Academic Press (ISBN 0-12-045540-4)

06 Mary Lee, Basic Skills in Interpreting Laboratory Data. Fourth Edition , (American Society of Health- system)

07 Amit Kessel and Nir Ben-Tal, Introduction to Protein (structure,function, and motion) CRC press, Taylor and Francis Group, A Chapman and Hall Book (ISBN 978-1-4398-1071-2).

08 Handbook of Pharmaceutical Biotechnology, Edited by Shayne Cox Gad Wiley – Interscience, (A John Wiley and Sons Inc. Publication)

09 Robert K. Murray,David A. Bender, Kathleen M. Botham,Peter J Kennelly, Victor W. Rodwell,p.Anthony Weil, Harpers's Illustrated Biochemiatry 28th Edtition, (Publised by Mc Graw Hill ISBN 978-0-07-163827-2:MHID 0-07-163827-X)

10 Harold Varley, Practical Clinical Biochemistry (Published by CBC , ISBN 81-239-0969-1)

2.1.2 PHARMACEUTICAL BIOCHEMISTRY – II (Practical) (3 Hrs/Week)

Course objective :

01 To study properties of important biomolecules such as proteins, aminoacids, vitamins.

02 To study various biochemical techniques such as precipitation, centrifugation, incubation, enzyme & colorimetric assays.

03 Estimations of marker or indicator metabolites form blood and urine to diagnose diseases.

Course outcome :

At the end of course the student shall be able to

01 Develop skill for handling of laboratory instruments and biological samples.

02 Estimate biomolecules for diagnosis of diseases.

03 Inculcate the separation technique for biomolecules and their characterization.

04 Record, compute and analyze the data.

Experiments :

01 Estimation of serum protein

02 Estimation of serum alkaline phosphotase.

03 Estimation of serum acid phosphotase

04 Estimation of titrable acidity and ammonia from urine

05 Estimation of bound and free acidity from gastric juice.

06 Estimation of serum uric acid .

07 Estimation of blood sugar.

08 Estimation of blood urea.

09 Estimation of serum creatinine .

10 Estimation of serum bilirubin

11 Urine analysis, normal and abnormal constituents of urine

12 Estimation of serum cholesterol.

13 Estimation of albumin to globulin ratio of serum

14 Estimation of salisylate from serum

Recommended Books :

1 Handbook of Bioseparations.Edited by Satindir Ahuja, Academic Press (ISBN 0-12-045540-4)

2 Mary Lee, Basic Skills in Interpreting Laboratory Data. Fourth Edition , (American Society of Health- system)

3 David T. Plummer, An Introduction to Practical Biochemistry (Tata Mc Graw Hill Publishing Company, Ltd., New Delhi).

4 Harold Varley, Practical Clinical Biochemistry (CBS Publishers and distributors, Delhi)

5 Handbook of Pharmaceutical Biotechnology, Edited by Shayne Cox Gad,Wiley – Interscience (A John Wiley and Sons Inc. Publication).

6 Harold Varley, Practical Clinical Biochemistry, (Published by CBC ,ISBN 81-239-0969-1)

2.1.3 PHARMACEUTICAL ANALYSIS- I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To provide the foundation in analysis of a drug and to train graduates in the basic analytical techniques.
2. To elucidate importance of titrimetric methods for application in drug analysis.
3. To integrate physicochemical & electrochemical properties with analytical methods for drugs.
4. To reinforce the topics studied in inorganic & organic chemistry.

Course Outcome :

At the end of course the student shall be able to

1. Apply mathematical tools for data treatment and data handling
2. Correlate principles of titrimetric techniques to quantitative determination of pure drug and drug content in dosage forms.

Unit-1

1. Introduction to pharmaceutical analysis :

Review of fundamental aspects qualitative and quantitative analysis. Different techniques of analysis, fundamentals of volumetric analysis, methods of expressing concentrations, primary and secondary standards, expressions of analytical results, errors involved in pharmaceutical analysis, types of errors, minimization of errors. **06 h**

Unit- 2

2. Aqueous acid base titrations :

Definition of acid and base, Acid base equilibrium, law of mass action, Henderson-Hasselbalch equation, dissociation constants for acids and bases, hydrolysis of salts, buffer index, neutralization curves, theory of indicators, mixed indicators, universal indicators, preparation of standards and standardization of solutions, acid base titrations. Assay of Aspirin, Boric Acid, Ibuprofen, Indomethacin, Citric acid, Sodium bicarbonate. **09 h**

3. Non-aqueous acid base titration :

Theoretical consideration, limitations, types of solvents and their properties, levelling and differentiating effect, ionization and dissociation in non-aqueous solvents, determination of weak acid and base, indicators in non- aqueous titrations, preparation of standards and standardization of solutions, non-aqueous end point detection.

Determination of amides, imides, barbiturates: Application in assay of Norfloxacin, Sodium acetate, Diazepam, Atenolol, Metformin-HCl, Quinidine sulphate, Phenobarbital-Sodium, Phenytoin, Lignocaine, Acetanilide. **05 h**

Unit-3

4. Oxidation reduction titration :

Theory of redox reactions and titrations, measurement of redox potential, redox curve, redox indicators, titration involving potassium permanganate, iodine titrations (Iodometry and Iodimetry) and ceriometric titrations. Assay of Ferrous sulfate, Hydrogen peroxide, Ascorbic acid, Ferrous fumarate, Iron-Dextran, Povidone Iodine. **10 h**

Unit-4

5. Complexometric titration :

Theory of complex formation and stability of complexes, titration curves, metallochromic indicators, types of EDTA titrations, masking and demasking agents. Assay of Magnesium sulphate, Calcium gluconate, Zinc chloride, Aluminum hydroxide, Calcium lactate, Calcium lavulinate. **6 h**

6 Precipitation titrations :

Theory of precipitation reaction, factors affecting solubility of a precipitate, Solubility of sparingly soluble salts, solubility products, effect of pH, temperature and solvent on solubility of precipitate. Fractional precipitation, precipitation titration methods, titration curve, detection of end points, indicators used in precipitation titration. Argentometric titrations, Mohr's, Volhard's and Fajan's methods. Assay of Potassium Chloride, Sodium Chloride injection, Yellow mercuric oxide, Thiomersal. **6 h**

Recommended Books:

1. A.H. Beckett and J.B. staenlake, Practical Pharmaceutical Chemistry (Part-I & II) (University of London, Antholone Press).
2. K.A. Conners, A Textbook of Pharmaceutical Analysis, (John Wiley and Sons).
3. Gary D. Christen, Analytical Chemistry, (Wiley University of Washington).
4. A.I. Vogel, A Textbook of Quantitative Inorganic Analysis, (E.L.B.S.,London).
5. J.G.Dick, Analytical Chemsitry, (International Student Edition) .
6. H. N. More, K. R. Mahadik & A.V. Kasture, Principles of Pharmaceutical Analysis, Vol-I & II Nirali Prakashan, Pune.

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2.1.3 PHARMACEUTICAL ANALYSIS- I
(Practicals) (3 Hrs/Week)

Course Objectives :

1. To create awareness and significance of calibration in analytical chemistry & safety measures.
2. To develop practical hand in titrimetric analysis.
3. To nurture fundamental understanding of analytical instruments and train for their handling with problem solving approach.
4. To understand the importance of terms SOP/ Procedure and Protocol.

Course Outcome :

At the end of course the student shall be able to

1. Correlate physicochemical and electrochemical properties with analytical methods for drugs
2. Master important analytical techniques and inculcate precautionary measures in handling of chemicals and instruments.
3. Compute and analyze the purity of drug substances.

Experiments :

1. General introduction

Discussion –concepts of analytical reagents (AR, GR, LR etc) purity and strength requirements, calculations etc.

2. Calibration of volumetric apparatus :

Burettes, pipettes and volumetric flasks

3. Assays based on following techniques as per IP including preparation and standardization of titrants.

1. Acid base titrations :

a) Direct titrations of strong acids and bases (02)

b) Weak acids and weak bases (02)

c) Back titrations with blank determination (01)

2. Non aqueous titrations :

a) Back titration with blank determination (02)

3. Oxidation-reduction titrations :

a) Permanganate titrations (01)

b) Iodine titrations (02)

c) Ceriometric titrations (01)

4. Complexometric titrations :

a) EDTA titrations (02)

5. Precipitation titrations :

a) Direct titration (01)

b) Indirect titrations (01)

Recommended Books :

1. A.H. Beckett and J.B. Staenlake, Practical Pharmaceutical Chemistry (Part-I & Part-II) (University of London, Anthlone Press).
2. K. A. Conners, A Textbook of Pharmaceutical Analysis, (John Wiley and Sons)
3. Gary D. Christian Analytical Chemistry, (Wiley University of Washington 4th edition)
4. A.I. Vogel, A Textbook of Quantitative Inorganic Analysis, (E.L.B.S., London)
5. H. N. More, K. R. Mahadik & A.V. Kasture, Principles of Pharmaceutical Analysis, Vol-I & II Nirali Prakashan, Pune.

2.1.4 PHYSICAL PHARMACY –I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To brush-up students with the fundamental aspects of physics and chemistry.
2. To help students understand application of these fundamental aspects in pharmaceutical field.
3. To make students well verse with the fundamental processes which play a key role in formulation design.
4 To develop independent thinking ability in students through problem solving approach.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate utility of physicochemical properties in design of pharmaceutical product.
2. Gain insight of techniques for determination of physicochemical properties.
3. Understand factors governing stability of finished pharmaceutical product.
4. Analyze and tackle problems encountered in formulation development.

Unit-1

1. Intermolecular Forces and Gaseous state of matter :
Binding forces between molecules; Gaseous State: Deviation from gas theory, compressibility factor, van der Waal's equation for real gases, Law of corresponding states (only equation), critical constants and their determination, Liquefaction of gaseous and its application to pharmacy.
7 h

2. Phase Rule :
Gibbs phase rule and its derivation, reduced phase rule, one component (water), two component (phenol- water and eutectic mixtures) and three component system. **4 h**

Unit-2

3. Solutions of non-electrolytes :
Properties and types of solutions, ideal and real solutions, various concentration terms, Raoult's law and its deviations, colligative properties: elevation of boiling point, depression of freezing point and osmotic pressure. Problems on colligative properties. **6 h**

4. Solutions of electrolytes :
Equivalent and specific conductance, activity co-efficient, degree of dissociation, Arrhenius theory, Debye Hückel theory, colligative properties of electrolytes **4 h**

Unit-3

5. Solubility and Distribution Phenomena :

Solute-solvent interactions, solubility of gases in liquids, liquids in liquids and solids in liquids: solubility of slightly soluble electrolyte, solubility of weak electrolyte, influence of pH, solvents, solubility parameters and combined effect of pH and solvents. Distribution Phenomenon: Nernst distribution law and its limitations, effect of ionic dissociation and association, application in pharmacy. **11 h**

Unit-4

6. Chemical Kinetics :

Reaction theories, rate, order and molecularity, Mathematical treatment of zero, first and second order, determination of order, influence of temperature, Arrhenius equation and activation energy, Decomposition and stabilization of medicinal agents, accelerated stability studies. Problems based on zero, first and second order kinetics. **7 h**

7. Introduction to thermodynamics of pharmaceutical systems 3 h

Recommended Books:

1. Martin A. N. Physical Pharmacy and Pharmaceutical Sciences. (Lipincott Williams and Wilkins) 5th Ed. ISBN-13: 978-81-8+836-61-0.
2. Florence A. T., David A. Physicochemical Principles of Pharmacy. (Pharmaceutical Press), ISBN: 085369608X.
3. Glasstone S., Lewis D. Elements of Physical Chemistry. (Palgrave Macmillan), 2nd edition (December 1963) ISBN-13: 978-0333038437.
4. David A., Florence A. T. FASTtrack: Physical Pharmacy. (Pharmaceutical Press), 2nd edition, ISBN-13: 978-0853697251.
5. Bahl A., Bahl B. S., Tuli G. D. Essentials of Physical Chemistry. (S. Chand and Company Ltd.) ISBN:81-219-2978-4.
6. Indian Pharmacopoeia 2007, 2014
7. Findlay A. Practical Physical Chemistry. (BiblioLife), ISBN-13: 978-1113872036.
8. Halpem A., McBane G. Experimental Physical Chemistry: A Laboratory Text. (W. H. Freeman) 3rd Edition edition, ISBN-13: 978-0716717355.
9. More H. N., Hajare A. Practical Physical Pharmacy (Career Publications) , ISBN-13: 978-8188739462.
10. Hadkar U. B. A Hand Book of Practical Physical Pharmacy & Physical Pharmaceutics. (Nirali Prakashan), ISBN-13: 978-8185790329

2.1.4 PHYSICAL PHARMACY –I
(Practical) (3 Hrs/Weeks)

Course Objectives:

1. To help students understand the fundamental concepts of physical pharmacy and their implications towards design of pharmaceutical formulations.
2. To give students hands on experience on determination of various physical properties.
3. To develop independent thinking ability of students through problem solving approach.

Course Outcomes :

At the end of the course students shall be able to

1. Understand utility of physicochemical properties in design of stable pharmaceutical formulation.
2. Gain expertise in determination of physicochemical properties as part of preformulation.

Experiments :

1. Determination of molecular weight by Rast camphor method.
2. Two component system: Phenol-water and eutectic system.
3. Three component system: Ternary phase diagram.
4. Determination of solubility of benzoic acid in solvents having different dielectric constants.
5. Study the effect of pH on solubility of benzoic acid.
6. Determination of partition coefficient of iodine between carbon tetrachloride and water.
7. Determination of association number of benzoic acid for distribution between benzene and water.
8. Determination of order of hydrolysis of methyl acetate (first order reaction).
9. To find degree of hydrolysis of second order reaction where a = b.
10. Determination of order of reaction by half-life method.
11. Determination of energy of activation of acid hydrolysis of methyl acetate.
12. To determine the strength of two acids kinetically.
13. Assignment on calculation of rate constant, half life and shelf life of pharmaceuticals.

Recommended Books :

1. Martin A. N. Physical Pharmacy and Pharmaceutical Sciences. (Lipincott Williams and Wilkins) 5th Ed. ISBN-13: 978-81-8+836-61-0.
2. Hadkar U. B. A Hand Book of Practical Physical Pharmacy & Physical Pharmaceutics. (Nirali Prakashan), ISBN-13: 978-8185790329
3. More H. N., Hajare A. Practical Physical Pharmacy. (Career Publications), ISBN-13: 978-8188739462.
4. David A., Florence A. T. FASTtrack: Physical Pharmacy. (Pharmaceutical Press), 2nd edition, ISBN-13: 978-0853697251.
5. Bahl A., Bahl B. S., Tuli G. D. Essentials of Physical Chemistry. (S. Chand and Company Ltd). ISBN:81-219-2978-4.
6. Indian Pharmacopoeia 2007, 2014
7. Findlay A. Practical Physical Chemistry. (BiblioLife) , ISBN-13: 978-1113872036.
8. Halpem A., McBane G. Experimental Physical Chemistry: A Laboratory Text. (W. H. Freeman); 3rd Edition edition, ISBN-13: 978-0716717355.

2.1.5 PHARMACEUTICAL MICROBIOLOGY – I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To introduce scope and applications of microbiology in pharmaceuticals.
2. To impart knowledge about micro-organisms.
3. To apprise with sterilization and disinfection.

Course Outcomes :

At the end of the course students shall be able to

1. Integrate basic knowledge of microbiology with pharmaceutical sciences.
2. Understand microbiological techniques.
3. Comprehend aspects of sterilization and disinfection.

Unit-1

1. Introduction to Microbiology :
Scope and applications of pharmaceutical microbiology, Classification of micro-organisms, Historical developments - Contribution of Louis Pasteur, Robert Koch, Paul Ehrlich in microbiology, discovery of antibiotics.
5 h

2. Microscopic techniques :
Basic terms and concepts, classification of microscopes, principle, working and applications of compound microscope, fluorescence microscope, electron microscope and advanced research microscopes. **6 h**

Unit-2

3. Bacteria :
Size, shape, structure, cell wall, capsules, spores, flagella and other parts of bacteria. Growth characteristics, culture media requirements, measurements of bacterial growth, counting methods, colony characteristics, methods for isolation, identification and preservation of microbial cultures, various staining techniques. Characteristics of *Staphylococcus, Pseudomonas, Escherichia* and *Salmonella species.* **10 h**

Unit-3

4. Yeasts and moulds :
Introduction, classification, characteristics and applications of *Saccharomyces cerevisiae, Candida albicans, Penicillum* and *Aspergillus species.*

Rickettsia: Introduction and pathogenesis.

Actinomycetes: Isolation and significance.

Viruses: Introduction, general properties, structure, bacteriophage-lytic and lysogenic growth cycle, cultivation and multiplication of human viruses. **11 h**

Unit-4

5. Sterilization and Disinfection :

Classification and characteristics of various sterilization techniques, sterilization monitors, sterilization criteria viz. D-value, Z-value, etc. Testing of sterile pharmaceutical products as per I.P.

Classification and characteristics of disinfectants, factors affecting disinfectant action, selection of disinfectants, evaluation of disinfectants. **10 h**

Recommended Books :

1. Tortora GJ, Microbiology: An Introduction, (Benjamin-Cummings Publishing Company)
2. Kokare CR, Pharmaceutical Microbiology Experiments and Techniques, (Career Publications).
3. Kokare CR, Pharmaceutical Microbiology Principles and Applications, (Nirali Prakashan.)
4. Ananthanarayan R and Paniker CK, Textbook of Microbiology, (Orient Longman Limited Universities Press (India) Pvt. Ltd.)
5. Indian Pharmacopoeia 2014,
6. Hugo WB and Russel AD, Pharmaceutical Microbiology, (Blackwell Science Publishing).
7. Baird RM, Hodges NA and Denyer SP, Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices, CRC Press.
8. Pelczar MJ, Chan ECS and Krieg NR, Microbiology, (McGraw-Hill Inc. US.)
9. Cappuccino JG and Sherman N, Microbiology – A Laboratory Manual. Pearson Education. (Dorling Kindersley publisher (India) Pvt. Ltd.)
10. Dubey RC and Maheswari DK, Practical Microbiology, (S. Chand & Co., New Delhi.)

2.1.5 PHARMACEUTICAL MICROBIOLOGY –I (Practical) (3 Hrs/Week)

Course Objectives :

1. To make students know about good laboratory practices in pharmaceutical microbiology.
2. To enhance practical skills for isolation and characterization of micro-organisms.
3. To learn use of microscope, hot air oven and autoclave.

Course Outcomes :

At the end of the course students shall be able to

1. Apply the techniques in identification, isolation and cultivation of microorganisms.
2. Perform microbiological assessment of antimicrobials, disinfectants and preservatives along with sterility testing of pharmaceuticals.
3. Develop practical skills in industrial microbiology.

Experiments:

1. To study the principle and working of microscopes.
2. To study the principle and working of laminar air flow, autoclave, hot air oven, incubator and other laboratory equipments.
3. Preparation and sterilization of different culture media.
4. To study different inoculation techniques.
5. Isolation of pure culture by streak plate technique. 2 expt
6. Isolation of pure culture by pour plate technique.
7. To study bacterial motility.
8. Identification of bacteria by various staining techniques- 4 expt
9. To study cultivation and growth characteristics of fungi. 2 expt

Recommended Books :

1. Tortora GJ, Microbiology: An Introduction, (Benjamin-Cummings Publishing Company.)
2. Kokare CR, Pharmaceutical Microbiology Experiments and Techniques, (Career Publications.)
3. Kokare CR, Pharmaceutical Microbiology Principles and Applications, (Nirali Prakashan.)
4. Ananthanarayan R and Paniker CK, Textbook of Microbiology, (Orient Longman Limited Universities Press (India) Pvt. Ltd.)
5. Indian Pharmacopoeia 2014,
6. Hugo WB and Russel AD, Pharmaceutical Microbiology, (Blackwell Science Publishing.)
7. Baird RM, Hodges NA and Denyer SP, Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices, (CRC Press.)
8. Pelczar MJ, Chan ECS and Krieg NR, Microbiology, (McGraw-Hill Inc. US.)
9. Cappuccino JG and Sherman N, Microbiology – A Laboratory Manual. Pearson Education. (Dorling Kindersley publisher (India) Pvt. Ltd.)
10. Dubey RC and Maheswari DK, Practical Microbiology, (S. Chand & Co., New Delhi.)

2.1.6 PATHOPHYSIOLOGY
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To study etiopathogenesis of diseases of the vital systems.
2. To impart knowledge of the specific pathological conditions associated with disorders and correlate pathophysiology with clinical manifestations.
3. To understand the convergence of pathology with physiology.

Course Outcomes :

At the end of the course students shall be able to

1. Explain functional changes associated with disease or injury.
2. Explain the physiological processes, mechanisms of disease and correlate with their clinical course.
3. Identify the targets for the treatment of disease.

Unit-1

1. Cell injury and adaptation.
Basic Principles, Causes, pathogenesis and morphology of cell injury. **4 h**

2. Abnormalities in lipoproteinemia, glycogen infiltration and glycogen storage disease. **2 h**

3. Pathophysiology of allergy, hypersensitivity and autoimmune diseases. **4 h**

Unit-2

4. Pathophysiology of Malignancy :
Disturbances of growth of cells, general biology of tumors, etiology and pathogenesis of cancer, spread of cancer.(direct spread and metastasis) **7 h**

5. Cardiovascular system :
Pathophysiology of hypertension, ischemic heart diseases (angina & infarct), shock. **4 h**

Unit-3

6. Respiratory system :
Pathophysiology of bronchial asthma, pneumonia, tuberculosis. **3 h**

7. Digestive system :
Pathophysiology of Peptic ulcer, amoebic and bacillary dysentery, hepatitis, typhoid fever. **2 h**

8. Central nervous system :
Pathophysiology of epilepsy, Parkinsonism. **2 h**

9. Endocrine system :
Pathophysiology of diabetes mellitus **2 h**

Unit-4

10 Urinary system :
Pathophysiology of urinary tract infections, acute and chronic renal failure **3 h**

11 Infectious Diseases:
HIV, Swine Flu, Ebola **3 h**

12 Basic mechanisms of inflammation and repair:
Pathogenesis and mediators in inflammation. Chronic inflammation. Wound repair and healing. **6 h**

Recommended Books :

1. Bhende, YM, Deodhare, SG, Kelkar, SS, General Pathology (popular Prakashan)
2. Rubin, E, Farber, Essential Pathology J (Lippincott)
3. Robins Pathological basis of Diseases, Indian Edition (Prism)
4. Harsh Mohan. Text Book of Pathology. (Jaypee Publishing House)
5. Bodhankar SL and Vyavahare, NS, A Textbook of Pathophysiology (Pragati Prakashan, Pune)

SEMESTER IV

2.2.1 PHARMACEUTICAL CHEMISTRY-VI (ORGANIC)
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1 To imbibe the foundation of organic chemistry.

2 To demonstrate logical approach to reaction mechanisms.

3 To ascertain basic understanding of heterocyclic compounds and biomolecules.

Course Outcomes :

At the end of the course students shall be able to

1 Understand the fundamentals of various organic reactions.

2 Understand the mechanism of different types of reactions

3 Understand IUPAC nomenclature, physico- chemical properties, methods of preparation, reactions of heterocyclic compounds, and biomolecules such as carbohydrates and proteins.

Unit-1

1 Chemistry of carbohydrates :

Introduction, classification and chemistry of C5 and C6 sugars and cyclic structures / glycosides. Stereochemistry, mutarotation, specific rotation, structures of some common diasaccharides, oligosaccharides, polysaccharides. **11 h**

Unit-2

2 Chemistry of amino acids:

Introduction, classification, structure of natural amino acids, isoelectric point. Charcterisation and methods of preparation and reactions of amino acids. Peptide bonds, structures of some biologically important simple peptides, protein structure and classification. **10 h**

Unit-3

3 Chemistry of heterocyclic compounds :

Structure, nomenclature, numbering and corresponding drugs of the following heterocyclic compounds: furan, thiophene, pyrrole, pyrazole, thiazole, imidazole, oxazole, isoxazole, hydantoin, pyridine, pyridazine, pyrimidine, indole, benzofuran, benzothiazole, benzimidazole, benzoxazole, quinoline, isoquinoline, cinnoline, purine, xanthine, pteridine, coumarin.

Syntheses and reactions of following compounds: furan, thiophene, pyrrole, imidazole, thiazole, pyridine, quinoline and isoquinoline. **10 h**

Unit-4

4 Synthon approach in the synthesis :

Introduction to reterosynthesis. Rules of disconnections. Synthesis (Any five) of some heterocyclic compounds like: furan, thiophene, pyrrole, benzimidazole, benzoxazole, pyridine, pyridazine, pyrimidine, indoles, quinoline and isoquinoline. **5 h**

5 Lipids :

Classification and general chemistry of lipids, their physicochemical properties and methods of analysis. Fatty acids and their reactions. Brief introduction to waxes, phospholipids, triglycerides, lecithins, cephalins, plasmalogens, spingomyelins, glycolipids, lipoproteins, fat soluble vitamins, steroids, terpenes, prostaglandins. **6 h**

Recommended Books :

1 E.L. Eliet, Stereochemistry of Carbon Compounds (Tata McGraw Hill Publishing Co. Ltd., New Delhi).

2 Nasipuri, Stereochemistry (Wiley Eastern Ltd.,) 1st Edition.

3 J. March, Mechanism and Structures in Organic Chemistry, (Wiley) Eastern Edition) 2nd Edition.

4 J. March, Advanced Organic Chemistry, J. March, (Wiley) Eastern Edition) 2nd Edition.

5 Norman, Principles of Organic Chemistry (Chapman & Hall).

6 Morrison Boyd, Organic Chemistry (Prentice Hall of India (P) Ltd., New Delhi.

7 Joule and Smith, Heterocyclic Chemistry (E.L.B.S., London).

8 Fieser and Fieser, Organic Chemistry, (Asia Publishing House).

9. Jie Jack Li, Name Reactions, (Springar Publications).

2.2.1 PHARMACEUTICAL (ORGANIC) CHEMISTRY- VI (Practical) (3 Hrs/Week)

Course Objectives :

1 To train for basic synthetic techniques.

2 To develop analytical tools for fats, oils and functional groups.

Course Outcomes :

At the end of the course students shall be able to

1 Correlate characteristic properties of organic compounds with synthetic tools to synthesize organic compounds.

2 Master important synthetic techniques and safety measures in handling of chemicals.

3 Apply analytical tools to check purity of organic compounds.

Experiments :

1 Quantitative determination of reactive groups :

i. Hydroxyl

ii. Primary amines

iii. Secondary amines

iv. Esters

v. Amides

vi. Carbonyl

vii. Phenol

2 Syntheses of eight organic/ heterocyclic compounds

Recommended Books :

1 A.I. Vogel, A Text Book of Practical Organic Chemistry, 4th Edition.

2 H. T. Cloke, Hand Book of Organic Analysis (Qualitative & Quantitative), (Arnold- Heinemann).

2.2.2 PHARMACEUTICAL MICROBIOLOGY –II
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To introduce sterility tests and microbial assays.
2. To enhance the technical know-how about industrial microbiology.
3. To elucidate the concepts and applications of immunology.
4. To impart knowledge about probiotics and biological hazards.

Course Outcomes :

At the end of the course students shall be able to

1. Integrate basic knowledge of microbiology with pharmaceutical sciences.
2. Apply microbiological techniques.
3. Apply knowledge for promotion of health and social safety.

Unit-1

1. **Microbial Evaluation of Pharmaceutical Products :**
   Factors affecting microbial spoilage, sources and types of microbial contamination, microbial standards for non-sterile pharmaceuticals, assessment of microbial contamination, microbial limit tests, preservative efficacy test: Challenge test. **7 h**

2. **Microbial Assays :**
   Significance, MIC, assay of antibiotics and vitamins. **3 h**

Unit-2

3. **Industrial Microbiology :**
   Isolation, screening and strain improvement techniques, Fermentation media, Fermentor – types and designs, downstream processing, Biological waste treatment. **11 h**

Unit-3

4. **Biohazards :**
   Significance and safety measures. **2 h**

5. **Probiotics :**
   Properties, mechanism and significance. **2 h**

6. **Immunological Principles :**
   Various terminologies, types of immunity, host-specific and non-specific defense mechanisms, immune responses, adjuvants, antigens and antibodies, significance of monoclonal and polyclonal antibodies. **6 h**

Unit-4

7. Scope and Significance of Immunology :

Antigen-Antibody reactions: Introduction, classification, precipitation, agglutination, compliment fixation, neutralization reactions, Immuno-fluorescence, RIA and ELISA.

Hypersensitivity reactions: Introduction, types and significance.

Vaccines: Introduction, types, preparation and quality control of vaccines, BCG, TAB, DPT, Polio, MMR and Rabies vaccines. **11 h**

Recommended Books :

1. Tortora GJ, Microbiology: An Introduction, (Benjamin-Cummings Publishing Company).
2. Kokare CR, Pharmaceutical Microbiology Experiments and Techniques, (Career Publications) .
3. Kokare CR, Pharmaceutical Microbiology Principles and Applications, (Nirali Prakashan).
4. Ananthanarayan R and Paniker CK, Textbook of Microbiology, (Orient Longman Limited Universities Press (India) Pvt. Ltd.)
5. Indian Pharmacopoeia 2014,
6. Hugo WB and Russel AD, Pharmaceutical Microbiology, (Blackwell Science Publishing.)
7. Baird RM, Hodges NA and Denyer SP, Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices, (CRC Press).
8. Pelczar MJ, Chan ECS and Krieg NR, Microbiology, (McGraw-Hill Inc. US.)
9. Cappuccino JG and Sherman N, Microbiology – A Laboratory Manual. Pearson Education. (Dorling Kindersley publisher (India) Pvt. Ltd.)
10. Dubey RC and Maheswari DK, Practical Microbiology, (S. Chand & Co., New Delhi).
11. Waites MJ, Morgan NL, Rockey JS and Higton G, Industrial Microbiology: An Introduction, (Wiley-Blackwell Publishers.)

2.2.2 PHARMACEUTICAL MICROBIOLOGY –II (Practical) (3 Hrs/Week)

Course Objectives :

1. To make students learn various official sterility tests and microbial assays as per I.P.
2. To develop practical skills in isolation and inoculum development of commercially important microbial species.

Course Outcomes :

At the end of the course students shall be able to

1. Apply the techniques in identification, isolation, and cultivation of microorganisms.

2. Perform microbiological assessment of antimicrobials, disinfectants and preservatives and sterility testing of pharmaceuticals.
3. Develop practical skills in industrial microbiology.

Experiments :

1. Determination of microbial count of air by any suitable method.
2. Determination of thermal death temperature and time. (2 expt)
3. Evaluation of disinfectants by phenol coefficient method.
4. Sterility testing of different pharmaceutical products –
   (a) Injections (b) Ophthalmic preparations. (2 expt)
5. Antibiotic assay – Penicillin and Streptomycin. (2 expt)
6. Perform microbial limits tests as per I.P. - Aluminum Hydroxide gel and Starch. (2 expt)
7. Isolation of microbes from soil. (2 expt)
8. Microbial study of water by MPN.
9. Determination of minimum inhibitory concentration (MIC).

Recommended Books :

1. Tortora GJ, Microbiology: An Introduction, (Benjamin-Cummings Publishing Company).
2. Kokare CR, Pharmaceutical Microbiology Experiments and Techniques, (Career Publications).
3. Kokare CR, Pharmaceutical Microbiology Principles and Applications, (Nirali Prakashan).
4. Ananthanarayan R and Paniker CK, Textbook of Microbiology, (Orient Longman Limited Universities Press (India) Pvt. Ltd).
5. Indian Pharmacopoeia 2014,
6. Hugo WB and Russel AD, Pharmaceutical Microbiology, (Blackwell Science Publishing).
7. Baird RM, Hodges NA and Denyer SP, Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices, (CRC Press).
8. Pelczar MJ, Chan ECS and Krieg NR, Microbiology, (McGraw-Hill Inc. US).
9. Cappuccino JG and Sherman N, Microbiology – A Laboratory Manual. Pearson Education. (Dorling Kindersley publisher (India) Pvt. Ltd).
10. Dubey RC and Maheswari DK, Practical Microbiology, (S. Chand & Co., New Delhi).
11. Waites MJ, Morgan NL, Rockey JS and Higton G, Industrial Microbiology: An Introduction, (Wiley-Blackwell Publishers).

2.2.3 PHARMACEUTICAL ANALYSIS-II
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1 To provide the basis of analytical techniques and analysis of drugs.

2 To elucidate importance of titrimetric methods for application in drug analysis.

3 To reinforce the topics studied in inorganic & organic chemistry.

Course Outcomes :

At the end of the course students shall be able to

1 Apply mathematical tools for data treatment and data handling.

2 Gain knowledge about the techniques based on electrochemical and optical properties of the drugs.

Unit-1

1 Introduction to instrumental methods, classification, advantages and disadvantages. Introduction and types of electroanalytical techniques, electrochemical cell potential and its measurements, current potential relationship, mass transfer by migration, convection and diffusion. **4 h**

2 Potentiometry :
Introduction, principle and theory, types of electrodes, measurement of electrode potential and pH, construction and working of pH meter and calibration. Potentiometric titrations, detection of end points and applications. **6 h**

Unit-2

3 Polarography :
Introduction, principle and theory, dropping mercury electrode, advantages and disadvantages, polarographic instrumentation and applications **3 h**

4 Coulometry :
Introduction, principle, theory, types of coulometry, coulometry at controlled potential (potentiostatic), constant current coulometry (Amperostatic) and applications. **2 h**

5 Amperometry :
Introduction, principle and theory, instrumentation, titration curves, biamperometric titrations, advantages and applications. **5 h**

Unit-3

6 Polarimetry :
Introduction, principle and theory, circularly polarized light, measurement of optical rotation, calibration and applications. Optical rotatory dispersion (ORD), circular dichroism (CD) and cotton effect (CE). **5 h**

7 Refractometry :

Introduction, principle and theory, factors affecting refraction, specific and molar refraction, instrumentation, Abbes refractometer, Pulfrich refractometer, image displacement refractometer, calibration and application. **4 h**

Unit-4

8 Conductometry :

Introduction, principle, instrumentation, conductometric titrations, determination of end point and applications. **5 h**

9 Gravimetric analysis :

Introduction, principle, precipitation techniques, factors affecting solubility product, unit operations in gravimetry. Assay of Calcium as Calcium oxalate and Magnesium as Magnesium sulphate. **6 h**

10 Gasometry :

Introduction, principle, gasometric assay methods for CO_2, O_2, N_2. **2 h**

Recommended Books :

1. A.H. Beckett and J.B. Staenlake, Practical Pharmaceutical Chemistry (Part-I & II) 3rd Edition (University of London, Anthlone Press)
2. K.A. Connors, A Text book of Pharmaceutical Analysis, (John Wiley and Sons)
3. Douglas A. Skoog, Principles of Instrumental Analysis .
4. L.K. Chatten, A Textbook of Pharmaceutical Chemistry, (Vol. I & II) (Marcel Decker, New York).
5. G.R.Chatwal, S.K.Anand, Instrumental Methods of Chemical Analysis (Analytical Chemistry).

2.2.3 PHARMACEUTICAL ANALYSIS-II (Practical) (3 Hrs/Week)

Course Objectives :

1 To create awareness and significance of calibration in analytical chemistry & safety measures.

2 To nurture fundamental understanding of analytical instruments and train for their handling with problem solving approach.

3 To understand the importance of terms SOP/ Procedure and Protocol.

Course Outcomes :

At the end of the course students shall be able to

1 Correlate physicochemical and electrochemical properties with analytical methods for drugs.

2 Master important analytical techniques and inculcate precautionary measures in handling of chemicals and instruments.

3 Compute and analyze the purity of drug substances.

Experiments :

1 Calibration of pH meter using different buffers.

2 Potentiometric titrations (Strong acid Vs. Strong base, Weak acid Vs. Strong base, Assay: Any one API/formulation).

3 Determination of pKa of (monobasic/dibasic/tribasic acids)

4 Determination of buffer capacity of given buffer solution by pH meter.

5 Calibration of conductometer.

6 Titration of strong acid strong base by conductometry.

7 Titration of weak acid strong base by conductometry.

8 Titration of mixture of acids and base by conductometry

9 Calibration of refractometer.

10 Measurement and molar refraction (Oil samples, glycerine-water, organic solvents)

11 Determination of specific rotation and unknown concentration of a sugar sample by Polarimetry.

12 Measurement of optical and specific rotaion assay of dextrose injection.

13 Gravimetric analysis of sodium sulphate.

14 Gravimetric analysis of lead acetate.

Recommended Books :

1. A.H. Beckett and J.B. Staenlake, Practical Pharmaceutical Chemistry (Part-I & II) 3rd Edition (University of London, Anthlone Press).
2. K.A. Conners, A Textbook of Pharmaceutical Analysis, (John and Wiley and Sons)
3. Indian Pharmacopoeia published by IPC, Govt. of India, Ministry of Health and Welfare, (Latest Edition).
4. British Pharmacopoeia Published by BPC Secretariat of the Medicines and Healthcare Regulatory Agency (Latest Edition).
5. G.R.Chatwal,S.K.Anand, Instrumental Methods of Chemical Analysis (Analytical Chemistry).

2.2.4 PHYSICAL PHARMACY –II
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To update students with recent developments in pharmaceutical formulations.
2. To give an insight about latest tools used for determination of physicochemical properties.
3. To make students well verse with the fundamental processes and its correlation with the formulation of stable finished product.
4 To develop independent thinking ability in students through problem solving approach.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate utility of physicochemical properties in design of pharmaceutical product.
2. Gain insight of techniques for determination of physicochemical properties.
3. Understand factors governing stability of finished pharmaceutical product.
4. Analyze and tackle problems encountered in formulation development.

Unit-1

1. Surface and interfacial Phenomenon :

Surface and interfacial tensions, surface free energy, measurement of surface and interfacial tensions, spreading coefficient.

- Adsorption at liquid-interfaces: Surfactants (Types, HLB scale and its applications including wetting, foaming, anti-foaming and micellar solubilization), soluble monolayer and Gibb's equation, insoluble monolayer and film balance.
- Adsorption at solid interfaces: adsorption isotherms (Langmuir and Freundlich), measurement of surface free area. **8 h**

2. Electrical properties at Interfaces: Nernst and Zeta potential, electrical double layer. **2 h**

Unit-2

3. Colloids :

Introduction and types, optical, kinetic and electrical properties of colloids, Stabilization of colloidal system, DLVO theory, Schulze Hardy rule, Hoffmeister series, applications in Pharmacy. **4 h**

4. Coarse dispersions :

Interfacial and thermodynamic properties of suspended particles, settling in suspensions, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles, controlled

flocculation, emulsions types, theories, physical stability, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsions formulation, multiple emulsions. Semisolid dispersions. **7 h**

Unit-3

5. Solid State :

Crystal analysis, X-ray diffraction studies, polymorphism: types and significance, Methods to differentiate crystalline and amorphous forms. **4 h**

6. Micromeritics :

Introduction and pharmaceutical importance, particle size and distribution, particle shape, particle volume, particle number, surface area, methods for determining particle size, particle volume measurement, specific surface, methods for determining surface area, Derived properties of powder, porosity, packing arrangement, densities, bulkiness, flow properties of powder, angle of repose, factors affecting flow of powders. **7 h**

Unit-4

6. Compaction and Compression :

Theory, thermodynamics, mechanisms of densification and strength producing, force distribution during compression, material properties, factors affecting. **5 h**

7. Rheology :

fundamentals of rheology, types of flow, quantitative measurement of flow, mechanical models to illustrate flow on viscoelasticity, thixotropy, measurement of thixotropy in formulation, rheology of disperse system, pharmaceutical application of rheology, Methods of viscosity measurements. **5 h**

Recommended Books :

1. Martin A. N. Physical Pharmacy and Pharmaceutical Sciences. (Lipincott Williams and Wilkins) 5th Ed. ISBN-13: 978-81-8+836-61-0.
2. Florence A. T., David A. Physicochemical Principles of Pharmacy. (Pharmaceutical Press), ISBN: 085369608X.
3. Glasstone S., Lewis D. Elements of Physical Chemistry. (Palgrave Macmillan; 2nd edition) ISBN-13: 978-0333038437.
4. David A., Florence A. T. FASTtrack: Physical Pharmacy. (Pharmaceutical Press), 2nd edition, ISBN-13: 978-0853697251.
5. Bahl A., Bahl B. S., Tuli G. D. Essentials of Physical Chemistry (S. Chand and Company Ltd.) ISBN:81-219-2978-4.
6. Indian Pharmacopoeia 2007, 2014
7. Findlay A. Practical Physical Chemistry. (BiblioLife) , ISBN-13: 978-1113872036.

8. Halpem A., McBane G. Experimental Physical Chemistry: A Laboratory Text. (W. H. Freeman) 3rd Edition edition, ISBN-13: 978-0716717355.
9. More H. N., Hajare A. Practical Physical Pharmacy. (Career Publications) , ISBN-13: 978-8188739462.
10. Hadkar U. B. A Hand Book of Practical Physical Pharmacy & Physical Pharmaceutics. (Nirali Prakashan), ISBN-13: 978-8185790329

2.2.4 PHYSICAL PHARMACY –II
(Practical)(3 Hrs/Week)

Course Objectives :

1. To give an insight about the fundamental concepts of physical chemistry and their implications towards design of pharmaceutical formulations.
2. To provide hands on experience on determination of various physicochemical properties.
3. To develop independent thinking ability of students through problem solving approach.

Course Outcomes :

At the end of the course students shall be able to

1. Understand utility of physicochemical properties in design of stable pharmaceutical formulation.
2. Gain expertise in determination of physicochemical properties as part of preformulation.

Experiments :

1. Determination of surface tension of given liquid.
2. Determination of CMC of a surfactant.
3. Determination of specific surface area of charcoal by adsorption.
4. Preparation of colloid by condensation method and dispersion method and its analysis. (2 Expts.)
5. Determination of derived properties of powders such as density, porosity, compressibility and angle of repose.
6. Determination of particle size distribution by sieve analysis and optical microscopy. (2 Expts.)
7. Determination of Sedimentation volume and degree of flocculation. (2 Expts.)
8. Determination of viscosity by capillary and Brookfield viscometer (2 Expts.)
9. Determination of molecular weight of polymer by viscosity.

Recommended Books :

1. Martin A. N. Physical Pharmacy and Pharmaceutical Sciences. (Lipincott Williams and Wilkins) 5th Ed. ISBN-13: 978-81-8+836-61-0.
2. Florence A. T., David A. Physicochemical Principles of Pharmacy. (Pharmaceutical Press), ISBN: 085369608X.
3. Glasstone S., Lewis D. Elements of Physical Chemistry. (Palgrave Macmillan) 2nd edition ISBN-13: 978-0333038437.
4. David A., Florence A. T. FASTtrack: Physical Pharmacy. (Pharmaceutical Press), 2nd edition, ISBN-13: 978-0853697251.
5. Bahl A., Bahl B. S., Tuli G. D. Essentials of Physical Chemistry (S. Chand and Company Ltd.) ISBN:81-219-2978-4.
6. Indian Pharmacopoeia 2007, 2014
7. Findlay A. Practical Physical Chemistry. (BiblioLife) , ISBN-13: 978-1113872036.
8. Halpem A., McBane G. Experimental Physical Chemistry: A Laboratory Text. (W. H. Freeman); 3rd Edition edition, ISBN-13: 978-0716717355.
9. More H. N., Hajare A. Practical Physical Pharmacy. (Career Publications), ISBN-13: 978-8188739462.
10. Hadkar U. B. A Hand Book of Practical Physical Pharmacy & Physical Pharmaceutics. (Nirali Prakashan), ISBN-13: 978-8185790329

2.2.5 PHARMACOGNOSY I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To introduce the concept and scope of Pharmacognosy and Traditional medicines.
2. To understand the basic principles of cultivation, collection, processing and storage of crude drugs.
3. To impart the knowledge of primary and secondary metabolites of the plant.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the concept and scope of Pharmacognosy and traditional medicines.
2. Understand the concepts of cultivation, collection, processing and storage of crude drugs.
3. Understand the applications of primary and secondary metabolites of the plant.

Unit-1

1. Introduction :

Definition, history, scope, development and future challenges of Pharmacognosy. Sources of drugs. **3 h**

2. Classification of drugs :

Organized and unorganized crude drugs, alphabetical, morphological, taxonomical, chemical and pharmacological classification of drugs. **3 h**

3. Cultivation and Collection :

Cultivation, Collection, Processing and storage of crude drugs: Factors influencing cultivation of medicinal plants. Types of soils and fertilizers of common use. Plant growth regulators and their role. **4 h**

Unit-2

4. Primary and secondary metabolites :

Introduction to Primary and secondary metabolites, comparative study, role of primary and secondary metabolites in plants. **2 h**

5. Plant Biosynthetic Pathways :

Introduction to Plant Biosynthetic Pathways and their medicinal role. Biosynthesis of carbohydrates, fatty acids, proteins, amino acids including Shikimic acid pathway, acetate and mevalonic acid pathway. **4 h**

6. Alternative systems of medicine :

Introduction to alternative systems of medicine Ayurveda, Homoeopathy, Traditional Chinese Medicine, Aromatherapy, Unani, Sidhha, Kampo etc. The holistic concept of drug administration in traditional systems of medicine. Introduction to Ayurvedic preparations like Arishtas, Asvas, Gutikas, Tailas, Churnas, and Bhasmas. **5 h**

Unit-3

7. Pharmacognostic scheme for study of crude drugs :

Meaning, component and significance of individual Pharmacognostic parameter.

Introduction to different categories of phytoconstituents with regard to their general properties of alklaoids, glycoside, terpenoids, resins, tannins, steroids, polyphenolics etc. **3 h**

8. **Introduction, occurrence, classification, biosynthesis, chemistry, general methods of isolation, chemical constituents, chemical tests, pharmacological effects, medicinal uses, drug interaction, side effects, toxicity, marketed formulations of following chemical group and drugs mentioned against them: Primary metabolites of Pharmaceutical and industrial utility:**

   Carbohydrates: Systematic Pharmacognostic study of: Agar, Guar gum, Acacia, Isabagol, Tragacanth, Okra mucilage, Starch, Pectin, Inulin, Chitosan, Cyclodextrins. **7 h**

Unit-4

9. **Lipids :**
   Systematic Pharmacognostic study of: Castor oil, Linseed oil, Neem oil, Hydnocarpus oil, Cod liver oil, Shark liver oil, Rice Bran oil, Saw Palmetto, Cocoa butter, Kokum butter, Wool fat, Bees wax, Lecithin, Polyunsaturated fatty acids, Carotenoids. **11 h**

Recommended Books :

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. (W.B. Saunders), 2002. 16th Ed. ISBN-10: 0702029335.
2. Gokhale S.B. et al., Pharmaceutical Biology, (Nirali Publications), ISBN 978-81- 85790-40-
3. Hopkins W. G. and Hüner Norman P. A., Introduction to Plant Physiology, 4th Ed., (John Wiley and Sons), 2008, ISBN 978-0-470-24766-2.
4. Kapoor K. and Sonie K.C. An Introduction to Pharmaceutical Biology, (Yash Pub), 2005, ISBN: 8186882189.
5. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, (NiraliPrakashan, Pune), 2008, ISBN: 8185790094.
6. Quality control methods for medicinal plant materials, (World Health Organization, Geneva), 1998.ISBN 9241545100.
7. Rangari V.D., Pharmacognosy and Phytochemistry (Vol I), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-45-5.
8. Rangari V.D., Pharmacognosy and Phytochemistry (Vol II), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-65-3.
9. Singh J. S., Singh S. P. and Gupta S. R., Ecology, environment and resource Conservation, (Anamya publication, New Delhi), ISBN 13: 9788188342556.
10. Sivarajan V. V. and Robson N. K. P. Introduction to the Principles of Plant Taxonomy, (Cambridge University Press; 2nd Ed.), ISBN-10: 0521356792.
11. Snustad D. P. and Simmons M. J., Textbook of Principles of Genetics, 6th Ed., (John Wiley and Sons Canada, Limited), 2011, ISBN 13: 9780470903599.
12. Wallis T. E., Textbook of Pharmacognosy. (CBS Publisher and Distributors), 1985. ISBN: 81-239-0886-5.

2.2.5 PHARMACOGNOSY I
(Practical) (3 hrs/week)

Course Objectives :

1. To understand different plant tissues and their characteristics.
2. To identify the crude drugs on the basis of morphological and microscopical characters of crude drugs.
3. To perform chemical tests to evaluate the crude drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Understand different plant tissues and their characteristics.
2. Identify the crude drugs on the basis of morphological and microscopical characters of crude drugs.
3. Perform chemical tests to evaluate the crude drugs.

Experiments :

1. Study of microscopy.
2. Study of different plant organs, their morphology and histological characters.
3. Study of different plant tissues and different staining techniques.
4. Study of stomata, trichomes, starch grains and calcium oxalate with their significance in identification of drugs.
5. Study of organized (Leaf, bark, root, fruit, flower) and unorganized drugs (Guggul, Agar, Storax, Aloe, Catechu).
6. Determination of palisade ratio, vein islet number and vein termination number of given drug sample.
7. Chemical tests for Acacia, Tragacanth, Agar, Starch.
8. Chemical tests for Shark liver oil, Bees wax
9. Isolation of starch from potato and comparison with maize, wheat and rice starch.
10. Extraction and isolation of mucilage of Isapgol seeds.
11. Identification of crude drugs (organized and unorganized) by morphology.
12. Extraction and isolation of mucilage of Okra seeds.
13. Chemical tests for Castor oil, Sesame oil. Field visits: Visit to industry/ cultivation farm/medicinal plant garden/ processing unit and submission of report thereof.
14. Assignment for market survey on Herbal product.

Recommended Books :

1. Brain K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceuticals, (Wright-Scientechnica, Bristol), 1975.
2. Khandelwal K. R., Practical Pharmacognosy, (Pragati Books Pvt. Ltd., Pune),ISBN 8185790302.
3. Kokate C. K., Practical Pharmacognosy, (VallabhPrakashan), 1993.
4. Wallis T. E., Practical Pharmacognosy (J.A. Churchill Ltd., London), 1953.
5. Jeffrey B. Harborne. Phytochemical Methods: A Guide to Modern Techniques ofPlant Analysis. (Springer), 1998.ISBN 0412572702, 9780412572708.
6. Manual of methods of analysis foods: Oils and Fats (http://www.fssai.gov.in/Portals/0/Pdf/15Manuals/OILS%20AND%20FATS.pdf)

2.2.6 PHARMACOLOGY- I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To introduce basic aspects and significance of pharmacology.
2. To identify therapeutic targets for drug therapy.
3. To reinforce the physiological and pathophysiological aspects of human body.
4. To develop competence on evaluating the efficacy, safety and risk profile of drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Acquaint with the basic concepts of pharmacology.
2. Understand the pharmacological basis of therapeutics.
3. Conceptualize the mode and mechanisms of action of drug in diseases.
4. Understand the uses, adverse effects and drug interactions.

Unit-1

1. General pharmacology:

a) Introduction, scope and branches of Pharmacology
b) Sources and active ingredients of drugs
c) Routes of drug administration
d) Absorption of drugs and factors affecting it, Concept of Bioavailability
e) Distribution of drugs and factors affecting it
f) Biotransformation (Metabolism) of drugs and factors affecting it
g) Excretion of drugs and factors affecting it **11 h**

Unit-2

2. General pharmacology :

a) Mechanisms of Action of Drugs
b) Drug Dependence and Drug abuse
c) Dose-Response Relationships, Time-Response Relationships
d) Adverse Drug reactions (ADR): Classification, Risk factors, Monitoring and Detecting ADR
e) Drug Drug Interactions, Food Drug Interactions. **10 h**

Unit-3

3. Basic and Clinical Pharmacology of drugs acting on Autonomic Nervous System:

a) Autonomic Nervous system-General Considerations

b) Cholinergic system and drugs

c) Anti-cholinergic drugs **11 h**

Unit-4

4. Basic and Clinical Pharmacology of drugs acting on Autonomic Nervous System:

a) Neuromuscular blocking agents

b) Adrenergic system and drugs

c) Anti-adrenergic drugs **10 h**

Recommended Books :

1. Barar, F.S.K., Essentials of Pharmacotherapeutics (S. Chand and Company, New Delhi), 6th edition (2011).
2. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, (Little Brown and Co, Boston)
3. Crossland, James and; Lewis's Pharmacology Basis of Therapeutics, (Pergamon Press, New York)
4. Das, M. M. and Dutta S. K. : R. Ghosh's Modern Concepts on pharmacology and Therapeutics, (HILTON and Co. Calcutta), 24th edition (2013).
5. Goodman and Gilman; Pharmacological Basis of Therapeutics, (McGraw-Hill), 12th edition (2011).
6. Katzung, B.G; Basic and Clinical Pharmacology, (Lange Medical Publisher, USA), 12th edition (2012).
7. Rang, H.P. and Dale, M.M.; Pharmacology, (Churchill Livingston, UK) 7th edition (2012).
8. Satoskar, R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay), 23rd edition (2013).
9. Sharma H.L. Sharma K. K. Principles of Pharmacology (Paras Publication), 2nd edition (2013).
10. Tripathi K. D. Essentials of Medical Pharmacology VII Edition (Jaypee Brothers, New Delhi).

SEMESTER –V

3.1.1 MEDICINAL CHEMISTRY-I

(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To correlate physico-chemical properties of a drug and its structure with the biological action.
2. To demonstrate the mechanism of action on a molecular basis.
3. To provide knowledge of therapeutic uses and adverse reactions of various drugs.
4. To apply principles of organic chemistry for synthesizing various clinically significant drugs.
5. To reinforce the topics studied in anatomy and physiology, biochemistry, organic chemistry and pharmacology.

Course Outcomes :

At the end of the course students shall be able to

1. Understand routes of synthesis of important drugs.
2. Conceptualize influence of substituents on the physico-chemical properties and biological activity of drugs.
3. Explain the uses and adverse reactions of drugs belonging to different classes.

Unit-1

1. General considerations :

Ferguson's principle, physico-chemical parameters like solubility, degree of ionization, partition coefficient affecting drug action, drug absorption, distribution, and elimination, bioisosterism, stereo-chemical aspects of drug action. **4 h**

Note: History and general aspects of design and development of the following categories of the drugs including classification, SAR, mechanism of action (biochemical and molecular basis wherever applicable), physico-chemical properties, adverse effects, therapeutic uses and recent developments.

*** Synthesis of drugs mentioned in each category.**

2. Diuretic agents:

Water and osmotic diuretics, acidifying salts, mercurials, sulphonamides, purines and related compounds, endocrine antagonists, miscellaneous agents.

*Ethacrynic acid, Acetazolamide, Furosemide, Mersalyl, Theophylline, Aminophylline, Chlorthiazide, Hydrochlorthiazide. **8 h**

Unit-2

3. Cholinergic agonists and antimuscarinic agents :

Neurotransmitters, generation of nerve impulse and its propagation, release of neurotransmitter in the synapse. Biosynthesis of acetylcholine, its storage, release and metabolism. Muscarinic receptors with their subtypes and structural features. Cholinergic agonists, cholinestrase inhibitors and antimuscarinic agents.

*Carbachol, Bethanechol, Demecarium bromide, Dicyclomine hydrochloride. **8 h**

Unit-3

4. Ganglionic blockers and neuromuscular blockers :

Ganglionic transmission, nicotinic receptors with their subtypes and structural features. Ganglionic stimulants, ganglionic blockers and neuromuscular blockers.

*Mecamylamine hydrochloride, Guanithidine monosulphate, Chlorzoxazone, Dantroline sodium, Gallamine. **3 h**

5. Adrenergic agonists and antagonists :

Biosynthesis, storage, release and metabolism of noradrenaline, adrenergic receptors subtypes and their structural features. Adrenergic agonists and adrenergic antagonists.

*Norepinephrine, Isoproterenol, Naphazoline, Propranolol, Phenoxybenzamine hydrochloride, Salbutamol. **8 h**

Unit-4

6. Cardiovascular drugs :

Cardiotonic drugs, antianginal agents, antiarrhythmic agents, antihypertensive agents, antihyperlipidemic agents.

*Methyldopa, Prazocin, Terbutaline, Isoxsuprine, Amyl nitrite, Fenofibrate. **11 h**

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).
4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .

8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).

3.1.1 MEDICINAL CHEMISTRY-I
(Practical) (3 Hrs/Week)

Course Objectives :

1. To integrate knowledge of organic chemistry for synthesis of medicinal compounds.
2. To analyze the purity of the drug substances by TLC and qualitative tests.
3. To record, analyze and document the results.

Course Outcomes :

At the end of the course students shall be able to

1. Apply principles of organic chemistry for synthesis of intermediates and drugs.
2. Apply TLC technique for monitoring reactions and checking purity of synthesized compounds.
3. Apply principles of qualitative analysis for identification and structural confirmation of synthesized compounds.

Experiments :

A. Synthesis of following compounds

1 Benzil from benzoin
2. Phenytoin from benzill
3. 7-Hydroxy-4-methyl coumarine from resorcinol
4. Benzimidazole from o-phenylenediamine
5. Hippuric acid from glycine
6. Phenothiazine from diphenylamine
7. 2-Methyl benzimidazole from o- phenylene diamine
8. 1-Phenyl-2-azo napthol
9. 2-Napthyl benzoate

B. Qualitative analysis of synthesized compounds (05)

C. Assignment: Recent advancements in therapy of diseases covered in syllabus

Recommended Books :

1. Vogel, Vogel's Textbook of Practical Organic Chemistry, 3rd Edition, (The English Language Book Society and Longman Group Limited, London).
2. Arthur, Vogel's Elementary Practical Organic Chemistry Small Scale Preparations, 1, 2nd edition, Part I CBS Publications.
3. Mann F C, Saunder B C, Practical Organic Chemistry (The English Language Book Society and Longman Group Limited, London).
4. Textbook of Practical Organic Chemistry, The ELBS, Longman, London.
5. S H Bhosale and K R Mahadik, Textbook of Qualitative Analysis (Nirali Prakashan).
6. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st Edition , (John Wiley and Sons, INC).
7. Ashutosh Kar, Advanced Practical Medicinal Chemistry 1st Edition, (New Age International Publications).

3.1.2 PHARMACEUTICAL ANALYSIS-III
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To impart knowledge about modern instruments in chromatographic analysis with special reference to quality control and quality assurance.
2. To apply principles of chromatographic techniques for analysis of pharmaceuticals.

Course Outcomes :

At the end of the course students shall be able to

1. Understand and apply principles of chromatographic techniques for qualitative and quantitative determination of pure drug and drug content in dosage forms.
2. Carry out separation of drugs from the mixtures and formulations.
3. Develop problem solving and mathematical approach in chromatographic analysis.

Unit-1

1. Introduction to chromatography :

Brief history, classification, principles, general terms- distribution co-efficient, effective distribution co-efficient, theories of chromatography -Rate theory and plate theory, selection of chromatographic method. **10 h**

Unit-2

2. Column chromatography :

Introduction, principle, technique- Columns, adsorbents, column packings, sample loading and elution techniques and applications.

Separation of different dyes, synthetic and herbal compounds. **4 h**

3. Paper chromatography :

Introduction, principle, technique -Types of papers, sample preparation, sample application, solvent selection, development modes, detection and applications.

Identification of Atenolol, Hydrochlorothiazide, Paracetamol. **7 h**

Unit-3

4. Gas chromatography (GC) :

Introduction, principle and theory, instrumentation- Types of carrier gas, sample injection, types of columns and stationary phases, detectors, temperature programming, derivatisation, advances in GC and applications.

Assay of Atropine sulphate eye ointment/ tablet, Fenfluramine hydrochloride tablet, Hyoscine hydrobromide injection. **11 h**

Unit-4

5. Ion exchange chromatography :
Introduction, principle, types of resins, technique and applications. **5 h**

6. Gel permeation chromatography :
Introduction, principle, technique -Columns, adsorbents, column packings, sample loading and elution techniques and applications. **5 h**

Recommended Books :

1. Douglas A Skoog, Donald M West, F James Holler, Stanley R Crouch, Fundamentals of Analytical Chemistry, 8th Edition, (Indian Edition, Thomson Brooks/Cole)
2. K R Mahadik, H N More, Pharmaceutical Analysis Instrumental Methods (Nirali Prakashan, Pune)
3. Hobart H Willard, L L. Merritt, John A. Dean, Frank A Settle, Instrumental Methods of Analysis 7th Edition, (CBS Publishers).
4. G R Chatwal, S K Anand, Instrumental Methods of Chemical Analysis (Himalaya Publishing House).
5. B K Sharma, Instrumental Methods of Chemical Analysis (Goel Publishing House).
6. Ashutosh Kar, Pharmaceutical Drug Analysis (New Age International (P) Limited, Publishers)
7. J Mendham, R C Denney, J D Barnes, M Thomas, B Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis 6th Edition, (Pearson).
8. Douglas A Skoog, F James Holler, Stanley R Crouch, Instrumental Analysis Indian Edition, (Cengage Learning).
9. Gaen W Ewing, Instrumental Methods of Chemical Analysis 5th Edition, (McGraw Hill Book Company).

3.1.2 PHARMACEUTICAL ANALYSIS-III
(Practical) (3 Hrs/Week)

Course Objectives :

1. To learn the working principles of various chromatographic techniques.
2. To perform the separation of drugs from mixture and formulations.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate principles of separation using chromatographic techniques for qualitative determination of pure drug.

2. Master important chromatographic techniques and separate drugs from mixtures and formulations.
3. Record, compute and analyze the data.

Experiments :

1. Practical based on paper chromatography (Ascending and circular).
   i) Amino acids **(02)**
   ii) Sugars **(02)**
   iii) Drugs & formulations **(06)**
2. Demonstration of gas chromatography.
3. Purify the drugs by column chromatography **(02)**
4. Separation of pharmaceuticals by ion exchange chromatography **(02)**
5. Assignments: Recent advancements in instrumentation and hyphenated techniques covered in syllabus .

Recommended Books :

1. Douglas A Skoog, Donald M West, F James Holler, Stanley R Crouch, Fundamentals of Analytical Chemistry 8th Edition, (Indian Edition, Thomson Brooks/Cole)
2. K R Mahadik, H N More, Pharmaceutical Analysis Instrumental Methods (Nirali Prakashan, Pune)
3. Hobart H Willard, L L. Merritt, John A. Dean, Frank A Settle, Instrumental Methods of Analysis 7th Edition, (CBS Publishers).
4. G R Chatwal, S K Anand, Instrumental Methods of Chemical Analysis (Himalaya Publishing House).
5. B K Sharma, Instrumental Methods of Chemical Analysis (Goel Publishing House).
6. Ashutosh Kar, Pharmaceutical Drug Analysis (New Age International (P) Limited, Publishers)
7. J Mendham, R C Denney, J D Barnes, M Thomas, B Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, (Pearson).
8. Douglas A Skoog, F James Holler, Stanley R Crouch, Instrumental Analysis Indian Edition, (Cengage Learning).
9. Gaen W Ewing, Instrumental Methods of Chemical Analysis 5th Edition, (McGraw Hill Book Company).

3.1.3 PHARMACEUTICAL TECHNOLOGY-I
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To give an insight about industrial scale manufacturing of pharmaceuticals.
2. To impart knowledge of cGMP.
3. To provide knowledge of cosmetics for formulation.

Course Outcomes :

At the end of the course students shall be able to

1. Integrate basics of physicochemical, biopharmaceutical and therapeutic aspects with formulation design.
2. Implement cGMP for large scale manufacturing of pharmaceuticals and cosmetics.
3. Evaluate quality of pharmaceuticals and cosmetics.

Unit-1

1. Good manufacturing practices :
Concept and application of cGMP. cGMP in relation to premises, personnel, manufacturing operations and machinery, Documentation, quality assurance and quality control. **3 h**

2. Pharmaceutical plant layout designing:
Concept, components and types of layout, flow chart and layout of manufacturing and packaging section. **2 h**

3. Concept of formulation design and Preformulation studies :
Physicochemical, Therapeutic, biopharmaceutical, aesthetic and technical criteria of formulation. Significance and testing of physicochemical properties in design of non-sterile dosage forms. **5 h**

Unit-2

4. Liquid orals :
Concept of formulation design, manufacturing, flow chart, layout, GMP requirements related to liquid orals. Packaging and Evaluation of monophasic liquids. **4 h**

5. Biphasic liquids :
Concept of formulation design, formulation, manufacturing, flow chart, layout. Selection and evaluation of containers. Evaluation of suspensions and emulsion. **7 h**

Unit-3

6. Semisolids :
Ointments, creams, pastes, gels. Topical liquids. Formulation, Manufacturing, flow chart, layout and GMP requirements. Packaging and evaluation. Skin irritation test. **6 h**

7. Skin cosmetics :

Formulation, manufacturing, regulatory requirements and evaluation (including Indian standards)

a) Moisturizers, cleansers, conditioners in various forms such as creams, gels, lotions, milks.

b) Suntan and anti-sunburn products

c) Anti-acne products

d) Antiperspirants and deodorants **5 h**

Unit-4

8. Cosmetics for hair, lip, eye and nail :

Formulation, manufacturing, regulatory requirements and evaluation.

a) Shampoos, hair dyes, depilatories and shaving preparations

b) Lip cosmetics: Lipstick

c) Eye cosmetics: Eye mascara, eye shadow, eye brow pencil

d) Nail paint and nail-paint remover **10 h**

Recommended Books :

1. Remington: The Science and practice of Pharmacy (Mack Publishing Company).
2. H. C. Ansel, N. G. Prporich, L. V. Allen; Pharmaceutical dosage forms and Drug Delivery Systems (Williams and Wilkins).
3. L. Lachman, H. A. Liberman, J. L. Kanig; The Theory and Practice of Industrial Pharmacy (Verghese Publishing House).
4. Bentley's : Text book of Pharmaceutics (Bailliere Tindal)
5. G. S. Banker, R. K. Chalmers; Pharmaceutics and Pharmacy Practice (J. B. Lippincott Company).
6. M. E. Aulton; Pharmaceutics – The science of dosage form Design (Churchill Livingstone).
7. Atmaram Pawar, Introduction to Pharmaceutics, (Career Publications).
8. J. Swarbrick, J. C. Boylan; Encyclopedia of Pharmaceutical Technology (Marcel Dekker) the Vol.-I.
9. K. Ridgway: Hard Capsules Development and Technology (Pharmaceutical Press, London).
10. Liberman, Rieser and Banker, Pharmaceutical Dosage forms, Disperse system, (Marcel Dekker).
11. James J. Wells, Pharmaceutical Preformulation (Ellis Horwood Ltd.)
12. J. Knowlton and S. Rearce, Handbook of cosmetic sciences and technology, (Elsevier science publisher).

13. J.B. Wilkinson and R.J. Moore, Harry's cosmetology, (Longman Science and Technical).
14. E.G. Thomson, Modern cosmetics, (Universal Publishing Corporation).
15. M.S. Balsam and E. Sagarin, Cosmetics, science and technology, (John Wiley & Sons)
16. R. L. Elder, Cosmetic Ingredients, their safety assessment, (Pathotox)
17. H. R. Moskowitz, Cosmetic product testing, (Marcel Dekker)
18. K.F.De Polo, A Short Textbook of cosmetology.
19. Andre O.Barel, Maec Paye, Howard I. Maibach, Handbook of cosmetic sciences and technology, (Marcel Dekker)
20. Charles Z viak, The Science of Hair Care, (Marcel Dekker)
21. P.P. Sharma, Cosmetics-Formulation, Manufacturing and quality Control, (Vandana Publications).

3.1.3 PHARMACEUTICAL TECHNOLOGY-I (Practical) (3 Hrs/Week)

Course Objectives :

1. To formulate liquid, semisolid pharmaceuticals and cosmetics.
2. To provide hands on training for preparation of pharmaceutical and cosmetic products.
3. To perform In-process quality control (IPQC) and quality control (QC) testing of pharmaceuticals and cosmetics.

Course Outcomes :

At the end of the course students shall be able to

1. Formulate liquid, semisolid pharmaceuticals and cosmetics.
2. Evaluate quality of pharmaceuticals and cosmetics.
3. Understand current scenario of pharmaceutical and cosmetic products.

Experiments :

1. Formulation approach : Survey/assignments related to types of marketed liquids/semisolids formulations, composition, containers, labels, expiry period, economy, acceptance drug products, one oral presentation.
2. An assignment on design of formulation, selection of process, equipments, packaging, labels for a formulation
3. Formulation design approach for liquid formulations
4. Formulation design, processing, manufacturing and evaluation of following:

   I. Monophasic Liquids (02)

   a) Paracetamol syrup/elixir

b) Cough syrup

c) Paediatric drops

II. Suspensions (02)

a) Calamine Lotion

b) Milk of Magnesia/antacid suspension

c) Paracetamol suspension

III. Emulsion (02)

a) Liquid paraffin and magnesium hydroxide mixture emulsion

b) Formulation of emulsion (HLB consideration)

c) Liniment

IV. Semisolids (02)

a) Pain balm

b) Cetrimide creams

c) Nimesulide gel

d) Methyl salicylate ointment

5. Formulation, preparation and evaluation for cosmetics (06)

Vanishing cream, cold cream, cleansing milk/lotion, moisturizing lotion, antiperspirants, deodorants, sunscreen, anti-acne preparation. Shampoo, Shaving Cream.

Recommended Books :

1. H. C. Ansel, N. G. Prporich, L. V. Allen; Pharmaceutical dosage forms and Drug Delivery Systems (Williams and Wilkins).
2. Atmaram Pawar, Modern Dispensing pharmacy, (Career Publications).
3. Liberman, Rieser and Banker, Pharmaceutical Dosage forms, Disperse system, (Marcel Dekker).
4. J. Knowlton and S. Rearce, Handbook of cosmetic sciences and technology, (Elsevier science publisher).
5. J.B. Wilkinson and R.J. Moore, Harry's cosmetology, (Longman Science and Technical)
6. E.G. Thomson, Modern cosmetics, (Universal Publishing Corporation).
7. M.S. Balsam and E. Sagarin, Cosmetics, science and technology, (John Wiley & Sons)
8. H. R. Moskowitz, Cosmetic product testing, (Marcel Dekker)
9. P.P. Sharma, Cosmetics-Formulation, Manufacturing and quality Control, (Vandana Publications).
10. Indian Pharmacopoeia.

3.1.4 PHARMACOLOGY- II
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To understand molecular targets of drug action.
2. To develop competence on evaluating the efficacy and safety profile of drugs.
3. To impart knowledge of pharmacotherapy in correlation with physiology and pathophysiology.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate the molecular basis of drug action.
2. Understand the uses of drugs in various diseases, their adverse effects and drug interactions.
3. Integrate pathophysiology with treatment approaches

Unit-1

1. Basic and Clinical Pharmacology of drugs acting on Blood and blood formation:

a) Haematinics, Plasma expanders, and Erythropoietin

b) Drugs affecting coagulation, bleeding and thrombosis **8 h**

2. Endogenous Nitric Oxide :

Biosynthesis and regulation, Physiological and Pathological role in clinical conditions, Therapeutic uses and nitric oxide donors. **3 h**

Unit-2

3. Basic and Clinical Pharmacology of drugs acting on Cardio-vascular diseases :

a) Drugs for Congestive Cardiac Failure (CCF)

b) Anti-arrhythmic drugs

c) Antianginal and other anti-ischemic drugs

d) Anti-hypertensive drugs **10 h**

Unit-3

4. Drug used in dyslipidemia **4 h**

5. Basic and Clinical Pharmacology of drugs acting on Urinary System :

a) Diuretics

b) Anti-diuretics **7 h**

Unit-4

6. Basic and Clinical Pharmacology of drugs acting on Gastrointestinal tract :

a) Peptic ulcer
b) Emetics and antiemetics
c) Constipation, IBD and diarrhea **6 h**

7. Basic and clinical Pharmacology of drugs acting on Respiratory Tract :

Drugs for cough and bronchial asthma **4 h**

Recommended Books :

1. Barar, F.S.K., Essentials of Pharmacotherapeutics; (S. Chand and Company, New Delhi)
2. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, (Little Brown and Co, Boston)
3. Crossland, James and Lewis's Pharmacology Basis of Therapeutics, (Pergamon Press, New York)
4. Das, M. M. and Dutta S. K. : R. Ghosh's Modern Concepts on pharmacology and Therapeutics, (HILTON and Co. Calcutta)
5. Goodman and Gilman; Pharmacological Basis of Therapeutics,(McGraw-Hill)
6. Katzung, B.G; Basic and Clinical Pharmacology, (Lange Medical Publisher, USA)
7. Rang, H.P. and Dale, M.M.; Pharmacology, (Churchill Livingston, UK)
8. Satoskar, R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay).
9. Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts. (Paras Publication)
10. Tripathi K. D. Essentials of Medical Pharmacology VII Edition, (Jaypee Brothers, New Delhi).

3.1.4 PHARMACOLOGY- II
(Practical) (3 Hrs/Week)

Course Objectives :

1. To imbibe ethics of animal experimentation and 3 R principles in animal experimentation.
2. To acquire expertise in in vitro experimental pharmacology.
3. To evaluate the efficacy and safety profile of drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Perform animal experiments ethically and comprehend the need of alternatives to animal experimentation.

2. Carryout bioassays for various drugs.
3. Elucidate treatment profiles for various diseases and assess risk benefit ratio in clinical pharmacology.

Experiments :

1. Study of laboratory animals, CPCSEA regulations, animal house requirements and experimental pharmacology (04)
2. Study of laboratory equipments and techniques (in vitro and, in vivo) used in experimental pharmacology (02)
3. Study of bioassay by concentration response curve and interpolation bioassay (02)
4. Demonstration of the routes of drug administrations
5. Demonstration of effects of drugs on blood pressure in rat by using power lab data acquisition system.
6. Demonstration of surface ECG in rat by using power lab data acquisition system.
7. Computer simulation of effects of various drugs using isolated frog heart.
8. Computer simulation of the mydriatic and miotic effects of drugs on rabbit's eye
9. Computer simulation of effects of drugs on frog esophagus
10 Prescription auditing and standard treatment protocols for the patient of following diseases: Congestive Cordiac Failure, hypertension, peptic ulcer (03)

Recommended Books :

1. Kulkarni, S.K.; Handbook of Experimental Pharmacology,(Vallabh Prakashan, New Delhi
2. Ghosh, M.N.: Fundamental of Experimental Pharmacology, (Scientific Book Agency, Calcutta)
3. Sheth, U.K, Dadkar, N.K. and Kamat, U.G., Selected Topics in Experimental Pharmacology, (Kothari Book Depot, Mumbai).
4. Perry, W.L.M., Pharmacological Experiments on isolated preparations, (E&S, Livingston, London)
5. Jaju B.P., Pharmacology: A practice Exercise book, (Japee Brothers, New Delhi)
6. Burn, J.H., Practical Pharmacology, (Blackwell Scientific, Oxford, London)
7. Lawrence, D.R., and Bacharch, A.L.; Evaluation of Drug Activities, Pharmacometrics, (Academic Press)
8. Turner, R.A., Screening Methods in Pharmacology, (Academic Press, London)
9. Thomson. E.B., Drug Bioscreening, (VCH, New York)
10. Vogel, H.G. and Vogel, W.H.: Drug Discovery and Evaluation: Pharmacological Assays, (Springer, New York).

3.1.5 PHARMACOGNOSY-II

Theory (3h/week) (42 Lectures)

Course Objectives :

1. To understand basics of crude drugs.
2. To understand different categories of plant constituents and know their characteristics.
3. To understand pharmacognostic account of some important secondary metabolite.

Course Outcomes :

At the end of the course students shall be able to

1. Understand basics on crude drugs.
2. Understand different categories of plant constituents and know their characteristics.
3. Understand pharmacognostic account of some important secondary metabolite.

Unit-1

Introduction, occurrence, classification, biosynthesis, chemistry, general methods of isolation, chemical constituents, chemical tests, pharmacological effects, medicinal uses, drug interaction, side effects, toxicity, marketed formulations of following chemical group and drugs mentioned against them: secondary metabolites of Pharmaceutical and industrial utility:

1. Alkaloids :

Tropane: Belladona, Piperidine amides: Black pepper, Phenylethylamines: Ephedra, Isoqunioline: Opium, Phenethylisoquinoline: Colchicum, Tryptophan: Ergot, Catharanthus, Rauwolfia, Quinoline: Cinchona, Imidazole: Pilocarpus, Diterpenoid and Steroidal: Aconite, Purine Bases: Tea. **10 h**

Unit-2

2. Glycosides :

Saponin glycosides: Liquorice, Ginseng, Dioscorea, Safed Musali, Momordica Cardioactive glycosides: Digitalis, Squill, Anthraquinone glycosides: Aloe, Senna, Hypericum, Cascara Others including Wild Cherry bark, Mustard, Psoralia, Gingko, Gentian. **11 h**

Unit-3

3. Terpenoids :

Monoterpenes and Iridoids: Camphor, Eucalyptus, Lemon grass, Turpentine, Peppermint, Caraway, Coriander, Ajowan, Dill, Fennel, Lemon peel, Nutmeg, Cinnamon, Jatamansi, Garlic, Black pepper, Mentha, Lavendar, Clove, Yew (Taxus), Coleus, Artemisia, Triterpenes and Steriods: General chemistry, Saponins, Liquorice. **9 h**

4. Marine drugs :

Cardio active drugs, cytotoxic drugs, antibiotics drugs, marine toxins. **2 h**

Unit-4

5. Proteins and enzymes : Thaumatin, Papain, Bromelin, Streptokinase.

Resin : Asafoetida, Cannabis, Ginger, Capsicum, Male fern, Podophyllum, Tolu Balsum, Guggul, Boswellia, Shellac, Colophony, Myrrh.

Tannins : Hydrolzable and condensed tannins, Hirda, Behda, Pale catechu, Black catechu, Arjuna, Ashoka. **10 h**

Recommended Books :

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. (W.B. Saunders), 2002. 16th Ed. ISBN-10: 0702029335.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, phytochemistry, medicinal plants. (Lavoisier), 1999.ISBN 1898298637.
3. Rangari V.D., Pharmacognosy and Phytochemistry (Vol I), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-45-5.
4. Rangari V.D., Pharmacognosy and Phytochemistry (Vol II), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-65-3.
5. Quality control methods for medicinal plant materials, (World Health Organization, Geneva), 1998.ISBN 9241545100.
6. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, (Nirali Prakashan, Pune), 2008, ISBN: 8185790094.
7. Seigler David S., Plant Secondary Metabolism, (Kluwer Academic Publishers, Dordrecht, the Netherlands). 1995. ISBN 0-412-01981-7.
8. Francisco A. Macias, Jose L.G. Galindo, Juan C.G. Galindo, Evolution and current status of ecological Phytochemistry, Phytochemistry 68 (2007) 2917–2936.
9. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. (Business Horizons), 2002.ISBN 8190078844.
10. Simon Gibbon et. al. Pharmacognosy and Phytochemistry, (Churchill Livingstone, UK.)
11. Wallis T. E., Textbook of Pharmacognosy. (CBS Publisher and Distributors), 1985.ISBN:81- 239-0886-5.
12. Ashutosh Kar, "Pharmacognosy and Biotechnology" (New Age International Publishers, New Delhi), 2003.
13. Indian Pharmacopoeia 2007, 2014
14. S.S. Agrawal and M. Paridhavi, Herbal Drug Technology, (University Press Publications, New Delhi)

3.1.5 PHARMACOGNOSY-II
(Practical) (3 hrs/week)

Course Objectives :

1. To understand different categories of plant constituents and know their characteristics.
2. To identify the crude drugs on the basis of their morphological characters.
3. To identify the crude drugs on the basis of their microscopical characters.

Course Outcomes :

At the end of the course students shall be able to

1. Understand different categories of plant constituents and know their characteristics.
2. Identify the crude drugs on the basis of their morphological characters.
3. Identify the crude drugs on the basis of their microscopical characters.

Experiments :

1. Macroscopic, Powder and microscopic study of Licorice.
2. Macroscopic, Powder and microscopic study of Rauwolfia.
3. Macroscopic, Powder and microscopic study of Fennel.
4. Macroscopic, Powder and microscopic study of Ephedra.
5. Macroscopic, Powder and microscopic study of Cinnamon.
6. Macroscopic, Powder and microscopic study of Cinchona.
7. Macroscopic, Powder and microscopic study of Kurchi.
8. Macroscopic, Powder and microscopic study of Clove.
9. Macroscopic, Powder and microscopic study of Senna.
10. Macroscopic, Powder and microscopic study of Vasaka.
11. Macroscopic, Powder and microscopic study of Vinca.
12. Macroscopic, Powder and microscopic study of Coriander.
13. Field visits: Visit to industry/ cultivation farm/medicinal plant garden/ processing unit and submission of report thereof.
14. Assignment for market survey on Herbal product.

Recommended Books :

1. Brain K.R. and Turner T.D, The Practical Evaluation of Phytopharmaceuticals, (Wright-Scientechnica, Bristol), 1975.
2. Khandelwal K. R., Practical Pharmacognosy, (Pragati Books Pvt. Ltd., Pune), ISBN 8185790302.
3. Kokate C. K., Practical Pharmacognosy, (Vallabh Prakashan), 1993.
4. Wallis T. E., Practical Pharmacognosy. (J.A. Churchill Ltd., London)-, 1953.

3.1.6 PHARMACEUTICAL JURISPRUDENCE
(Theory) (3 hrs/week) (42 Lecturer)

Course Objectives :

1. To introduce various regulatory authorities to regulate the Pharmacy profession in India
2. To understand different Legislations related to drugs and pharmaceuticals
3. To impart the knowledge of different regulatory authorities for international pharmaceutical market.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the regulatory authorities regulating the Pharmacy profession in India
2. Understand different legislations related to drugs and pharmaceuticals
3. Understand different regulatory authorities for international pharmaceutical market.

Unit-1

1. Legislation to regulate the profession of Pharmacy. The Pharmacy act 1948 **(06h)**
2. Legislation to regulate import, manufacture, distribution & sales of drugs & cosmetics. The Drugs and Cosmetics Act 1940 & rules 1945 & amendments. **(05h)**

Unit-2

3 Legislations to control the advertisements, excise-duty and prices of drugs.

a) The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954.

b) Medicinal & Toilet Preparations Excise Duty Act. 1955.

c) Drug Prices and Control Order 1979. **(05h)**

4. Legislations to control the operations relating to Dangerous Drugs.

a) Dangerous Drugs Act 1930.

b) Poisons Act 1919

c) Opium Act 1978 **(05h)**

Unit-3

5. Legislations affecting pharmaceutical & food industry.

a) Industries (Development & Regulations) Act. 1951

b) Prevention of Food Adulteration Act 1954

c) Shops Establishment Act of Maharashtra State **(05h)**

6. Miscellaneous Acts

a) Consumer Protection Act

b) Prevention of Cruelty to Animals Act

c) Insecticides Act

d) Code of Pharmaceutical Ethics framed by Pharmacy Council of India **(05h)**

Unit-4

7. Introduction to various drug regulatory authorities vis., FDA, WHO, ISO.
Brief Information of agencies of Drug Regulatory affairs in different countries

- U.S. - Food & Drug Administration (FDA)
- Australia- Therapeutic Goods Administration (TGA)
- Europe- European Agency for the Evaluation of Medicinal Products (EMEA)
- Japan-Ministry of Health and Welfare (MHW)
- U.K. (MHRA) **(06h)**

8. Introduction to Indian Patent Regulations, WTO and FDA, Drug Import Export Policy.

a) Introduction of IPR (Patents, Design, Trademarks, Copyrights, Geographical Indications etc)

b) Patent System, Definition of Patent, Criteria for obtaining patent (Novel, Non-obvious Applications) **(05h)**

Recommended Books :

1. Kuchekar B. S., Khadtare A. M., Itkar S. C., Forensic Pharmacy, 6 th Edition, Aug. (Nirali Prakashan). 2006.
2. Mittal B. M.- A Textbook of Forensic Pharmacy, 9 th Edition, (Vallabh Prakashan), 1999
3. James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2 th Edition, (Marcel Decker Inc.)1998
4. Deshpande S. W. -Drugs & Cosmetics Act; 4th Edition;2006
5. Bubharam N. R. - Whatever one should know about patents, 2nd Edition, (Pharma book Syndicate).
6. Guarino Rechard A. – New Drug Approval Process, 3rd Edition, (Marcel Decker), 2004
7. Deshpande S. W. – Drug & Magic Remedies Act, 1954.;2008
8. P. Narayan – Intellectual Property Law, Edition 3rd; (Eastern Law House), 2001.

SEMESTER-VI

3.2.1 MEDICINAL CHEMISTRY-II

(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To integrate structural requirements of drugs with their biological action.
2. To demonstrate the mechanism of action on a molecular basis.
3. To highlight significance of drug metabolism in drug discovery and toxicity.
4. To provide knowledge of therapeutic uses and adverse reactions of various drugs.
5. To apply principles of organic chemistry for synthesizing various clinically significant drugs and optimizing drug delivery.

Course Outcomes :

At the end of the course students shall be able to

1. Describe the metabolic pathways and understand routes of synthesis of clinically important drugs.
2. Conceptualize influence of structure on biological activity of drugs.
3. Explain the uses and adverse reactions of drugs.
4. Suggest chemical approaches to optimize drug delivery.

Unit-1

1. Drug metabolism :

Phase-I metabolic pathways (oxidation, reduction and hydrolysis) and Phase-II (conjugation) metabolic pathways (glucuronic acid conjugation, sulphate conjugation, glycine/glutamine conjugation, glutathione conjugation, acetylation and methylation), significance of drug metabolism studies in drug development. **8 h**

Note : History and general aspects of design and development of the following categories of the drugs including classification, SAR, mechanism of action (biochemical and molecular basis wherever applicable), physico-chemical properties, adverse effects, therapeutic uses and recent developments.

***Synthesis of drugs mentioned in each category.**

2. Drugs used in neurodegenerative diseases :

Antiparkinson agents, Antialzheimer agents. **4 h**

Unit-2

3. CNS depressant drugs :

i) General anaesthetics :

Various stages of anaesthesia and theories of general anaesthesia, pre-anaesthetic medication.

*Synthesis of Ketamine hydrochloride, Methohexital sodium,Thiamylal sodium. **3 h**

ii) Sedative- hypnotics :
Barbiturates and non-barbiturates.

*Synthesis of Barbituric acid, Phenobarbital sodium, Thiopental sodium. **4 h**

iii) Anticonvulsants :
Types of epilepsy
*Synthesis of Phenytoin sodium, Trimethoprim, Phensuximide. **3 h**

Unit-3

4. Local anaesthetic agents :
Various routes of administration of local anaesthetics

*Synthesis of Benzocaine, Procaine hydrochloride, Lignocaine hydrochloride, Dibucaine hydrochloride. **4 h**

5. Psychotherapeutic agents :

i) Antipsychotic agents

ii) Antidepressant agents: Tricyclic antidepressants, MAO inhibitors and selective serotonin reuptake inhibitors

iii) Anxiolytic agents

*Synthesis of Imipramine, Doxepin, Diazepam, Chlorpromazine, Haloperidol, Meprobamate. **8 h**

Unit-4

6. Prodrug concept :
Principles of prodrug design, classification of prodrugs, pharmaceutical, pharmacokinetic and pharmacodynamics applications of prodrugs, limitations and drawbacks. **8 h**

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).
4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .

8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).

3.2.1 MEDICINAL CHEMISTRY-II
(Practical) (3 Hrs/Week)

Course Objectives :

1. To integrate knowledge of organic chemistry for synthesis of medicinal compounds.
2. To analyze the purity of the drug substances by TLC and qualitative tests.
3. To record, analyze and document the results.

Course Outcomes :

At the end of the course students shall be able to

1. Apply principles of organic chemistry for synthesis of intermediates and drugs.
2. Apply TLC technique for monitoring reactions and checking purity of synthesized compounds.
3. Apply principles of qualitative analysis for identification and structural confirmation of synthesized compounds.

Experiments :

A. Synthesis of following compounds

1 2,3-Diphenyl quinoxaline from o-phenylenediamine

2. Dibenzylidene acetone from benzaldehyde and benzophenone
3. p-Nitroacetanilide from acetanilide
4. Benzophenoneoxime from benzophenone
5. Benztriazole from o-phenylenediamine
6. Phenothiazine from diphenylamine
7. 2-Phenyl indole
8. β-napthol benzoate from benzoic acid

B. Qualitative analysis of any 3 synthesized compounds

C. Purity check and reaction monitoring by TLC.

D. Assignment: Recent advancements in therapy of diseases covered in syllabus.

Recommended Books :

1. Vogel, Vogel's Textbook of Practical Organic Chemistry, 3rd Edition, (The English Language Book Society and Longman Group Limited, London).
2. Arthur, Vogel's Elementary Practical Organic Chemistry Small Scale Preparations, 1, 2nd edition, Part I CBS Publications.
3. Mann F C, Saunder B C, Practical Organic Chemistry (The English Language Book Society and Longman Group Limited, London).
4. Textbook of Practical Organic Chemistry, The ELBS, Longman, London.
5. S H Bhosale and K R Mahadik, Textbook of Qualitative Analysis (Nirali Prakashan).
6. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st Edition , (John Wiley and Sons, INC).
7. Ashutosh Kar, Advanced Practical Medicinal Chemistry 1st Edition, (New Age International Publications).

3.2.2 PHARMACEUTICAL ANALYSIS-IV
(Theory) (3 Hrs/Week) (42 Lecrures)

Course Objectives :

1. To impart knowledge about modern instruments in chromatographic analysis with special reference to quality control and quality assurance.
2. To impart knowledge about food analysis.
3. To apply principles of chromatographic techniques for analysis of pharmaceuticals.

Course Outcomes :

At the end of the course students shall be able to

1. Understand and apply principles of chromatographic techniques for qualitative and quantitative determination of pure drug and drug content in dosage forms.
2. Carry out separation of drugs from the mixtures and formulations.
3. Develop problem solving and mathematical approach in chromatographic analysis.
4. Apply the methods of food analysis.

Unit-1

1. Thin layer chromatography (TLC) :
Introduction, principle, technique – types of adsorbents preparation of TLC plate, modes of development, visualization. Method development and applications.

Identification of Amlodipine, Fenofibrate, Meclizine hydrochloride. **8 h**

2. High Performance Thin Layer Chromatography (HPTLC) :
Introduction, instrumentation, detection of spot, scanning, documentation and applications.

Identification of Salbutamol sulphate, Metformin hydrochloride, Nebivolol hydrochloride. **7 h**

Unit-2

3. Food Analysis :
Introduction, legislation, standards and nutrition, analysis of food additives, contaminants, preservatives, fruit and vegetable products, beverages, spices, fermentation products and dairy products. **6 h**

Unit-3

4. High performance liquid chromatography (HPLC) :
Introduction, principle, instrumentation- types of pumps and principle of working, types of columns, column packing materials, commercially available columns, column efficiency, types of sample injectors, detectors, technique -Sample preparation, mobile phase preparation, degassing, column washing, elution and method development), trouble shooting and applications.

Assay of Rabeprazole, Telmisartan, Ranitidine, Captopril. **11 h**

Unit-4

5. Supercritical fluid chromatography (SFC) :
Theory, principle, instrumentation, supercritical fluid extraction and applications.**10 h**

Recommended Books :

1. Douglas A Skoog, Donald M West, F James Holler, Stanley R Crouch, Fundamentals of Analytical Chemistry, 8th Edition, (Indian Edition, Thomson Brooks/Cole)
2. K R Mahadik, H N More, Pharmaceutical Analysis Instrumental Methods (Nirali Prakashan, Pune)
3. Hobart H Willard, L L. Merritt, John A. Dean, Frank A Settle, Instrumental Methods of Analysis, 7th Edition, (CBS Publishers).
4. G R Chatwal, S K Anand, Instrumental Methods of Chemical Analysis (Himalaya Publishing House).
5. B K Sharma, Instrumental Methods of Chemical Analysis (Goel Publishing House).
6. Ashutosh Kar, Pharmaceutical Drug Analysis (New Age International (P) Limited, Publishers)
7. J Mendham, R C Denney, J D Barnes, M Thomas, B Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition,(Pearson).
8. Douglas A Skoog, F James Holler, Stanley R Crouch, Instrumental Analysis, Indian Edition, (Cengage Learning).
9. Gaen W Ewing, Instrumental Methods of Chemical Analysis, 5th Edition, (McGraw Hill Book Company).
10. Ronald S. Kirk and Ronald Sawyer, Person's Composition and Analysis of Foods: (Longman scientific & Technical)
11. R M Verma, Analytical Chemistry Theory and Practice 3rd Edition, (CBS Publishers and Distributors).
12. P D Sethi, HPTLC Quantitative Analysis of Pharmaceutical Formulations (CBS Publishers and Distributors).

3.2.2 PHARMACEUTICAL ANALYSIS-IV
Practical (3 Hrs/Week)

Course Objectives :

1. To learn the working principles of various chromatographic techniques.
2. To perform the separation of drugs from mixture and formulations.
3. Define quality control criterion for food substances.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate principles of separation using chromatographic techniques for qualitative determination of pure drug.
2. Master important chromatographic techniques and separate drugs from mixtures and formulations.
3. Understand and perform basic techniques of food analysis.
4. Record, compute and analyze the data.

Experiments :

1. Preparation of TLC plates.
2. Practicals based on thin layer chromatography (Ascending)
   i) Amino acids (01)
   ii) Sugars (01)
   iii) Drugs & formulations (04)
3. Comparison of TLC and paper chromatography
4. Comparison of effect of particle size of adsorbents on separation (TLC Vs. HPTLC)
5. Demonstration of HPLC
6. Demonstration of HPTLC
7. Food analysis-tests for adulterants in milk
8. Food analysis-tests for adulterants in spices (Turmeric, Clove and Cardamom)
9. Food analysis-tests for adulterants in tea
10. Isolation of components from mixture using preparative TLC
11. Assignment: Recent advancements in instrumentation and hyphenated techniques covered in syllabus.

Recommended Books :

1. J Mendham, R C Denney, J D Barnes, M Thomas, B Sivasankar, Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, (Pearson).

2. Douglas A Skoog, F James Holler, Stanley R Crouch, Instrumental Analysis, Indian Edition, (Cengage Learning).
3. Gaen W Ewing, Instrumental Methods of Chemical Analysis, 5th Edition, (McGraw Hill Book Company).
4. Ronald S. Kirk and Ronald Sawyer, Person's Composition and Analysis of Foods: (Longman scientific & Technical)
5. R M Verma, Analytical Chemistry Theory and Practice 3rd Edition, (CBS Publishers and Distributors).
6. P D Sethi, HPTLC Quantitative Analysis of Pharmaceutical Formulations CBS Publishers and Distributors.

3.2.3 PHARMACEUTICAL TECHNOLOGY-II
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To reinforce concepts of basic powder technology in formulation design.
2. To Give an insight of advanced solid dosage forms.
3. To provide knowledge for selection and evaluation of packaging for pharmaceuticals.

Course Outcomes :

At the end of the course students shall be able to

1. Integrate basics of pharmaceutical engineering and powder technology with formulation and manufacturing of solid pharmaceuticals.
2. Select specialized solid dosage form.
3. Operate quality control equipments for pharmaceuticals.

Unit-1

1. Powders and granules :
Characteristics of powder to process for tablets and capsules, need and mechanism of granulation, mixing equipments and manufacturing, Evaluation of granules. **5 h**

2. Face Powder and Tooth powder :
Concept of formulation design, manufacturing, packaging and evaluation. **3 h**

3. Reconstituted syrups :
Concept of formulation design, manufacturing, flow chart, layout, GMP requirements related to reconstituted syrups. Packaging and Evaluation of reconstituted syrups.**3 h**

Unit-2

4. Tablets :
Types of tablets. Tabletting properties of drug and additives. Tablet formulation: diluents, binders, disintegrants, lubricants, directly compressible filler/binders and other additives. Manufacturing, single punch and rotary tablet machine, flow chart, layout, GMP requirements related compressed tablet and Problems in tabletting and remedies thereof. **6 h**

5. Specialized tablets :
Concept of formulation design of lozenges, chewable, mouth-dissolving, dispersible, sublingual, effervescent tablets. **4 h**

Unit-3

6. Tablet coating :
Reasons for coating, Types of coating: Sugar coat, film coat, compression coating, techniques, equipments. Problems in tablet coating and remedies thereof. **5 h**

7. Packaging and Evaluation of Tablets :

Selection and evaluation of packaging of tablets, Quality control of tablets. **5 h**

Unit-4

8. Capsule :

Raw material for capsule shell, Manufacturing of gelatin for capsule, fabrication of capsule shell, Sizes, standards and defects thereof. Hard Gelatin Capsules: Concept of formulation design, manufacturing, flow chart, layout, GMP requirements. Soft Gelatin Capsules: Concept of formulation design, manufacturing. Defects during capsule filling, Packaging and evaluation of capsules. **7 h**

9. Suppositories :

Physiological consideration, selection of bases, drug related aspects, manufacturing, packaging, evaluation. **4 h**

Recommended Books :

1. Remington: The Science and practice of Pharmacy (Mack Publishing Company).
2. H. C. Ansel, N. G. Prporich, L. V. Allen; Pharmaceutical dosage forms and Drug Delivery Systems (Williams and Wilkins).
3. L. Lachman, H. A. Liberman, J. L. Kanig; The Theory and Practice of Industrial Pharmacy (Verghese Publishing House).
4. Bentley's : Test book of Pharmaceutics (Bailliere Tindal)
5. G. S. Banker, R. K. Chalmers; Pharmaceutics and Pharmacy Practice (J. B. Lippincott Company).
6. M. E. Aulton; Pharmaceutics – The science of dosage form Design (Churchill Livingstone).
7. Atmaram Pawar, Introduction to Pharmaceutics, (Career Publications).
8. J. Swarbrick, J. C. Boylan; Encyclopedia of Pharmaceutical Technology; (Marcel Dekker) the Vol.-I.
9. K. Ridgway: Hard Capsules Development and Technology; (Pharmaceutical Press, London).
10. Liberman, Rieser and Banker, Pharmaceutical Dosage forms, Disperse system, (Marcel Dekker).
11. James J. Wells, Pharmaceutical Preformulation, (Ellis Horwood Ltd.)
12. H.A. Liberman, L. Lachman and J.B. Schwart; Pharmaceutical dosage forms,Tablets, (Marcel Dekker).
13. Ansel and Loyd: Pharmaceutical Dosage Forms and drug delivery systems. (B.I.Waverly).
14. I.R. Berry, R.A. Nash Pharmaceutical Process validation (Marcel & Dekker)
15. D.H. Shah SOP Guidelines (Business Horizons Publishers)
16. Indian Pharmacopoeia.

3.2.3 PHARMACEUTICAL TECHNOLOGY-II
(Practical) (3 Hrs/Week)

Course Objectives :

1. To impart knowledge on the formulation design, manufacturing and evaluation of solid pharmaceuticals.
2. To provide hands on training for manufacturing pharmaceuticals.
3. To demonstrate techniques involved specialized solid pharmaceuticals.

Course Outcomes :

At the end of the course students shall be able to

1. Formulate, manufacture and evaluate solid pharmaceuticals.
2. Interpret quality control parameters.
3. Understand current scenario of solid pharmaceuticals.

Expeiments :

1. Formulation approach: Survey/assignments related to types of marketed solid formulations, composition, containers, labels, expiry period, economy, acceptance drug products, one oral presentation
2. An assignment on design of formulation, selection of process, equipments, packaging, labels for a formulation
3. Formulation design, processing, manufacturing and evaluation of following:

Topics :

1. Powders: (Face powder, Tooth powder, body powder) (02)
2. Granules: Preparation and evaluation of granules (02)
3. Reconstituted syrups (01)
4. Tablets: Paracetamol Tablet (wet granulation), Aspirin tablets (effervescent technique) and direct compression (03)
5. Quality control of marketed tablets: Compressed, coated, Mouth-dissolving, dispersible, effervescent tablets (03)
6. Capsules: (including overages) (02)
7. Suppositories: using natural and synthetic bases (02)
8. Tablet coating: Sugar and film coating (demonstration)

Recommended Books :

1. Remington: The Science and practice of Pharmacy (Mack Publishing Company).
2. H. C. Ansel, N. G. Prporich, L. V. Allen; Pharmaceutical dosage forms and Drug Delivery Systems (Williams and Wilkins).

3. L. Lachman, H. A. Liberman, J. L. Kanig; The Theory and Practice of Industrial Pharmacy (Verghese Publishing House).
4. K. Ridgway: Hard Capsules Development and Technology (Pharmaceutical Press, London).
5. Liberman, Rieser and Banker, Pharmaceutical Dosage forms, Disperse system, (Marcel Dekker).
6. James J. Wells, Pharmaceutical Preformulation, (Ellis Horwood Ltd.)
7. H.A. Liberman, L. Lachman and J.B. Schwart; Pharmaceutical dosage forms,Tablets, (Marcel Dekker).
8. I.R. Berry, R.A. Nash Pharmaceutical Process validation (Marcel & Dekker)
9. D.H. Shah SOP Guidelines (Business Horizons Publishers)
10. Indian Pharmacopoeia.

3.2.6 PHARMACOLOGY- III
(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To understand molecular targets of drug action.
2. To develop competence on evaluating the efficacy and safety profile of drugs.
3. To comprehend the concepts of toxicology.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the molecular basis of drug action.
2. Understand the uses of drugs in various diseases, their adverse effects and drug interactions.
3. Integrate the general management of poisoning and drug toxicity.

Unit-1

1. Basic and Clinical Pharmacology of

a) Sedatives and Hypnotics
b) Antiepileptic drugs
c) Anti-Parkinsonian drugs
d) CNS stimulants and Cognition enhancers **9 h**

Unit-2

2. Basic and Clinical Pharmacology of

a) Drugs used in Mental illness (Psychopharmacological drugs)-Antipsychotic, anti-anxiety, antidepressant, anti-mania drugs
b) General anesthetics
c) Local Anesthetics **12 h**

Unit-3

3. Basic and Clinical Pharmacology of

a) Hisamine and Antihistaminics, Prostaglandins, Leukotrienes (Eicosanoids), Platelet Activating Factor.
b) Opioid analgesics and antagonists
c) Non-Steroidal Anti inflammatory drugs, antipyretics and analgesic drugs
d) Antirheumatoid and Antigout drugs. **11 h**

Unit-4

4. Principles of Toxicology

a) General management of poisoning

b) Signs, Symptoms and treatment of acute and chronic poisoning due to: Barbiturates, Heavy metals (Lead, Mercury, Arsenic), Alcohol, Snake venom and Insecticides **10 h**

Recommended Books :

1. Barar, F.S.K., Essentials of Pharmacotherapeutics (S. Chand and Company, New Delhi)
2. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, (Little Brown and Co, Boston)
3. Crossland, James and Lewis's Pharmacology Basis of Therapeutics, (Pergamon Press, New York)
4. Das, M. M. and Dutta S. K. : R. Ghosh's Modern Concepts on pharmacology and Therapeutics, (HILTON and Co. Calcutta)
5. Goodman and Gilman; Pharmacological Basis of Therapeutics, (McGraw-Hill)
6. Katzung, B.G; Basic and Clinical Pharmacology, (Lange Medical Publisher, USA)
7. Rang, H.P. and Dale, M.M.; Pharmacology, (Churchill Livingston, UK)
8. Satoskar, R.S. and Bhandarkar S.D. Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay).
9. Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts.(Paras Publication)
10. Tripathi K. D. Essentials of Medical Pharmacology VII Edition, (Jaypee Brothers, New Delhi).

3.2.4 PHARMACOGNOSY-III

Theory (3h/week) (42 Lectures)

Course Objectives :

1. To acquaint with the techniques and methods for herbal drug standardization as per WHO guidelines.
2. To understand the biotechnological techniques for obtaining and improving the quality of phytoconstituents.
3. To understand different extraction techniques for separation of phyto-constituents.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the techniques and methods for herbal drug standardization as per WHO guidelines.
2. Understand the biotechnological techniques for obtaining and improving the quality of phytoconstituents.
3. Understand different extraction techniques for separation of phyto-constituents.

Unit-1

1. Analytical Pharmacognosy :
Adulteration of crude drugs and their detection by organoleptic, microscopic, physical, chemical and biological methods. Study in detail organoleptic, microscopic, physical, chemical and biological methods of evaluation of crude drugs with respect to pharmacopoeias. **6 h**

Unit-2

2. Quality control and standardization of crude drugs :
basic concepts of quality control, WHO guidelines for standardization of drugs. **5 h**

3 Medicinal Plant Biotechnology :
History, introduction, Organization of tissue culture laboratory, Totipotency, Nutritional requirement for *in vitro* plant cell growth (Culture media), Types of culture, Cell suspension and Growth parameters. Strategies for enhanced production of phyto-pharmaceuticals from plant cells. Concept of elicitation. **10 h**

Unit-3

4. Drugs of mineral origin:
Asbestos, Bentonite, Calamine, Chalk, Kaolin, Kieselguhr, Talc, Shilajit, Mica. **6 h**

5. Fibers, sutures and surgical dressings:
Study of cotton, jute, flax, silk, wool. **5 h**

Unit-4

7. Extraction :

Introduction to general methods of extraction of different classes of phytochemicals from crude drugs viz. maceration, percolation, Soxhlet extraction, Successive solvent extraction, Supercritical fluid Extraction, Ultrasound-assisted extraction, Microwave-assisted extraction. **5 h**

8. Traditional Drugs :

Study of traditional drugs, their vernacular names, botanical sources, morphology, chemical constituents, uses, drug interactions, toxicities and marketed formulations of following indigenous drugs: Adulsa, Amla, Ashoka, Ashwagandha, Brahmi, Chirayata, Giloy, Gokharu, Guggul, Gudmar, Safed Musli, Shatavari, Tulsi, Vachaa. **5 h**

Recommended Books :

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy.(W.B. Saunders), 2002. 16th Ed. ISBN-10: 0702029335.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, phytochemistry, medicinal plants. (Lavoisier), 1999.ISBN 1898298637.
3. Rangari V.D., Pharmacognosy and Phytochemistry (Vol I), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-45-5.
4. Rangari V.D., Pharmacognosy and Phytochemistry (Vol II), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-65-3.
5. Quality control methods for medicinal plant materials, (World Health Organization, Geneva), 1998.ISBN 9241545100.
6. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, (Nirali Prakashan, Pune), 2008, ISBN: 8185790094.
7. Seigler David S., Plant Secondary Metabolism, (Kluwer Academic Publishers, Dordrecht, the Netherlands). 1995. ISBN 0-412-01981-7.
8. Francisco A. Macias, Jose L.G. Galindo, Juan C.G. Galindo, Evolution and current status of ecological Phytochemistry, Phytochemistry 68 (2007) 2917–2936.
9. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. (Business Horizons), 2002. ISBN 8190078844.
10. Simon Gibbon et. al. Pharmacognosy and Phytochemistry, (Churchil Livingstone, UK.)
11. Wallis T. E., Textbook of Pharmacognosy.(CBS Publisher and Distributors,) 1985.ISBN:81- 239-0886-5.
12. Ashutosh Kar, "Pharmacognosy and Biotechnology" (New Age International Publishers, New Delhi), 2003.
13. Indian Pharmacopoeia 2007, 2014
14. S.S. Agrawal and M. Paridhavi, Herbal Drug Technology, (University Press Publications, New Delhi)

15 Namdeo Ajay G, Medicinal Plant Biotechnology.(Career Publication, Nasik)

3.2.4 PHARMACOGNOSY-III
Practical (3h / week)

Course Objectives :

1. To understand basic of isolation of phytoconstituents.
2. To understand pharmacognostic account of some important secondary metabolite.
3. To analyze quality of herbal drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Extract phyto constitutent from crude drugs by different extraction methods.
2. Understand pharmacognostic account of some important crude drugs.
3. Analyze quality of herbal drugs.

Experiments :

1. Determination of swelling index of mucilage/pectin containing crude drugs.
2. Determination of total alkaloidal content of Nux vomica seeds.
3. Soxhlet extraction, Microwave extraction (Demo), Isolation of phytoconstituents by column chromatography (Demo).
4. Demo of estimation of total tropane alkaloids by UV-visible Spectrophotometer
5. Detection of adulteration in herbal drugs.
6. Extraction caffeine from tea leaves.
7. Extraction of volatile oil by hydro distillation.
8. Extraction and isolation of mucilage of Okra fruits.
9. Extraction of volatile oil by microwave distillation of any crude drug.
10. Determination of ash value of given drug sample.
11. Determination of extractive value of given drug sample.
12. Determination of loss on drying of given sample of crude drug.
13. Field visits: Visit to industry/ cultivation farm/medicinal plant garden/ processing unit and submission of report thereof.
14. Assignment for market survey on Herbal product.

Recommended Books :

1. Brain K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceuticals, (Wright-Scientechnica, Bristol), 1975.
2. Khandelwal K. R., Practical Pharmacognosy, (Pragati Books Pvt. Ltd., Pune), ISBN 8185790302.
3. Kokate C. K., Practical Pharmacognosy, (Vallabh Prakashan), 1993.
4. Wallis T. E., Practical Pharmacognosy. (J.A. Churchill Ltd., London), 1953.

3.2.5 PHARMACEUTICAL BIOTECHNOLOGY

(Theory) (3 Hrs/Week) (42 Lectures)

Course Objectives :

1. To understand and correlate the biological process mediated by principal biomolecules and their significance in regulating complex life functions
2. To emphasize unified nature of the molecular basis of life, units of inheritance and the basis of diversity in life forms
3. To create knowledge base for molecular genetics, cell biology and molecular basis of aetiology and treatment of diseases
4. To study principles of molecular biology for application in drug discovery, diagnosis and action of drugs

Course Outcomes :

At the end of the course students shall be able to

1. Understand the principle and techniques involved in basics of molecular biology
2. Learn the concepts of basic and advance techniques of DNA manipulation
3. Understand the recombinant DNA technology and its applications in pharmaceutical sciences

Unit-1

1. Introduction to Biotechnology and Molecular Biology :

Scope of the Subject, relevance to Pharma Industry, Various Biotechnology based products, rDNA technology, National and International Scenario. Molecular biology concepts with reference to Central Dogma of Molecular Biology, Translation, Transcription. Genomics and evolution, DNA packaging and chromosomes, DNA replication, mutations, Transformation, Transduction and conjugation **6 h**

2. Techniques in molecular Biology :

DNA separation methods, fragmentation, DNA sequencing, DNA hybridization and blotting techniques: Southern blotting, Northern blotting, Western blotting, PCR, DNA finger printing: RAPD, RFLP, cloning, transgenic animals and transgenic plants **5 h**

Unit-2

3. Recombinant DNA technology :

Techniques in DNA recombination, molecular cloning of genes, Processes involved in rDNA technology, enzymes in DNA technology, Plasmid vectors, Bacterial Artificial Chromosomes, Yeast Artificial Chromosomes, expression vectors for recombinant proteins **5 h**

4. Advanced Biotechnological products and techniques :

Application of rDNA technology for production of pharmaceutical products such as Humulin, Somatotropin, Interferons, erythropoietin etc, anti-sense technology and RNAi **5 h**

Unit-3

5. Immunology :

Self-Non-self-Recognition. Factors affecting pathogenicity and infection, Innate defence mechanism – first line of body's defence, physiological phenomena-inflammatory response, Phagocytosis. Cell signalling, MHC, Antigen presentation. cellular mediators; soluble (humoral) mediators, **5 h**

6. Immunological techniques :

Molecular basis of Cell-mediated immunity, Variability of Antibody structure and types, pathways of immune response, Clonal selection theory, Hybridoma technology, production and application of MAb, Immunological techniques like Enzyme Linked Immuno Sorbent Assay, Immuno-fluorescence and flow cytometry, recombinant vaccines **6 h**

Unit-4

7. Enzyme technology :

Enzymes as industrial tools, application of enzymes: protease, amylase, streptokinase etc., Sources of enzymes, Protein engineering, Site-directed mutagenesis, Single cell protein and oil **5 h**

8. Fermentation technology :

Example of products of fermentation (microbial, animal and plant), types of fermenters and Bioreactors (mechanically stirred, air-lift, tray), factors affecting fermentation (inoculum preparation, temperature, pH, media composition, aeration, agitation, antifoam agents, strain optimization, growth kinetics) and down-stream processing. **5 h**

Recommended Books :

1. Olive Kaiser, Rainer Muller, Pharmaceutical Biotechnology: Drug Discovery and Clinical Application, (Wiley VCH publisher), 2004.
2. Peter J. Russel, Genetics 5th Edition, (The Benjamin Cummins Publishing California)
3. Watson W H Freeman and company N. Y. Recombinant DNA 2nd edition (Holtzbrinck Publishers).
4. Gliek, Molecular biotechnology 3rd edition (A S M press Washington, USA).
5. Vyas and Dixit Pharmaceutical Biotechnology, 1st (CBS Publisher New Delhi,).
6. Dr. S. Iganacimuthu, Basic Biotechnology (Tata McGraw Hill Publishers).
7. P.K.Gupta, Elements of Biotechnology, (Rastogi Publication), 10th edition.
8. Kuby, R A Goldsby, T J Kindt B A Osborne Immunology, 6th Edition, (Freeman),
9. Brostoff J, Seaddin J K, Male D, Roitt I M, Clinical Immunology, 6th Edition, (Gower Medical Publishing).
10. Paul, Fundamentals of Immunobiology, 4th Edition, (Lippencott Raven, 1999).
11. K. Sambamurthy, Ashutosh Kar, Pharmaceutical Biotechnology, 2nd edition (New AGE International (LP) Limited).

3.2.5 PHARMACEUTICAL BIOTECHNOLOGY
(Practical) (3 Hrs/Week)

Course Objectives :

1. To study of properties of important biomolecules such as DNA and RNA
2. To study separations methods like agarose gel electrophoresis and visualization.
3. To study various techniques of DNA handling and manipulation such as restriction digestion, ligation and PCR amplification.
4. To study different aspects of industrial use of enzymes and whole cells immobilization

Course Outcomes :

At the end of the course students shall be able to

1. Learn about techniques of DNA and plasmid isolation.
2. Learn how to run a horizontal agarose gel electrophoresis to analyze and visualize DNA and RNA
3. Understand basics of DNA manipulation like restriction digsation and ligation.
4. Carry out DNA amplification through PCR using specific and random primers
5. Enzymes in free and immobilized form

Experiments :

1. DNA gel electrophoresis (06)
2. Isolation of Plasmid DNA from bacteria
3. Restriction of DNA (05)
4. DNA ligation
5. PCR using random primers
6. PCR using gene specific primers
7. Enzyme immobilization

Recommended Books :

1. Olive Kaiser, Rainer Muller, Pharmaceutical Biotechnology: Drug Discovery and Clinical Application, (Wiley VCH publisher).
2. Peter J. Russel, Genetics 5th Edition, (The Benjamin Cummins Publishing California).
3. Watson W H Freeman and company N. Y. Recombinant DNA 2nd edition (Holtzbrinck Publishers).
4. Gliek, Molecular biotechnology 3rd edition (A S M press Washington, USA).
5. Vyas and Dixit Pharmaceutical Biotechnology, 1st (CBS Publisher New Delhi).
6. Dr. S. Iganacimuthu, Basic Biotechnology (Tata McGraw Hill Publishers).
7. P.K.Gupta, Elements of Biotechnology, (Rastogi Publication), 10th edition.
8. Kuby, R A Goldsby, T J Kindt B A Osborne Immunology, 6th Edition, (Freeman).
9. Brostoff J, Seaddin J K, Male D, Roitt I M, Clinical Immunology, 6th Edition, (Gower Medical Publishing).
10. Paul, Fundamentals of Immunobiology, 4th Edition, (Lippencott Raven).
11. K. Sambamurthy, Ashutosh Kar, Pharmaceutical Biotechnology, 2nd edition (New AGE International (LP) Limited).

SEMESTER–VII

4.1.1 MEDICINAL CHEMISTRY- III

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To study basic principles of chemotherapy and recent advancements therein.
2 To provide knowledge of drug metabolism, physico-chemical properties and structure activity relationships.
3. To provide knowledge of therapeutic uses and adverse reactions of various drugs.
4 To apply principles of organic chemistry for synthesizing clinically significant drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the principles of chemotherapy.
2. Describe the synthesis of important drugs.
3. Demonstrate influence of structural modification of drugs on the physic-chemical properties and biological activity.
4. Demonstrate the uses and adverse reactions of drugs belonging to different classes.

Note : History and general aspects of design and development of the following categories of the drugs including classification, SAR, mechanism of action (biochemical and molecular basis wherever applicable), physico-chemical properties, adverse effects, therapeutic uses and recent developments.

*** Synthesis of drugs mentioned in each category.**

Unit-1

1. Synthetic antibacterial agents :

Topical and systemic antibacterial agents

*Nitrofurazone, Nitrofurantoin, Furazolidone and Hexyl resorcinol. **04 h**

2. Antiprotozoal agents :

i) Antimalarials :

Life cycle of malarial parasite, natural products: cinchona alkaloids and artemisinin, synthetic antimalarials : 4- amino quinolines, 8- amino quinolines and 9-amino acridines, DHFR inhibitors, combination therapy.

*Pyrimethamine, Chloroquine, Hydroxychloroquine, Amodiaquine, Primaquine, Choloroguanide, Quinacrine.

ii) Antiamebic agents :

Introduction to amebiasis and chemotherapy.

*Iodoquinol, Diloxanide, Metronidazole, Tinidazole.

iii) Drugs acting against trypanosomiasis and leishmaniasis.

iv) Anthelmintics:

Introduction to helminthiasis, classification of helminths, and treatment

*Mebendazole, Albendazole, Thiabendazole, Niridazole, Piperazine, Diethylcarbamazine, Pyrantel, Niclosamide, Bephenium and Bithionol. **08h**

Unit-2

3. Antimycobacterial agents :

Mycobacteria, nature of the disease, laboratory models for screening drugs, and chemotherapy

i) Antitubercular agents :

Introduction to tuberculosis.

*Isoniazid, Ethambutol, Pyrazinamide, Ethionamide and Paramino salicylic acid.

ii) Antileprotic agent :

Introduction to leprosy.

*Dapsone and their derivatives. **04 h**

4. Antiviral agents :

General aspects, classification of viruses, agents interfering with nucleic acid replication including those with modification with bases , sugars and phosphate, amantidine and its analogs, interferon and its inducers, nuraminidase inhibitors, antiretroviral drugs and protease inhibitors.

*Amantadine. **02 h**

5. Antineoplastic agents :

Introduction to neoplasm, classification of antineoplastic agents, DNA alkylating agent, antimetabolites including DNA polymerase inhibitors, pyrimidine and purine antagonists and miscellaneous agents, natural products (Antibiotics,enzymes). mitosis inhibitors, hormones and miscellaneous agents.

*Methotrexate, Thioguanine, Fluorouracil, Mechlorethamine, Chlorambucil, Melphalan, Cyclophosphamide, Thiotepa, Busulfan, Lomustine, Mitotane and Procarbazine. **05 h**

Unit-3

6. Sulfonomides :

Short, intermediate and long acting sulfonamides, sulfonamides for ophthalmic infections, burn therapy and intestinal infections, ulcerative colitis and reduction of bowel flora, combination therapy.

*Sulfadiazine, Sulfaguanidine, Sulfamerazine, Sulfamethoxazole, Sulfadoxine, Sulfapyridine, Sulfacetamide, Trimethoprim. **05 h**

7. Quinolones :

Floroquinolones

*Nalidixic acid , Ciprofloxacin and Norfloxacin **02 h**

8. Antifungal agents :

Fungal disease, antifungal agents and novel approaches to antifungal therapy, Azoles, polyene antibiotics, griseofulvin and miscellaneous agents

*Miconazole, Clotrimazole, Ketokonazole, Flucanazole,Terbinafine and Tolnaftate. **02 h**

Unit-4

9. Antibiotics :

Introduction, classification, Beta lactam antibiotics: (Penicillins and Cephalosporins), Aminoglycosides, Tetracyclins, Macrolides, Lincomycins, Polypeptides, Lactamase inhibitors and Unclassified antibiotics (Chloramphenicol, Cephalexin).

*Chloramphenicol, 6-Amino penicillanic acid, Methicillin, Oxacillin, Amoxicillin, Carbenicillin, Cefalotin and Cepapirin. **10 h**

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).
4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .
8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).

4.1.1 MEDICINAL CHEMISTRY-III
Practicals(3 Hrs/Week)

Course Objectives :

1. To synthesise medicinal compounds and drug intermediates by simple chemical reactions.
2. To confirm structure of synthesized compounds by spectral analysis (IR, UV).
3. To carry out the monograph analysis of the medicinal compounds and assess the quality of the product.
4. To determine important physico-chemical parameters experimentally.

Course Outcomes :

At the end of the course students shall be able to

1. Apply principles of organic chemistry for synthesis of intermediates and drugs.
2. Apply principles of qualitative and spectral analysis for identification and structural confirmation of synthesized compounds.
3. Compute, analyze and record the observations.

Expriments :

1. **Synthesis of following (Any Six)**
   - i) Benzillic acid from benzil
   - ii) Phthalimide from phthalic anhydride
   - iii) Anthranilic acid from phthalic anhydride
   - iv) o Todo benzoic acid from anthranilic acid
   - v) 2- Hydroxy 4- methyl quinoline from acetoacetanilide
   - vi) Methyl paraben from p-hydroxy benzoic acid
   - vii) Sulfanilamide
2. IR and UV spectral analysis of synthesized compounds (any five).
3. Carry out the monograph of a drug from course content.
4. **Assignment:** Recent advancements in therapy of diseases covered in syllabus.

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).

4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .
8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).

4.1.2 PHARMACEUTICAL TECHNOLOGY-III
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To understand significance of aseptic techniques in sterile formulations
2 To provide knowledge of selection of excepients and containers for parenterals
3. To evaluate the formulation as per standards
4 To emphasize on importance on cGMP in sterile formulations.

Course Outcomes :

At the end of the course students shall be able to

1. Apply the concept of physicochemical, biopharmaceutical and therapeutic aspects in formulation design.
2. Design formulation, select appropriate processes and equipment for the manufacturing of sterile formulations.
3. Follow cGMP practices in carrying out the manufacturing controlled areas
4. Carry out quality control evaluation of sterile preparations

Unit-1

1. Concept of formulation design of sterile products :
Physicochemical, therapeutic, biopharmaceutical parameters, parenteral routes of drug administration. **03 h**

2. Design considerations of parenterals :
Batch and continuous operation. Area planning, study of layout of parenteral section considering floor plans - single , double and quadruple filling areas, environmental control zones. Utility distribution systems - Oxygen, nitrogen, deionized /sterile water. Air treatment -HVAC systems, HEPA filters testing and rating, Water treatment. Clean in place and steam in place systems. **07 h**

Unit-2

3. Formulation of Small Volume Parenterals :
Formulation principles, Drug, vehicles and additives. Solutions, specialized parenterals- suspensions , emulsion, dry powders ready for reconstitutions , freeze dried products. Isotonicity- sodium chloride equivalency test , L-iso test. Endotoxins and methods used to detect and remove pyrogens.Container selectionfor SVP. **06 h**

4. Evaluation of sterile products :
Content uniformity, isotonicity, Leak test, Clarity test, pyrogen testing, Sterility tests and other pharmacopoeial tests. **03 h**

5. Stability evaluations and protocols **02 h**

Unit-3

6. Large volume Parenterals :

Concept of Formulation, physiological and physicochemical parameters, manufacturing, layout, Formulations as electrolytes , carbohydrates, nutritional solutions and TPNs , IV admixtures , dialysis fluids. Packaging parameters, processing conditions affecting formulation of LVP. **05 h**

7. Ophthalmic Products :

Development of ophthalmic formulation, absorption of drug from eye. . Irrigating Solutions, solutions, suspensions, gels, ointment and contact lens solutions. **05 h**

Unit-4

8. Blood and biological products :

Constituents of blood, plasma and its fractions, Concentrated RBC, plasma substitutes biological products- insulin and thyroxin **03 h**

9 Radio pharmaceuticals :

Concept, formulations, closures and containers, QC of formulations. **02 h**

10 Packaging of Parenterals :

Selection of container: Glass, plastic. FFS technology, Elastomeric closures: vial closures and syringe plungers. Classification of elastomers. Rubber additives and compounding. Testing of elastomers. Product-packaging interactions. Evaluation of containers and closures as per pharmacopoeia. **04 h**

11 Use of controlled drug delivery systems in parenterals :

Proteins and peptides, niosomes, liposomes and erythrosomes, sustained release parenteral formulations. **02 h**

Recommended Books :

1. K.E. Avis, H.A. Liberman and L. Lachman: Pharmaceutical dosage forms: Parenteral Medications, (Marcel Dekker)
2. P. Tyle, Drug delivery system; (Marcel Dekker)
3. I.R. Berry, R.A. Nash Pharmaceutical Process validation; (Marcel & Dekker)
4. J.Swarbrik, J. Boylan; Encyclopedia of Pharmaceutical Technology, (Marcel Dekker
5. D.H. Shah SOP Guidelines; (Business Horizons Publishers)
6. Indian Pharmacopoeia
7. ME Aulton,Pharmaceutics, (Inform Healthcare).
8. Banker and Rodes,Modern Pharmaceutics, (Informa Healthcare).

4.1.2 PHARMACEUTICAL TECHNOLOGY-III

Practicals (3 Hrs/Week)

Course Objectives :

1. To impart knowledge of importance of aseptic techniques in sterile formulations
2. To provide knowledge of selection of excepients and containers for parenterals
3. To evaluate the sterile formulations.
4. To emphasize on importance on cGMP in sterile formulations

Course Outcomes :

At the end of the course students shall be able to

1. Apply the concept of physicochemical, biopharmaceutical and therapeutic aspects in formulation design .
2. Design formulation , select appropriate processes and equipment for the manufacturing of sterile formulations.
3. Follow cGMP practices in carrying out the manufacturing in an environmental controlled areas

Experiments :

1. Pharmacopoeial evaluation of glass and plastic containers, and rubber closures used for injectables. 5 expt

2. Preformulation of drug and additives. Raw material analysis of NaCl, dextrose ascorbic acid , sodium thiosulphate , calcium gluconate , 2 expt

3. Assignment based on

a) Layout design of a parenteral section
b) Schematic presentation of water treatment
c) Schematic presentation of air treatment.
d) To study environment control area

4. Preparation and evaluation of following (9 preparations)

a) Sterile water for Injection,
b) Ascorbic Acid Injection,
c) Atropine Sulphate Injection,
d) Calcium Gluconate Injection,
e) Intraperitoneal dialysis fluid,
f) Sodium chloride and Dextrose infusion,
g) Ringer and Ringer lactate solution,
h) Dextrose 5 % solution,
i) TPN

j) Chloramphenicol / tetracycline eye drops

k) Ciprofloxacin eye ointment

Recommended Books :

1. Recommended Books
2. K.E. Avis, H.A. Liberman and L. Lachman: Pharmaceutical dosage forms: Parenteral Medications, (Marcel Dekker)
3. P. Tyle, Drug delivery system; (Marcel Dekker)
4. I.R. Berry, R.A. Nash Pharmaceutical Process validation; (Marcel & Dekker)
5. J.Swarbrik, J. Boylan; Encyclopedia of Pharmaceutical Technology, (Marcel Dekker
6. D.H. Shah SOP Guidelines; (Business Horizons Publishers)
7. Indian Pharmacopoeia
8. ME Aulton,Pharmaceutics, (Inform Healthcare).
9. Banker and Rodes,Modern Pharmaceutics, (Informa Healthcare).

4.1.3 BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge about absorption, distribution, metabolism and elimination process and factors affecting it.
2. To provide concept of different pharmacokinetic compartment models.
3. To understand computation of pharmacokinetics parameters through compartmental modelling approach.
4. To impart knowledge of the bioavailability/ bioequivalence studies through statistical design

Course Outcomes :

At the end of the course students shall be able to

1. Apply biopharmaceutical properties of drug in dosage form design.
2. Derive the pharmacokinetic parameters by applying compartmental modelling concepts.
3. Integrate the pharmacokinetic parameters in clinical studies.
4. Design protocols in conduct of bioavailability/ bioequivalence studies

Unit-1

1. **Introduction to Biopharmaceutics and Pharmacokinetics, concepts and applications.**
   Absorption of drugs:
   Definition, structure of cell membrane and composition, mechanisms of gastrointestinal absorption, factors affecting absorption: physicochemical, pharmaceutical and patient related factors. Methods of determining absorption: In vitro and in vivo models **09 h**
2. **Distribution of drugs :**
   General principles, physiological barriers to distribution, factors affecting distribution and volume of distribution **02**

Unit-2

3. **Protein binding of drugs :**
   Factors affecting, significance and kinetics of protein/tissue drug binding
4. **Metabolism of drugs :**
   Definition, brief overview of Phase I and Phase II reactions. Factors affecting biotransformation. **06 h**

5. Excretion of drugs:

Definition, renal and non renal excretion, factors affecting excretion and dose adjustment in renal failure. Concept of renal clearance, organ clearance, first pass effect and extraction ratios. **04 h**

Unit-3

6. Basic concepts of Pharmacokinetics :

Plasma concentration time profile, mathematical expressions for zero, first, second order reactions and their applications to biological systems, introduction to Laplace transformation, approximate integration including Trapezoidal rule and various types of graphical representations. **02 h**

7. Compartmental modeling :

Concept of compartmental models and its significance. Determination of various one compartment pharmacokinetic parameters of drug after intravenous bolus, infusion and extravascular administration after single dose oral administration, determination of absorption rate constant and elimination rate constants and other parameters using residual method and Wagner Nelson method. Multi compartment model in brief. **09 h**

Unit-4

8. Non Compartmental Analysis :

Introduction, Statistical moment's theory, are under curve (AUC) & area under the first-moment curve (AUMC) Nonlinear Pharmacokinetics. Introduction, factors causing Non-linearity. **04 h**

9. Bioavailability and bioequivalence :

Introduction, absolute and relative bioavailability, study design and methods of assessing bioavailability, significance of bioavailability studies in animals, methods of enhancing bioavailability. In vitro dissolution testing models, in vitro in vivo correlation, Bioequivalence study parameters and study protocols, Latin square and cross over design.

Note : Problems based on pharmacokinetics and compartmental modeling. **06 h**

Recommended Books :

1. D.M. Brahmankar, S.B. Jaiswal, Biopharmaceutics and Pharmacokinetics Treatise; (Vallabh Prakashan).
2. J.B. Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability; (K. Karger Publication).
3. Rowland & Tozer, Lea & Febriger, Clinical Pharmacokinetics: Concepts and applications.
4. ME Aulton, Pharmaceutics the science of dosage forms, (Elsveir).
5. Banker and Rhodes Modern Pharmaceutics, (Informa Healthcare).
6. Kulkarni JS and Atmaram Pawar, Text Book of Biopharmaceutics, (CBS Publications).

4.1.3 BIOPHARMACEUTICS AND PHARMACOKINETICS (Practicals) (3Hrs /Week)

Course Objectives :

1. To understand effect of physicochemical factors affecting drug bioavailability.
2. To impart knowledge about absorption, distribution, metabolism and elimination process.
3. To provide the concept of bioavailability/ bioequivalence.

Course Outcomes :

At the end of the course students shall be able to

1. Estimate effect of physicochemical parameters on bioavailability of drug.
2. Apply principles of absorption, distribution, metabolism and elimination of drugs.
3. Determine the bioavailability/ bioequivalence parameters.

Experiments :

1. Improvement of dissolution characteristics of slightly soluble drugs (2 methods)
2. Influence of polymorphism on solubility and dissolution.
3. In vitro absorption studies (2 experiments)
4. Protein binding studies of a highly and poorly protein bound drug.
5. Concentration dependent plasma-protein binding studies for highly and poorly protein bound drugs.
6. Time dependent plasma-protein binding studies of drugs.
7. Estimation of Ka, Ke, t1/2, Cmax, AUC, AUMC, MRT etc. from blood profile data using semilog plot
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10 Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
11. Determination of renal clearance.
12. Assignment on absorption, distribution, metabolism and elimination

Recommended Books :

1. D.M. Brahmankar, S.B. Jaiswal, Biopharmaceutics and Pharmacokinetics Treatise; (Vallabh Prakashan).
2. J.B. Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability; (K. Karger Publication).
3. Rowland & Tozer, Lea & Febriger, Clinical Pharmacokinetics: Concepts and applications.
4. ME Aulton, Pharmaceutics the science of dosage forms, (Elsveir).
5. Banker and Rhodes Modern Pharmaceutics, (Informa Healthcare).
6. Kulkarni JS and Atmaram Pawar, Text Book of Biopharmaceutics, (CBS Publications).

4.1.4 PHARMACOGNOSY IV

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge on drug discovery and development from natural products
2. To familiarize with different applications of phytoconstituents.
3. To promote safe use of medicinal plants and phytopharmaceuticals, herbal cosmetics and their formulations.

Course Outcomes :

At the end of the course students shall be able to

1. Understand different aspects of drug discovery and development from natural products.
2. Understand the different applications of phytoconstituents.
3. Safe use of medicinal plants and phytopharmaceuticals, herbal cosmetics and their formulations.

Unit-1

1. Herbal cosmetics :

Introduction, skin and hair care products, hygiene products, production and their quality control including Indian Standards Institution (ISI). Cosmetic potential of Aloe, Haldi, Neem, Chandan, Shikakai, Henna and Cucumber **05 h**

2. Natural products as :

a] Oral bioavailability enhancers

b] Skin permeation enhancers

c] Radiation protection agents

d] Natural products used in wound management

e] Immunomodulators **05 h**

Unit-2

3. Nutraceuticals :

Definition, role of Nutraceuticals, classification, functional food, dietary supplements, Dietary Supplement and Health Education Act (DSHEA), food guide pyramid, pre and pro-biotic, Antioxidants and Plant Nutraceuticals including lycopene, lutein, alpha linolenic acid, resveratrol, grapeseed , soya isoflavones, tea catechins, cocoa, flaxseed, olive, spirulina **06 h**

4. Herbal drug regulatory affairs :

Different regulatory bodies and laws, regulations related to herbal drugs. Role of Ayurved, Yoga, Unani, Siddha and Homeopathy (AYUSH), Schedule T, Salient features of Indian Herbal Pharmacopoeia 2007. The Food Safety and Standard Authority of India (FSSAI), 2010. **05 h**

Unit-3

5. Drug discoveries from natural sources :

Target selection, lead optimization, high throughput screening, biological assays, and examples of drug and new leads from natural products. Process of development and launch of herbal formulation in market **05 h**

6. Natural products used as Pharmaceutical excipients and of allied industrial utility

a] Natural coloring and flavoring agents

b] Natural sweeteners

c] Plant bitters

d] Natural pesticides

e] Natural liver tonic **05 h**

Unit-4

7. Natural products as Phytopharmaceuticals :

Introduction and therapeutic profile of following phytopharmaceuticals: Digoxin Guggulipids, Boswellic acids, Resveretrol. Plants containing anticancer agents in current use: Vinca, Taxus, Podophyllum, Camptotheca **08 h**

8. Pharmacovigilance of herbal drugs :

Herb-drug interactions, herb-food interactions, side effects and toxicities of important herbal drugs. **03 h**

Recommended Books :

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. (W.B. Saunders), 2002. 16th Ed. ISBN-10: 0702029335.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, phytochemistry, medicinal plants. (Lavoisier), 1999.ISBN 1898298637.
3. Rangari V.D., Pharmacognosy and Phytochemistry (Vol I), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-45-5.
4. Rangari V.D., Pharmacognosy and Phytochemistry (Vol II),(Career Pub., Nashik), 2009, ISBN: 978-81-88739-65-3.
5. Quality control methods for medicinal plant materials, (World Health Organization, Geneva), 1998.ISBN 9241545100.
6. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, (Nirali Prakashan, Pune), 2008, ISBN: 8185790094.
7. Seigler David S., Plant Secondary Metabolism, (Kluwer Academic Publishers, Dordrecht, the Netherlands). 1995. ISBN 0-412-01981-7.
8. Francisco A. Macias, Jose L.G. Galindo, Juan C.G. Galindo, Evolution and current status of ecological Phytochemistry, Phytochemistry 68 (2007) 2917–2936.

9. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. (Business Horizons), 2002.ISBN 8190078844.
10. Simon Gibbon et. al. Pharmacognosy and Phytochemistry, (Churchil Livingstone, UK).
11. Wallis T. E., Textbook of Pharmacognosy. (CBS Publisher and Distributors), 1985.ISBN:81- 239-0886-5.
12. "Pharmacognosy and Biotechnology" Ashutosh Kar, (New Age International Publishers, New Delhi), 2003.
13. Indian Pharmacopoeia 2007, 2014
14. S.S. Agrawal and M. Paridhavi Herbal Drug Technology, (University Press Publications, New Delhi)

4.1.4 PHARMACOGNOSY-IV
Practical (3h / week)

Course Objectives :

1. To understand principles of herbal cosmetic formulation.
2. To understand pharmacognostic account of some important secondary metabolite.
3. To analyze quality of herbal drugs.

Course Outcomes :

At the end of the course students shall be able to

1. Formulate and evaluate herbal cosmetics.
2. Understand pharmacognostic account of some important crude drugs.
3. Analyze quality of herbal drugs.

Practicals :

1	Determination of swelling index of mucilage/pectin containing crude drugs.	01
2	Assignment on preparation of Herbal Monograph.	01
3	Introduction, preparation and evaluation of ayurvedic dosage form asava, arishta.	01
4	Preparation of herbal cosmetics for hair care (Shampoo, hair oil etc.).	01
5	Quality evaluation of hair care cosmetic products (Shampoo, hair oil etc.).	01
6	Preparation of herbal cosmetics skin care (face pack, lotion, cream).	01
7	Quality evaluation of skin care cosmetic products (face pack, lotion, cream).	01
8	Study of some nutraceuticals.	01
9	Macroscopic, Powder and microscopic study of natural sweetner (Licorice).	01

10 Macroscopic, Powder and microscopic study of plant bitters (Kalmegh/ chirata). 01

11 Determination of swelling index, foaming index, crude fiber content. 01

12 Determination of total phenolic content/ total flavanoids content/ total tannin content 01

13 Field visits: Visit to medicinal plant garden/ processing unit and submission of report thereof. 01

14 Assignment for market survey on Herbal product. 01

Recommended Books (Practical) :

1. Brain K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceuticals, Wright-Scientechnica, Bristol, 1975.
2. Khandelwal K. R., Practical Pharmacognosy, Pragati Books Pvt. Ltd., Pune, ISBN 8185790302.
3. Kokate C. K., Practical Pharmacognosy, Vallabh Prakashan, 1993.
4. Wallis T. E., Practical Pharmacognosy. J.A. Churchill Ltd., London, 1953.

4.1.5 PHARMACEUTICAL ANALYSIS – V
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge about basic concepts of spectroscopy
2. To make familiar with different spectroscopic techniques and their applications in modern analysis

Course Outcomes :

At the end of the course students shall be able to

1. Understand the basic principles of spectroscopy.
2. Apply spectroscopic techniques for structural elucidation and analysis of pharmaceuticals.
3. Apply the knowledge for problem solving approach.

Unit-1

1. Electromagnetic radiation (EMR) :
Theory, electromagnetic spectrum and interaction of EMR with matter. **5 h**

2. Types of spectroscopic techniques. General components of spectroscopic instruments, radiation sources, wavelength selectors, sample cells, radiation detectors, signal processor and read out devices. **3 h**

Unit-2

3. Ultraviolet and visible spectroscopy :
Fundamental laws of absorption, theory of UV – Visible spectroscopy, instrumentation, applications : Spectrophotometric titrations, Woodward Fieser Rule and derivative spectroscopy. Problems based on UV-Visible spectra. **12 h**

Unit-3

4. Infrared spectroscopy :
Basic principle, theory, instrumentation, Fourier Transform Infrared (FTIR) spectroscopy, applications, important spectral regions and basics of interpretation of IR spectrum. Overview of Raman spectroscopy , Comparison of IR with Raman spectroscopy. Problems based on IR spectra . **12 h**

Unit-4

5. Nephelometry and turbidimetry :
Introduction, instrumentation, turbidimetric titrations and applications . **4 h**

6. Fluorimetry and phosphorimetry :
Molecular luminescence, fluorescence and phosphorescence, measurement of fluorescence, factors affecting fluorescence, quantitative aspects of fluorescence,

excitation and emission spectra, instrumentation, advantages and disadvantages, applications, synchronous fluorescence, spectroflourimetry. **6 h**

Recommended Books :

1 H.N.More, K.R. Mahadik & A.V. Kasture, Principles of Pharmaceutical Analysis, Vol-I & II NiraliPrakash, Pune.

2 B.K.Sharma, Instrumental Methods of Chemical Analysis (Goel Publishing house)

3 Donald L. Pavia, Gary M Lampman, George S. Kriz, Introduction to Spectroscopy (Thomson/Brooks Cole).

4 Willard, Merrit, Instrumental Methods of Analysis (CBS Publishers and Distributors)

5 Douglas, A Skoog, Saunders, Principles of Instrumental Analysis, (Golden Sunburst Series)

6 L.G.Chatten, A Text – book of Pharmaceutical Chemistry, Vol.I and II, (Marcel Dekker, New York)

7 G.W.Ewing, Instrumental Methods of Chemical Analysis (McGraw-Hill Book Company)

8 I.R. Dyer, Applications of Absorption Spectroscopy of Organic Compounds, (Prentice Hall Inc.)

9 William, Organic Spectroscopy: (English Language Book Society, Mc Milan)

10 James W. Munson , Pharmaceutical Analysis : Modern Methods, (Dekker)

4.1.6 CLINICAL PHARMACY
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To monitor drug therapy of patient through medication chart review and clinical review.
2. To obtain medication history interview and counsel the patients.
3 To identify and resolve drug related problems.
4 To detect, assess and monitor adverse drug reaction.
5 To interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states.
6 To retrieve, analyze, interpret and formulate drug or medicine information

Course Outcomes :

At the end of the course students shall be able to

1. Reviewing patient's clinical data and solving patient's medication related problems.
2. Provide drug information to community and all healthcare professionals.
3. Manage, assess and report adverse drug reactions.
4 Interpret laboratory data with respect to each disease and therapy outcomes, ultimately leading to patient benefits in terms of positive clinical outcomes.

Unit-1

1. Definitions, development and scope of clinical pharmacy **2 h**
2. Activities of a clinical pharmacist

a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
b. Ward round participation
c. Medication history
d. Patient counseling
e. Drug utilization evaluation (DUE) and review (DUR)
f. Quality assurance of clinical pharmacy services
g. Medication errors. **9 h**

Unit-2

3. Medical Terminology :
Understanding common medical abbreviations and terminologies used in clinical pharmacy **1 h**

4. Principle & Significance of Clinical laboratory tests :
a. Haematological, Liver function, Renal function, thyroid function tests

b. Tests associated with cardiac disorders
c. Fluid and electrolyte balance
d. Microbiological culture sensitivity tests **8 h**

Unit-3

5. 5. Drug & Poison information

a. Introduction to drug information resources available
b. Systematic approach in answering DI queries
c. Critical evaluation of drug information and literature
d. Preparation of written and verbal reports
e. Establishing a Drug Information Centre
f. Poisons information- organization & information resources **6 h**

6 Pharmacovigilance

a Scope, definition and aims of pharmacovigilance
b Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
c Reporting, evaluation, monitoring, preventing & management of ADRs
d Role of pharmacist in management of ADR. **6 h**

Unit-4

7. Essential drug concept & Rational drug therapy. :

Role of Pharmacist. **3 h**

8. Design & Conduct of Clinical Trials :

a. Brief introduction to phases of clinical trials
b. ICH & GCP guidelines
c. Role of clinical pharmacist in clinical trials. **7 h**

Recommended Books :

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 A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathietal, (Orient Langram Pvt.Ltd.) ISSBN8125026
3 Tipnis& Bajaj's Clinical Pharmacy, (Career Publication, Nasik)
4 Basic skills in interpreting laboratory data - Scott LT, (American Society of Health System Pharmacists Inc.)
5 Textbook of Clinical Trails, edited by David machine, Simon Day & Sylvan Green, March 2005, (Jon Wiley & sons.)
6 Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, (Prentice Hall publication)
7 SHPA Guidelines

4.1.7 SOFT SKILLS
(Practicals) (3 Hrs/Week)

Course Objectives :

1. To provide basic knowledge of soft skills to students which are required for successful career.
2. To train students to develop overall soft skills, to be competitive in career development

Course Outcomes :

At the end of the course students shall be able to

1. Prove them competitive to meet the challenges in their career.
2. Learn overall soft skills required for career development

(Methodolgy :- Below mentioned practicals may be imparted by using Movie clips, games, examples, story / sharing questionnaire /role play/ exercise/task, video / audio recording, group discussion, role play etc.)

Practicals :

1. **Effective Communication :**
   Components of effective communication- Conviction, confidence & enthusiasm, listening communication process & handling them, KISS (keep it short & simple) in communication – composing effective messages, Barriers to communication- Int. & Ext Barriers :- Intrinsic motivation, perception, language, fear power of speech etc. Listening -it's importance, Good and bad listening, Non-verbal communication – its importance and nuances :- Facial expression, posture, gesture, eye contact and Grooming

2. **Self &Time Management :**
   Self Management: Self evaluation, self discipline, self criticism, recognition of one's own limits and deficiencies. Independency etc., Thoughtful & responsible Self awareness, *SWOT analysis, planning, & goal setting managing self –emotions, ego, pride.

   Time Management: Practice by game play and other learning methodology for achieving targets and getting of right first time. Time Management concept, attendance, discipline & punctuality act in time on commitment, Quality /Productive time

3. **Interpersonal Skill Development :**
   Positive relationship, positive attitudes, empathise: Comprehend other opinions points of views, and face them with understanding, mutuality, Trust, Emotional bonding, handling Situations (Interview) and Team building

Recommended Books :

1. Fredrick H. Wentz , Soft skills Training – A workbook to develop skills for employment
2. Barun K. Mitra, Personality Development and Soft skills , (Oxford University Press)
3. R. Alec Mackenzie, The Time Trap : the Classic book on Time Management
4. Rajiv K. Mishra,Personality Development (Rupa & Co.)

SEMESTER–VIII

4.2.1 MEDICINAL CHEMISTRY-IV

(Theory) (3 h/Week) (42 lectures)

Course Objectives :

1. To correlate structure with biological activity of drug.
2. To provide knowledge of drug metabolism, physico-chemical properties and their relationship with the drug action.
3. To provide knowledge of therapeutic uses and adverse reactions of various drugs.
4. To apply principles of organic chemistry for synthesizing various clinically significant drugs.
5. To acquaint with basic principles of drug design, discovery and development.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the principles of drug design and QSAR.
2. Understand the synthesis of important drugs.
3. Correlate structural modification on the drug with biological activity.
4. Demonstrate the uses and adverse reactions of drugs belonging to different classes.

Unit-1

1. Introduction to drug design and discovery :

General principle, objectives of drug design, phases involved, common approaches used in drug design, physico-chemical properties and drug design. Introduction to quantitative structure activity relationships (QSAR), lead discovery and optimization. Methods of QSAR, molecular modelling. Simple correlation equations and interpretation of regression analysis. Applications of QSAR in drug discovery. **3 h**

Note : History and general aspects of design and development of the following categories of the drugs including classification, SAR, mechanism of action (biochemical and molecular basis whenever applicable), physico-chemical properties, adverse effects, therapeutic uses and recent developments.

*** Synthesis of drugs mentioned in each category.**

2. Steroids :

Nomenclature and stereochemistry, metabolism of steroids, corticosteroids (Glucocorticoids and Mineralocorticoids), male sex steroids and other related agents (Androgens and anabolic steroids), antiandrogens, androgen biosynthesis inhibitors, estrogens (steroidal and non-steroidal), antiestrogens, progestins & its inhibitors.

*Diethyl stibesterol, Dienestrol, Progesterone, Oestrogen and Ethinyloestradiol, 16- DPA and Testosterone. **8 h**

Unit-2

3. Antihistaminics :

Structural features of histamine receptor, subtypes and their structural features, H1 blockers (Classical antihistaminics), H2 blockers and proton pump blockers.

* Chlorpheniramine, Tripelennamine, Pyralamine, Antazoline, Cyclizine, Meclizine, Terfenadine, Cimetidine, Ranitidine and Famotidine. **4 h**

4. Eicosanoids :

Prostaglandin analogs (nomenclature and uses) **2 h**

5. Narcotic analgesics :

Morphine, morphine receptors, nuclear and peripheral modifications, narcotic agonists and antagonists.

* Methadone, Meperididne, Diphenoxylate. **4 h**

Unit-3

6. Non-narcotic analgesics :

Antipyretic analgesics, salicylates, aryl alkanoic acids, N-aryl anthranillic acids, oxicams, selective COX-2 inhibitors, 5-LOX/COX inhibitors.

*Aspirin, Diflunisal, Phenylbutazone, Sulfinpyrazone, Acetaminophen, Flufenamic acid, Mefenamic acid, Meclofenamic acid, Ibuprofen, Fenprofen, Diclofenac, Tolmetin and Piroxicam. **8 h**

7. Anticoagulants, antiaggregants, thrombolytics and hemostatics :

Blood coagulation process, heparin and heparionoids, defibrillating agents, oral anticoagulants, inhibitors of platelet aggregation, fibrinolytic agents, hemostatic agents.

* Dicoumarol, Warfarin, Phenindione, Ticlopidine. **2 h**

Unit-4

8. Hormones :

Thyroid and antithyroidal agents, insulin and oral antidiabetic agents.

*Levothyroxine, Methimazole, Carbimazole, Tolbutamide, Chlorpropamide, Acetohexamide, Tolazamide, Glyburide, Glipizide. **8 h**

9. Combinatorial chemistry :

Basics of combinatorial chemistry and high throughput screening. **2 h**

10. Microwave- assisted synthesis :

Basic principle, advantages over conventional synthesis. **2 h**

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).
4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .
8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).
11. Organic Chemistry, The Fundamental Principles Vol-I and II ; (Finar (ELBS)
12. Hugo Kubingi, QSAR: Hansch Analysis and Related Approaches (Vol-I).
13. Paul S. Charifson, Practical Applications of Computer-aided Drug Design Ed. (Marcel Dekker, In New York).
14. V.M.Kulkarni Drug Design, (Nirali Prakashan, Pune)

4.2.1 MEDICINAL CHEMISTRY-IV
Practicals(3 h/Week)

Course Objectives :

1. To synthesise medicinal compounds and drug intermediates by simple chemical reactions.
2. To confirm structure of synthesized compounds by spectral analysis (IR, UV).
3. To carry out the monograph analysis of the medicinal compounds and assess the quality of the product.
4. To determine important physico-chemical parameters experimentally.

Course Outcomes :

At the end of the course students shall be able to

1. Apply principles of organic chemistry for synthesis of intermediates and drugs.
2. Apply principles of qualitative and spectral analysis for identification and structural confirmation of synthesized compounds.
3. Compute, analyze and record the observations.

Experiments :

1. Synthesis of following (Any six)

   a. p-Bromo acetanilide from acetanilide
   b. p-Bromo anililine from p-bromo acetanilide
   c. p-Nitro acetanilide from acetanilide
   d. Esterification of ibuprofen using DCC coupling
   e. Dichloramine T from p-toluene acetamide
   f. Chloramine T from dichloramine T
   g. Anthrone from antraquinone
   h. Dimethylaminopropiophenone (Mannich reaction)

2. IR and UV spectral analysis of synthesized compounds (any five).
3. Experimental determination of partition coefficient, dissociation constant, molar refractivity of compounds.
4. Microwave assisted synthesis of any two drug or drug intermediates.
5. Assignment: Recent advancements in therapy of diseases covered in syllabus.

Recommended Books :

1. Bentley and Driver, Pharmaceutical Chemistry, 8th Edition, Oxford University Press.
2. Wiliam O. Foye, Foye's Principles of Medicinal Chemistry (6th Edition, Lippincott William Wilkins).
3. Wilson and Gisvold, Text Book of Organic, Medicinal Chemistry and Pharmaceutical Chemistry (J Lipincott Co. 10th Edition, Philadelphia).
4. Wolff M E, Burger's Medical Chemistry (John Wiley and Sons, NY).
5. Kadam S S, Mahadik K R and Bothara K G, Principles of Medicinal Chemistry Vol I & II, 10th Edition, (Nirali Prakashan).
6. Hansch C, Comprehensive Medicinal Chemistry Vol-IV, Elsevier Pergamon.
7. Ledincer Mistscher, The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 .
8. Acheson R N, An Introduction to the Chemistry of Heterocyclic Compounds (Interscience Publishers).
9. Lednicer Daniel, The Organic Chemistry of Drug Synthesis, Vol I, II, III, IV 1st edition, (John Wiley and Sons, INC).
10. Ashutosh Kar, Medicinal Chemistry 3rd Edition, (New Age International Publishers, New Delhi).

4.2.2 PHARMACEUTICAL ANALYSIS –VI
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To impart knowledge about spectroscopy and thermal methods of analysis

2 To make familiar with spectroscopic techniques and their applications in modern analysis.

Course Outcomes :

At the end of the course students shall be able to

1 Apply knowledge of spectroscopic techniques for structural elucidation and thermal analytical techniques for analysis of pharmaceuticals.

2 Understand the concept of validation of analytical methods.

3 Apply knowledge in problem solving approach

Unit-1

1 Nuclear magnetic resonance (NMR) :
Principle, theory, chemical shift, shielding, deshielding, spin-spin coupling and basics of interpretation aspects. Introduction to C – 13 NMR **11 h**

Unit-2

2 Flame Photometry :
Principle, theory, instrumentation and applications **5 h**

3 Atomic absorption spectroscopy :
Principle, theory, instrumentation and applications **5 h**

Unit-3

4 Mass spectrometry :
Introduction, theory, types of ions, fragmentation rules, instrumentation and applications. Problems based on mass spectra. Brief discussion on hyphenated techniques. **9 h**

5 Basics of validation parameters as per ICH guidelines. 2 h

Unit-4

6 X ray diffraction techniques :
Introduction, principle, Braggs's Law, instrumentation and applications. **4 h**

7 Thermal methods :
Introduction, principle, types of thermal analytical methods (DSC, DTA and TGA), instrumentation and applications. **6 h**

Recommended Books :

1 H.N.More, K.R. Mahadik& A.V. Kasture, Principles of Pharmaceutical Analysis, Vol-I & II (NiraliPrakash, Pune).

2 Willard, Merrit, Instrumental Methods of Analysis (CBS Publishers and Distributors).

3 Douglas, A skoog, Saunders, Principles of Instrumental Analysis, (Golden Sunburst Series)

4 G.W. Ewing, Instrumental Methods of Chemical Analysis (McGraw- Hill book) Co.

5 L.G. Chatten, A Text book of Pharmaceutical Chemistry, vol.I& II (Marcel Dekker, New York).

6 I.R. Dyer, Applications of Absorption Spectroscopy of Organic Compounds, (Prentice Hall Inc.)

7 William Kemp, Organic Spectroscopy (English Language book Society, Mc Milan).

8 Pharmaceutical Analysis by Higuchi

9 James W. Munson, Pharmaceutical Analysis: Modern methods, (dekker)

10 Donald L Pavia, Gary M Lempman, George S Kriz, Introduction to Specroscopy (Thomson Brooks Cole).

4.2.2 PHARMACEUTICAL ANALYSIS VI
(Practical) (3 Hrs. /Week)

Course Objectives :

1 To develop expertise in analysis of drugs using spectroscopic techniques.

2 To provide hands on experience for handling of analytical instruments.

3 To provide expertise in spectral interpretations.

Course Outcomes :

At the end of the course students shall be able to

1 Harness technical skills to handle sophisticated instruments for quantitative analysis of bulk drugs and formulations.

2 Enrich knowledge base about working principle, instrumentation and industrial applications of various analytical techniques and interpretation of spectra.

3 Record, compute and analyze the data.

Experiments :

1 Calibration of spectrophotometer as per official procedure.

2 Recording of UV-visible spectrum and determination of λmax, calculation of E 1% and molar absorptivity.

3 Spectrophotometric analysis of pharmaceutical drugs (Three methods).

4 Simultaneous analysis of combination of drugs using UV spectrophotometer.

5 Estimation of sulphate ions using nephelo-turbidimeter.

6 Fluorimetric estimation of fluorescent compounds.

7 Flame photometric analysis (Sodium/potassium determination).

8 Demonstration of DSC.

9 IR demonstration and interpretation problems.

10 NMR interpretation problems.

11 Simple combined spectral problems.

Recommended books :

1 Willard, Merrit, Instrumental Methods of Analysis (CBS Publishers and Distributors).

2 L.G. Chatten, A Text Book of Pharmaceutical Chemistry, Vol.I& II (Marcel Dekker, New York).

3 I.R. Dyer, Applications of Absorption Spectroscopy of Organic Compounds, (Prentice Hall Inc.).

4 Indian Pharmacopoeia, Latest edition.

4.2.3 PHARMACEUTICAL TECHNOLOGY IV
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To familiarize the concept of novel DDS and their applications

2 To provide knowledge of techniques in formulation design of drug delivery systems

3 To evaluate the controlled drug delivery systems.

Course Outcomes :

At the end of the course students shall be able to

1. Select appropriate novel drug delivery systems.
2. Design the drug delivery systems.
3. Carry out quality control evaluation of Drug delivery systems using standard techniques.

Unit-1

1. Controlled Drug Delivery systems :
Concepts of Novel Drug Delivery systems: rate pre-programmed, activation modulated, feedback regulated and site targeting drug delivery systems and their types. **3 h**

2. Fundamentals of rate controlled drug delivery systems :
Mechanism of drug release from membrane permeation, matrix and reservoir drug delivery systems. Factors influencing the release of the drug from devices. **5 h**

3 Oral controlled drug delivery :
Osmotic pressure, hydrodynamic, membrane, bioadhesive, gel diffusion, pH controlled, Ion exchange controlled. Mouth dissolving formulations. **3 h**

Unit-2

4. Transdermal drug delivery systems :
Concept of design- topical and, skin transport mechanism , fabrication of TDDS , Evaluation . **6 h**

5. Trans mucosal DDS :
Oral, rectal and nasal mucosal drug delivery systems **4 h**

Unit-3

6. Pharmaceutical Aerosols :
Container and closure systems, Propellants and their selection, Formulations manufacturing , Quality control tests. Pulmonary drug delivery systems: deposition into lung, Metered dose inhalers (MDI), Dry powder Inhalers (DPI) ,quality control tests. **6 h**

7 Microencapsulation :
Introduction, methods of microencapsulation,

8 Polymers used and applications of microencapsulation. 3 h

9 Advance drug delivery systems :
Intra Uterine devices, Introduction to liposomes, niosomes, nanoparticulate systems, targeted drug delivery systems **2 h**

Unit-4

9. Quality assurance in Pharma Industry :
Pharmaceutical validation : Concept of process validation, validation of building and facilities, equipment process cleaning, specific dosage forms, master plans. **5 h**

10. Documentation and formats 2 h

11. ICH guide lines – Overview of ICH guidelines. 3 h

Recommended Books :

1. A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology, (Marcel Dekker)
2. P. Tyle, Drug delivery system (Marcel Dekker)
3. I.R. Berry, R.A. Nash Pharmaceutical Process validation (Marcel & Dekker)
4. J.Swarbrik, J. Boylan; Encyclopedia of Pharmaceutical Technology, (Marcel Dekker
5. D.H. Shah SOP Guidelines (Business Horizons Publishers)
6. Indian Pharmacopoeia
7. Yie Chien Novel Drug Delivery Systems, (Marcel Dekker) Series Vol 50
8. Alexander Florence and Juergen Siepmann Modern Pharmaceutics Applications and Advances, (Informa Health Care) Vol 189

4.2.3 PHARMACEUTICAL TECHNOLOGY IV
Practicals (3 Hrs/Week)

Course Objectives :

1. To Impart knowledge of design and fabrication of controlled drug delivery systems
2. To provide the knowledge of evaluation of drug delivery systems
3. To familiarize with concept of Quality Assurance

Course Outcomes :

At the end of the course students shall be able to

1. Design and evaluate drug delivery systems
2. Apply the concepts of quality assurance in pharmaceutical manufacturing .
3. Carry out stability testing of pharmaceuticals.

Experiments :

1	Microencapsulation and evaluation of microcapsules	2 expt
2	Design of controlled release tablets and their evaluation	2 expt
3.	Dissolution study of marketed CR and IR dosage forms	4 expt
4.	In Evaluation of marketed transdermal patch	1 expt
5.	Validation of Autoclave and hot air oven	2 expt
6.	Validation of aseptic area	1 expt
7	Accelerated stability testing	2 expt
8	Assignment related to documentation	1 expt.

Recommended Books :

1. A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology, (Marcel Dekker)
2. P. Tyle, Drug delivery system (Marcel Dekker)
3. I.R. Berry, R.A. Nash Pharmaceutical Process validation (Marcel & Dekker)
4. J.Swarbrik, J. Boylan; Encyclopedia of Pharmaceutical Technology, (Marcel Dekker
5. D.H. Shah SOP Guidelines (Business Horizons Publishers)
6. Indian Pharmacopoeia
7. Yie Chien Novel Drug Delivery Systems, (Marcel Dekker Series) Vol 50
8 Alexander Florence and Juergen Siepmann Modern Pharmaceutics Applications and Advances, (Informa Health Care) Vol 189

4.2.4 PHARMACOLOGY- IV
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge of pharmacotherapy in correlation with physiology and pathophysiology.
2. To identify molecular targets for a drug action.
3. To develop competence on evaluating the efficacy and safety profile of drugs.
4. To comprehend the concepts of chemotherapy.

Course Outcomes :

At the end of the course students shall be able to

1. Correlate the mechanism involved in physiology and pathophysiology of various organ systems.
2. Understand the use of appropriate drug with respect to the disease mechanisms
3. Implicate the uses of individual drugs in various diseases, their adverse effects and drug interactions.
4. Acquaint with the treatment of infectious diseases

Unit-1

1. Aritimicrobial Drugs

a) General Consideration
b) Sulfonamides, Cotrimoxazole and Quinolones
c) Penicillins, Cephalosporins
d) Tetracyclines and Chloramphenicol
e) Macrolide antibiotics, Aminoglycoside antibiotics
f) Antifungal Drugs
g) Antiviral Drugs **11 h**

Unit-2

2. a) Antiamoebic and other Antiprotozoal drugs
b) Anthelmintic drugs
c) Antitubercular drugs, Antileprotic drugs, Antimalarial drugs
d) Anticancer drugs **10 h**

Unit-3

3. Hormones and Related Drugs **14 h**

a) Pituitary hormones
b) Corticosteroids
c) Thyroid Hormones and thyroid inhibitors
d) Insulins, Oral hypoglycemic drugs and Glucagon
e) Estrogens, Progestins and Oral contraceptives
f) Oxytocin and other drugs acting on uterus

Unit-4

4. Drugs used in Special Population : **4 h**

a) Pediatric patients
b) Geriatric patients
c) Pregnant and breast-feeding women

5. Immunopharmacology : **3 h**

Pharmacology of immunosuppressants and immuno stimulants

Recommended Books :

1. Barar, F.S.K., Essentials of Pharmacotherapeutics (S. Chand and Company, New Delhi)
2. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, (Little Brown and Co, Boston)
3. Crossland, James and Lewis,s Pharmacology Basis of Therapeutics, (Pergamon Press, New York)
4. Das, M. M. .and Dutta S. K. : R. Ghosh,s Modern Concepts on pharmacology and Therapeutics, (HILTON and Co. Calcutta)
5. Goodman and Gilman; Pharmacological Basis of Therapeutics, (McGraw-Hill)
6. Katzung, B.G; Basic and Clinical Pharmacology, (Lange Medical Publisher, USA)
7. Rang, H.P. and Dale, M.M.; Pharmacology, (Churchill Livingston, UK)
8. Satoskar , R.S. and Bhandarkar S.D> Pharmacology and Pharmacotherapeutics (Popular Prakashan, Bombay).
9. Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts. (Paras Publication)
10. Tripathi K. D. Essentials of Medical Pharmacology VII Edition, (Jaypee Brothers, New Delhi.)

4.2.4 PHARMACOLOGY-IV (PRACTICAL) (3 Hrs/week)

Course Objectives :

1. To illustrate treatment profiles for diseases.
2. To evaluate the efficacy and safety profile of drugs
3. To demonstrate knowledge on fixed dose combinations
4. To acquire expertise in in vivo experimental pharmacology.

Course Outcomes :

At the end of the course students shall be able to

1. Elucidate treatment profiles for various diseases
2. Assess risk benefit ratio in clinical pharmacology.
3. Understand the basis of rational and irrational fixed dose combination of drugs
4. Perform in vivo experiments

Experiments :

1. Prescription auditing and standard treatment protocols for the patients of following diseases: Malaria, Tuberculosis, Depression, Mania, Obesity
2. An exercise based on evaluation of drug promotional literature
3. Demonstration of Experiments carried out using intact animals:
   i. To study the hypnotic activity of drug / drugs using mice/rats as experimental animals
   ii. To study the drug induced motor activity using actophotometer
   iii. To evaluate anti-inflammatory activity of drug using plethysmometer.
   iv. To study drug induced catalepsy using bar test in mice.
4. Critical appraisal of fixed dose drug combinations with respect to comments on prescriptions of some proprietary preparations and multiple drug therapy (rational /irrational) mentioning possible indications, dose, route of drug administration, justification for use for inclusion of each ingredient, and adverse reactions, contraindications, precautions and special instructions for patients.
5. Assignment on therapeutic profile of diseases like Ebola, Swine Flu, SAARS, Rabies, Chickungunya, Dengue, Bird flu, Malaria.
6. Visit to Drug and Poison Information Centre.

Recommended Books :

1. Kulkarni, S.K.; Handbook of Experimental Pharmacology, (Vallabh Prakashan, New Delhi)
2. Ghosh, M.N.: Fundamental of Experimental Pharmacology,(Scientific Book Agency, Calcutta)

3. Crossland, James and Lewis,s Pharmacology Basis of Therapeutics, (Pergamon Press, New York)
4. Das, M. M. .and Dutta S. K. : R. Ghosh,s Modern Concepts on pharmacology and Therapeutics, (HILTON and Co. Calcutta)
5. Goodman and Gilman; Pharmacological Basis of Therapeutics, (McGraw-Hill)
6. Katzung, B.G; Basic and Clinical Pharmacology, (Lange Medical Publisher, USA)
7. Rang, H.P. and Dale, M.M.; Pharmacology, (Churchill Livingston, UK)
8. Turner, R.A., Screening Methods in Pharmacology, (Academic Press, London)
9. Sharma H.L. Sharma K. K. General Pharmacology Basic Concepts. (Paras Publication)
10. Tripathi K. D. Essentials of Medical Pharmacology VII Edition, (Jaypee Brothers, New Delhi).
11. Rodger Walker and Cate Whittlesea. Clinical Pharmacy and Therapeutics, (Churchill Livingstone, London)
12. Vogel, H.G. and Vogel, W.H.: Drug Discovery and Evaluation: Pharmacological Assays, (Springer, New York)
13. Thomson. E.B., Drug Bioscreening, (VCH, New York)

4.2.5 PHARMACEUTICAL MANAGEMENT
(Theory) (3 h/Week) (42 lectures)

Course Objectives :

1. To apprise with the system approach of managerial process in the pharmaceutical industry
2. To create understanding of standards of cGMP and ISO.
3. To provide the knowledge about the concepts of marketing, and sales.
4. To familiarize the students about recent global developments in pharma sector

Course Outcomes :

At the end of the course students shall be able to

1. Apply the management principles and built the attitude to attain definite goals in the profession .
2. Opt for marketing, export and sales as a base to develop their career.
3. Meet the global challenges in pharma sector.

Unit-1

1 Growth of Pharmacy Profession in India, current status of pharma industries in India, Influence of GATT, WTO, Dunkel Text on Pharmacy profession **3 h**

2 R and D in Pharma Industry – basic concept, types of research, target identification, drug development process **3 h**

3 Intellectual Property Rights : its applications in Pharmacy **2 h**

4 Meaning and Concept of Management, differentiation between management, administration and organization. Evolution of Management thought- F W Taylor and Henry Fayol contribution to Management.Economic and human resource **3 h**

Unit-2

5. Functions of management

- **i) Planning –** Classification, steps in planning, management by objectives, its benefits and weakness.
- **ii) Staffing :** Manpower planning, sources of recruitment, selection process, training and development, performance appraisals technique, Manager and his role
- **iii) Organizing :** Organization structures, Departmentation, Decentralization and delegation of authority and Responsibility.
- **iv) Direction :** Characteristics and importance, motivation and theories of motivation. Leadership and theories of leadership.Policies.Procedures.Strategies.
- **v) Control :** control areas and techniques as BEP PERT, CPM, Inventory model, budget and audits and their importance **10 h**

Unit-3

6. Marketing management :

Core concepts of marketing and market orientation. Marketing research process. Developing, Testing and launching of a new product , Product life cycle. Recall of drug from market, 7 P's of Marketing mix with special reference to promotional techniques of Marketing Pharmacy products. Brand Equity,and 'brand-standing' Basic concepts of Export procedure and documentation. **7 h**

7. Sales Management in pharmacy :

Qualities of sales person for Pharmacy Industry, Sales promotion **3 h**

Unit-4

8. Pharmaceutical Production Management :

Methods to increase the productivity in Pharmaceuticals **5 h**

9. ISO Standardization :

ISO 9000- 2008 , and 14000 - Series **4 h**

10 Concept of TQM, QM, 2 h

Recommended Books :

1. Harry A.Smith, Lea and Febiger, Principles and methods of Pharmacy Management
2. Essentials of Management: An International Perspective, Harold Koontz Heinz Weihrich,6th Edition, (Tata Mc Graw Hill Publishing Co.Ltd, India.)
3. Sachin Itkar, Pharmaceutical management (Nirali Prakashan), Pune,India
4. G.Vidya Sagar,Pharmaceutical Industrial management (Pharma Book Syndicate), Hyderabad, India
5. David Hoyle, Quality system development Hand book (Butterworth Heinemann Ltd, U.K.)
6. Pharmaceutical Marketting in India S.V.R Rao, (Asian INSTITUTE OF Pharmaceutical Markettng, Hyderabad, India).

4.2.6 ELECTIVES

1. DRUG REGULATORY AFFAIRS

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To introduce various regulatory authorities to regulate the Pharmacy profession in India and abroad.
2. To understand different Legislations related to drugs and pharmaceuticals
3. To impart the knowledge of different regulatory authorities for international pharmaceutical market.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the regulatory authorities regulating the Pharmacy profession in India and abroad.
2. Understand different legislations related to drugs and pharmaceuticals.
3. Understand different regulatory authorities for international pharmaceutical market.

Unit-1

1. The Drugs and Cosmetics act, 1940 and Rules with emphasis on GLP (Schedule L-I), GMP (Schedule M), Good Manufacturing Practices for Ayurvedic, Siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics. Requirements for registration of pharmaceutical products into India. Preparation of dossier for product registration as per Indian legislative requirements.**6 h**

2. Documentation: Master formula record (MFR), Master formula card (MFC), Batch Manufacturing Record (BMR), Batch Packing Record (BPR), Standard operating procedure (SOP), Site Master File, specifications, Certificate of analysis (COA), Material safety data sheet (MSDS), Method of Analysis (MOA), Annual product review, validation protocols, Stability protocol, T- License, forms, maintenance of records in Pharmaceutical industry. Regulatory requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials (Schedule Y). **5 h**

Unit-2

3 Requirements of cGMP with specific reference of USFDA (21 CFR part 210 and 211), European Medicines Agency (EMEA) guidelines. **5 h**

4. Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act. **5 h**

Unit-3

5. Registration of product in European market: New drug product and generic product. Preparation of dossier of Drug product and Drug master file. Regulatory requirements good laboratory practice in US (USFDA 21 CFR part 58). **6 h**

6. Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA Brazil guidelines and Japanese regulation. Association of South East Asian Nations (ASEAN) CTD guidelines. **5 h**

Unit-4

7. International Organization for Standardization (ISO): Fundamentals of quality management system. ICH Guidelines with specific reference to stability, analytical validation, impurities, pharmacopeias, specification, quality risk management and pharmaceutical development. **5 h**

8. Preparation of Common technical document (CTD) as per ICH guidelines, electronic documentation and e-filing (e-CTD). Guidelines for reporting adverse drug reaction in various countries. **5 h**

Recommended Books :

1. Kuchekar B. S., Khadtare A. M., Itkar S. C., Forensic Pharmacy, 6 th Edition, Aug. (Nirali Prakashan). 2006.
2. Mittal B. M.- A Textbook of Forensic Pharmacy, 9 th Edition, (Vallabh Prakashan)1999
3. The Drug and Cosmetics Act and Rules and its Latest amendments.The Gazettes of India.
4. The Patent Act 1970 and its Latest amendments. The Gazettes of India.
5. Central Drug Standards Control Organization, DCGI website http://cdsco.nic.in/
6. P. Narayan – Intellectual Property Law, Edition 3rd; (Eastern Law House;) 2001.
7. WHO GMP guidelines
8. James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2 th Edition, (Marcel Decker Inc.)1998
9. Deshpande S. W. -Drugs & Cosmetics Act; 4th Edition;2006
10. Bubharam N. R. - Whatever one should know about patents, 2nd Edition, (Pharma book Syndicate).
11. Guarino Rechard A. – New Drug Approval Process, 3rd Edition, (Marcel Decker.)2004
12. www.ich.org
13. www.anvisa.gov.
14. www.picscheme.org
15. www.mhra.gov.uk
16. www.tga.gov.au
17. www.mccza.com
18. www.who.int
19. www.ep.espace.net

2. PHARMACOVIGILANCE AND MEDICINE SAFETY
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart the knowledge of Identify and report medication errors and adverse drug reactions to appropriate individuals and organizations
2. To develop an understanding of the system based approach to improve medication use safety
3. To explain why error reporting is so vital to improving medication safety

Course Outcomes :

At the end of the course students shall be able to

1. Interpret and evaluate patient and drug-related data needed to identify actual or potential drug therapy problems
2. Participate as part of a multidisciplinary team in the pharmaceutical care system's process for conducting medication use evaluations
3. Evaluate information obtained from adverse drug reaction and medication error reporting systems to identify preventable causes.

Unit-1

1. Introduction to adverse drug reactions :

- Definitions and classification of ADRs,
- Detection and reporting,
- Causality assessment,
- Severity and seriousness assessment,
- Predictability and preventability assessment Management of adverse drug reactions. **8 h**

2. Introduction to Pharmacovigilance :

History and development of pharmacovigilance, Pharmacovigilance in India and global perspective, WHO international drug monitoring programme **4 h**

Unit-2

3 Information resources in pharmacovigilance :

Basic drug information resources Specialised resources for ADRs, Critical evaluation of medication safety literature **3 h**

4 Pharmacovigilance methods :

- Passive surveillance
- Spontaneous reports and case series
- Drug event monitoring and registries

- Comparative observational studies - Cross sectional study, case control study and cohort study
- Targeted clinical investigations Vaccine safety surveillance. **6 h**

Unit-3

5. Adverse drug reaction reporting :

Introduction to reporting systems, Spontaneous reporting system, Reporting to regulatory authorities, Guidelines for reporting ADRs in biomedical literature **4 h**

6. Signal detection, Risk assessment and management

- Identification of new adverse drug reactions
- Signal detection in pre and post marketing period
- Prioritization and risk assessment
- Risk management **6 h**

Unit-4

7.
- Science of safety
- Errors and adverse events in health care
- Models of safety and change
- Detection and reporting of injuries and errors **6 h**

8.
- Investigative methods
- Disclosure of adverse events
- Improvements of clinical systems
- Policy intervention **5 h**

Recommended Books :

1. Standards of Hospital Pharmacists of Australia (SHPA)
2. G. Parathasarathi, Texbook of Clinical Pharmacy
3. Revikumar, Textbook of Hospital Pharmacy
4. www.ashp.org
5. www.consumermedsafety.org
6. www.patientsafety.gov/index.html

3. SPECTROSCOPIC PROBLEMS
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge about basic concepts of spectroscopic interpretation
2. To provide expertise in spectral interpretations

Course Outcomes :

At the end of the course students shall be able to

1. Interpret UV, IR, NMR and Mass spectrums.
2. Elucidate structures using spectral data.

Unit-1

1. Basic principle and interpretation aspects of UV-Visible spectroscopy; Applications of Woodward fieser rule; Problems based on UV-Visible spectrum **8 h**

Unit-2

2. Basic principle and interpretation aspects of IR spectroscopy. Important regions of IR spectrum, base values and problems based on IR spectrum **8 h**

Unit-3

3. NMR : Basic principle and interpretation aspects of NMR. Chemical shifts and multiplicity and problems based on NMR spectrum **10 h**

Unit-4

4. Mass Spectra: Basic principle and interpretation aspects of mass spectrum **10 h**
5. Combined spectral problems **6 h**

Recommended Books :

1. Spectrometric identification of organic compounds. Robert M. Silverstein, Francis X Webster, David J Kiemle.John Wiley& sons Inc.
2. Principles of Instrumental Analysis, Douglas, A skoog, Saunders (Golden Sunburst Series)
3. A Text book of Pharmaceutical Chemistry, L.G. Chatten, vol.I & II (Marcel Dekker, New York).
4. Instrumental Methods of Chemical Analysis by G.W. Ewing, (McGraw- Hill book) Co.
5. Applications of Absorption Spectroscopy of Organic Compounds, I.R. Dyer, (Prentice Hall Inc.)
6. Organic Spectroscopy : William Kemp (English Language book Society, Mc Milan).
7. Introduction to spectroscopy : a guide for students of organic chemistryOrganic spectroscopy – Donald Pavia, Gary Lampman, George Kriz, James Vyvyan

4. HERBAL DRUG TECHNOLOGY
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To impart knowledge on Herbal drug technology
2. To familiarize with different extraction techniques
3. To familiarize novel techniques like plant biotechnological aspects, High throughput screening.

Course Outcomes :

At the end of the course students shall be able to

1. Understand different aspects of herbal drug technology
2. Understand the application of different extractions techniques.
3. Understand novel techniques like plant biotechnological aspects, High throughput screening.

Unit-1

1. Phytochemical Screening :

Preparation of extracts, Phytochemical tests for detection of common plant constituents, Biosynthetic pathways for secondary plant constituents, General principles of formation of primary and secondary plant metabolites. Biogenesis of medicinally important glycosides, alkaloids, carbohydrates, lipids, volatile oils and steroids. **5 h**

2. Extraction :

Methods of extraction of different classes of phytochemicals from crude drugs viz. maceration, percolation, Soxhlet extraction, Successive solvent extraction, Supercritical fluid Extraction, Ultrasound-assisted extraction, Microwave-assisted extraction. **5 h**

Unit-2

3. Nutraceuticals :

Definition, classification, functional food, dietary supplements, Dietary Supplement and Health Education Act (DSHEA), food guide pyramid, pre and pro-biotic, Antioxidants and Plant Nutraceuticals including Lycopene, Lutein, Resveratrol, Soya isoflavones, Tea Cocoa, Flaxseed, Olive, Spirulina. **6 h**

4. Medicinal Plant Biotechnology :

Introduction, Nutritional requirement for in vitro plant cell growth (Culture media), Types of culture, Cell suspension and Growth parameters. Strategies for enhanced production of phyto-pharmaceuticals from plant cells. Concept of elicitation. **5 h**

Unit-3

5. Drug discoveries from natural sources :

Target selection, lead optimization, high throughput screening, biological assays and examples of drug and new leads from natural products. Process of development and launch of herbal formulation in market. **5 h**

6. Quality Control and Standardization :

Introduction, classification, Application of chromatography methods in evaluation of herbal drugs. Extractive values, Ash values, Chromatographic techniques (TLC, HPTLC, HPLC), Concept of marker compounds. WHO Guidelines for rational use of herbal drugs **5 h**

Unit-4

7. Herbal drug regulatory affairs :

Different regulatory bodies and laws, regulations related to herbal drugs. Role of Ayurved, Yoga, Unani, Siddha and Homeopathy (AYUSH), Schedule T, Salient features of Indian Herbal Pharmacopoeia 2007. The Food Safety and Standard Authority of India (FSSAI), 2010. **8 h**

8. Pharmacovigilance of herbal drugs :

Herb-drug interactions, herb-food interactions, side effects and toxicities of important herbal drugs. **3 h**

Recommended Books :

1. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. (W.B. Saunders), 2002. 16th Ed. ISBN-10: 0702029335.
2. Jean Bruneton, Caroline K. Hatton, Pharmacognosy, phytochemistry, medicinal plants. (Lavoisier), 1999.ISBN 1898298637.
3. Rangari V.D., Pharmacognosy and Phytochemistry (Vol I), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-45-5.
4. Rangari V.D., Pharmacognosy and Phytochemistry (Vol II), (Career Pub., Nashik), 2009, ISBN: 978-81-88739-65-3.
5. Quality control methods for medicinal plant materials, (World Health Organization, Geneva), 1998.ISBN 9241545100.
6. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, (Nirali Prakashan, Pune), 2008, ISBN: 8185790094.
7. Seigler David S., Plant Secondary Metabolism, (Kluwer Academic Publishers, Dordrecht, the Netherlands). 1995. ISBN 0-412-01981-7.
8. Francisco A. Macias, Jose L.G. Galindo, Juan C.G. Galindo, Evolution and current status of ecological Phytochemistry, Phytochemistry 68 (2007) 2917–2936.
9. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. (Business Horizons), 2002.ISBN 8190078844.

10. Simon Gibbon et. al. Pharmacognosy and Phytochemistry, (Churchil Livingstone, UK).
11. Wallis T. E., Textbook of Pharmacognosy. (CBS Publisher and Distributors), 1985. ISBN:81- 239-0886-5.
12. "Pharmacognosy and Biotechnology" Ashutosh Kar, (New Age International Publishers, New Delhi), 2003.
13. Indian Pharmacopoeia 2007, 2014.
14. S.S. Agrawal and M. Paridhavi Herbal Drug Technology, (University Press Publications, New Delhi).
15. A.G. Namdeo, Medicinal Plant Biotechnology, (Career Publication, Nashik), 2011

5. TOXICOLOGY
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1 To introduce the basic aspects and significance of toxicology.

2 To identify the toxins and analyze their kinetic and dynamic effects on human body.

3 To elucidate treatment profile for toxins.

Course Outcomes :

At the end of the course students shall be able to

1 Acquaint the basic knowledge of toxicology.

2 Understand the effects and symptoms of poisoning.

3 Integrate the management of poisoning and drug toxicity.

Unit-1

1. Introduction, Toxicological evidence, common household poisons, description of sub disciplines of toxicology. 02 h

2. General principles involved in the management of poisoning.

a. Diagnosis of poisoning.

b. Supportive care in clinical Toxicology.

c. Gut Decontamination.

d. Elimination Enhancement.

e. Antidotes **05 h**

3. Toxicokinetics. 02 h

Unit-2

4. Symptoms and management of poisoning with the following agents

a) Opiates overdose.

b) Antidepressants

c) Non-steroidal anti-inflammatory drugs – Paracetamol, Salicylates

d) Hydrocarbons: Petroleum products and PEG.

e) Caustics: inorganic acids and alkalis. **12 h**

Unit-3

5. Pesticide Poisoning 02 h

6. Venomous snake bites:

Venomous snakes, effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries **05 h**

7. Envenomations :

Arthropod bites and stings. **04 h**

Unit-4

8. Plants poisoning. Mushrooms, Mycotoxins. **03 h**
9. Food poisonings **02 h**
10. Radiation poisoning **02 h**
11. Disposal of biological hazards **03 h**

Recommended Books :

1. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. (Williams and Willkins publication, London)
2. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 (Paras Publication, Hyderabad)
3. C.K. Parikh. Textbook of Medical Jurisprudence, Forensic Medicine and Toxicoloty. Sixth Edition. (CBS Publishers and Distributors Pvt. Ltd., New Delhi)

6. QUALITY ASSURANCE TECHNIQUES
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To help students understand the fundamental concepts of quality assurance.
2. To give an insight of basic concepts and objectives of stability study.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the concepts of quality assurance and pharmaceutical validation.
2. Design protocols for assessing stability studies of pharmaceutical product.

Unit-1

1. Quality :

Concept of quality, developing quality culture , Quality audits and inspection, key activities in quality management. Difference between quality assurance and quality control.

Quality benchmarking, introduction to international standards (ISO, GMP, GLP, TGM, VAN and ISI), Measurement of quality, information and decision making or utilization of data. **10 h**

Unit-2

2. Quality operations, its inspection and test used for it.

Quality improvement process: Quality in research and development, Complaints and recalls: evaluation of complaints, recall procedure, related records and documents. Manufacturing operations and Controls: Control of mix-ups and cross contamination, IPQC activities, Process Deviation, Drug product inspection, calculation of yields **11 h**

Unit-3

3. Introduction to pharmaceutical validation :

Definition, manufacturing process model, scope of validation, advantage of validation, organization for validation, validation master plan, types of process validation, design qualification, installation qualification, operational qualification and performance qualification of equipment & facilities.

Process validation: prospective, concurrent, retrospective and revalidation. **10 h**

Unit-4

4. Stability aspects: Basic concept and objectives of stability study.

- Regulatory requirement for stability studies: A very brief introduction to FDA

and WHO guidelines. Study of ICH stability guidelines [Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C].

Different approaches for stability testing of solid and liquids, kinetic principles, physical and chemical stability testing of pharmaceutical dosage forms and packages. Product life-cycle management **11 h**

Recommended Books :

1. Juran's Quality Handbook, 5th Ed, by J M Juran, A B Godfrey, (McGrawHill International Edition)
2. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
3. Sadhank. G. Ghosh, ISO 9000 and Total Quality Management .
4. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO.
5. Syed Imtiaz Haider and Erfan Syed Asif, Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries
6. Carleton and Agalloco, Validation of Aseptic Pharmaceutical Processes, (Marcel Dekker Inc., New York).
7. B. T. Loftus and R. A. Nash, Pharmaceutical Process Validation, Drugs and Pharm Sci. Series, Vol. 129, (Marcel Dekker Inc., New York).
8. Swarbric, J and Bolyln, J. C., Encyclopedia of Pharmaceutical Technology Vol.1-3, (Marcel Dekker, Inc., New York).
9. Helene I. Dumit, Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series)
10. United States Pharmacopoeia-27(NF-22), United State of Pharmacoppeal convention,INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
11. Helene I. Dumitriu, FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series)

7. INTELLECTUAL PROPERTY RIGHT
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To introduce the concept and scope of Intellectual Property Right
2. To understand the principles of Intellectual Property Right
3. To impart the knowledge of patent and its applications in pharmaceutical industry

Course Outcomes :

At the end of the course students shall be able to

1. Understand the concept and scope of Intellectual Property Right
2. Understand the principles of Intellectual Property Right
3. Understand of patent and its applications in pharmaceutical industry

Unit-1

1. Introduction to Intellectual Property Right (IPR): Definition, history, scope, importance, development and future challenges. **3 h**

2. Different forms of IPR, patent, copyright, trademark and industrial design, geographical indication. **3 h**

3. Introduction to Patent **4 h**

Unit-2

4. Indian patent laws: Bodies governing patent, Patent filing process, Indian Patent Act 1970 and its latest amendments. **4 h**
5. Copyright & Trademark **4 h**
6. PCT/WO Patents World patent processing **3 h**

Unit-3

7. Patent laws in Europe **4 h**
8. Patent laws in US: United state patent Act, OB patents and related patents – Product patents, process patents etc. Patent term extension, Hatch-Waxmann Act **7 h**

Unit-4

9. Patent and its application to pharmaceutical industry: Study of GATT & WTO treaty. Effect of GATT and WTO on commerce of pharmaceuticals. **10 h**

Recommended Books :

1. The Drug and Cosmetics Act and Rules and its Latest amendments. The Gazettes of India.
2. The Patent Act 1970 and its Latest amendments. The Gazettes of India.
3. Vijay Malik, Law relating to Drugs & Cosmetics.
4. www.patentoffice.nic.in
5. www.ep.espace.net
6. www.uspto.gov
7. www.epa.gov
8. www.picscheme.org

8. PACKAGING TECHNOLOGY
(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To acquaint about pharmaceutical packaging.
2. To impart knowledge of packaging materials and processes.
3. To introduce testing of packaging materials..

Course Outcomes :

At the end of the course students shall be able to

1. Understand pharmaceutical packaging.
2. Apply principles of packaging for selection of materials and process..
3. Evaluate pharmaceutical packaging.

Unit-1

1. Pharmaceutical Packaging :
Need, types and functions of pharmaceutical packaging with examples **02 h**

2. Packaging requirements of pharmaceuticals :
Ideal requirements of packaging materials for pharmaceuticals. **04 h**

3. Primary packaging materials :
Properties and information of packaging materials including glass, metals, plastics as primary packaging **05 h**

Unit-2

4. Equipments used in primary packaging :
Equipments and processes for strip, blister packaging, powder and liquid filling **05 h**

5. Sterilization of primary packaging materials :
Definition, Factors affecting dose selection. Calculation of children and infant doses. **03 h**

6. Closures for glass and plastic containers :
Requirements of closure, functions of closures **02 h**

Unit-3

7. Child resistant packaging :
Need and design of child resistant packaging **03 h**

8. Secondary packaging materials :
Materials, carton types, designs, and specifications **05 h**

9. Quality assurance of packaging materials :
Stability and compatibility evaluation parameters **02 h**

Unit-4

10. Quality control tests of packaging :
Quality control tests as per IP, USP for pharmaceutical packaging including following tests:

Leakage test, Chemical resistance test, collapsibility test, non volatile redsidue tesing, light absorption, reducing substances, residue on ignition test, biological tests, extractable test. **05 h**

11. Laws and regulations governing pharmaceutical packaging :
Regulatory requirements of pharmaceutical packaging materials and packaging **02 h**

12. Tamper evedent packaging :
Need , types and design of tamper evident packaging with examples **04 h**

Recommended Books :

1. The Indian Pharmacopoeia, 2014.
2. Remington Pharmaceutical sciences
3. H Lockhart, F A Paine, Packaging of pharmaceutical and healthcare products
4. United States Pharmacopoeia.
5. R K Khar, S P Vyas, F J Ahmed, G K Jain, Theory and practice of Industrial Pharmacy, 4th edition.

9. COSMETICOLOGY

(Theory) (3 Hrs/Week) (42 lectures)

Course Objectives :

1. To provide general understanding of cosmetics
2. To provide knowledge of different cosmetics of skin care products
3. To provide hands on experience of preparation and evaluation of skin care cosmetic products.

Course Outcomes :

At the end of the course students shall be able to

1. Understand the principles involved in formulation of cosmetic products.
2. Learn, select and apply appropriate process and equipment in manufacturing cosmetic products.
3. Acquaint regulatory aspects in manufacturing and evaluation of cosmetic products

Unit-1

1. Introduction:
Cosmetics v/s drug formulation. Types of cosmetics **02 h**

2. Physiological consideration:
Skin, hair, in relation to cosmetic application. **03 h**

3. Cosmetic products:
Formulation, manufacturing and evaluation (including Indian standards) of following cosmetics. Skin Products: Moisturising, cleansing, cold and vanishing cream Lip products: Lipstick **05 h**

Unit-2

4 Formulation, manufacturing and evaluation (including Indian standards) of following cosmetics **10 h**

Hair Products: Shampoo, hair dyes, depilatories and shaving preparations Oral hygiene products: Tooth paste, tooth powder, mouthwash Baby cosmetics: baby powder, baby oil Manicure products: Nail paint and nail paint remover Eye cosmetic: eye mascara, eye shadow, eye liner, eye brow pencil

Unit-3

5. Herbal Cosmetics :
Study of utility of herbs used in cosmetics, soap nut, amla, Henna, hibiscus, tea, aloe vera, turmeric, sandal wood. Herbal hair, skin and dental preparations. **05 h**

6. Evaluation of Cosmetics :

Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives **06 h**

Unit-4

6. Regulatory requirements :

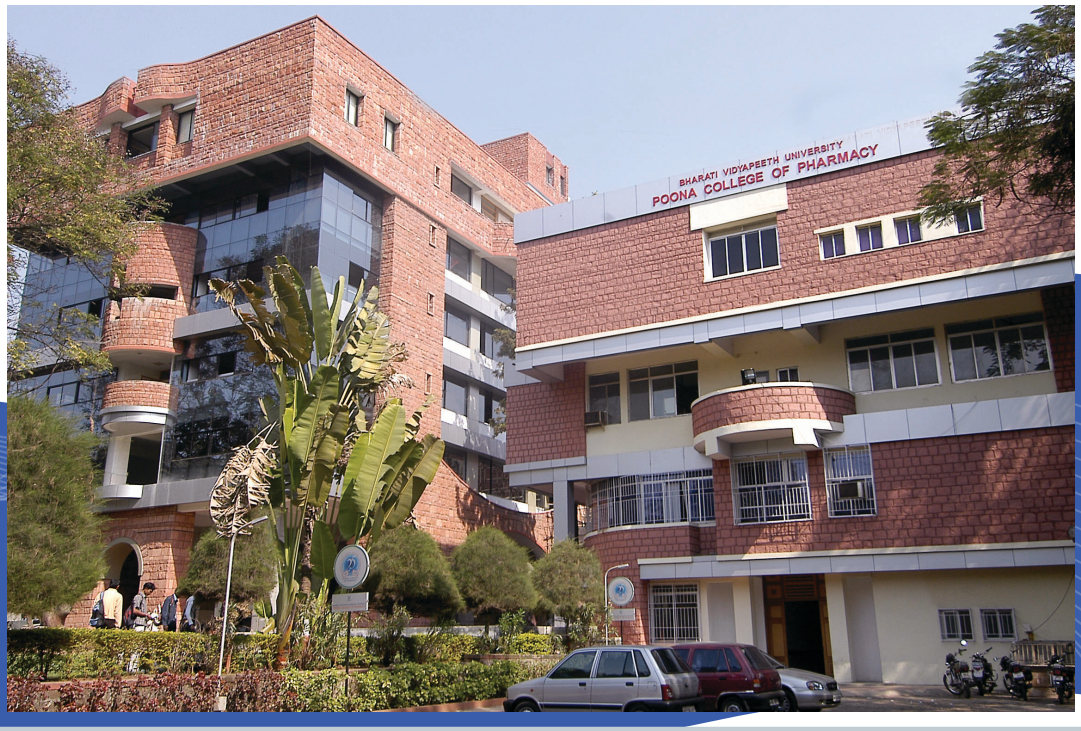
Manufacturing and sales of cosmetics. **04 h**

7. Advances in cosmetics :

Liposomes, multiple and microemulsions, hair waving, cosmetic surgery. **06 h**

Recommended Books :

1. J. Knowlton and S. Rearce, Handbook of cosmetic sciences and technology, (Elsevier science publisher).
2. J.B. Wilkinson and R.J. Moore, Harry's cosmetology, (Longman Science and Technical)
3. S.N. Katju's Law of Drugs, (Law Publishers (India) Pvt. Ltd.)
4. E.G. Thomseen, Modern cosmetics, (Universal Publishing Corporation)
5. M.S. Balsam and E. Sagarin, Cosmetics, science and technology, (John Wiley & Sons)
6 R.L. Elder, Cosmetic Ingredients, their safety assessment, (Pathotox)
7 H.R. Moskowitz, Cosmetic product testing, (Marcel Dekker)
8 W.C. Waggoner, T.C.Cheng and V.C. Yang, cosmetic and Pharmaceutical applications of polymers, (Plenum)
9 C.G. Gebelein, T.C. Cheng and V.C. Yang, cosmetic and Pharmaceutical applications of polymers, (Plenum).
10 L. Appell, The formulation and preparation of cosmetics, fragrances and flavours, (Micelle Press).
11 W.A. Pocher, Poucher's Perfumes, cosmetics and soaps, Vol.3, (Chapman and Hall).
12 Dr. Laba, Rheological properties of cosmetics and toiletries, (Marcel Dekker)
13 K.F.De Polo,A Short Textbook of cosmetology.
14 Andre O Barel, Maec Paye, Howard I.Maibach, Handbook of cosmetic sciences and technology, (Marcel Dekker)
15 Charles Z viak, The Science of Hair Care, (Marcel Dekker)
16 P. P. Sharma, Cosmetics-Formulation, Manufacturing and quality Control, (Vandana Publications).



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