

Pharmacy Council of India
New Delhi

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

[Framed under Regulation 6, 7 & 8 of the Bachelor of
Pharmacy (B. Pharm) course regulations 2014]

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 Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

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

11.1. End semester examinations

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

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

Semester I

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

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

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

* Non University Examination (NUE)

Semester II

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

* The subject experts at college level shall conduct examinations

Semester III

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

Semester IV

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

Semester V

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

Semester VI

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

Semester VII

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

* The subject experts at college level shall conduct examinations

Semester VIII

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

Total	40	60	4 Hrs	100	450	16 Hrs	550
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11.2. Internal assessment: Continuous mode

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

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

Theory		
Criteria	Maximum Marks	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
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) (Answer all the questions)	=	05 x 2 = 10
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10

Total	=	30 marks

For subjects having Non University Examination

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

Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05

Total	=	40 marks

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Re-examination of end semester examinations

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

Table-XIII: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations

For 75 marks paper

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

Total	=			75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3)	=	2 x 10	=	20
II. Short Answers (Answer 6 out of 8)	=	6 x 5	=	30

Total	=			50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2)	=	1 x 10	=	10
II. Short Answers (Answer 5 out of 7)	=	5 x 5	=	25

Total	=			35 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5

Total	=	35 marks

16. Academic Progression:

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

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

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

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

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

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

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

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

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

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

17. Grading of performances

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:

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

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

$$C_1G_1 + C_2G_2 + C_3G_3 + C_4* \text{ZERO} + C_5G_5$$

$$\text{SGPA} = \frac{\text{-----}}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

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

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{\text{-----}}$$

$$C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8$$

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

21. Project work

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

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

Evaluation of Dissertation Book:

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

Total	75 Marks
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Evaluation of Presentation:

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

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

22. Industrial training (Desirable)

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

23. Practice School

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

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

24. Award of Ranks

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

25. Award of degree

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

26. Duration for completion of the program of study

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

27. Re-admission after break of study

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

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

CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

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

Course Content:

Unit I

10 hours

- **Introduction to human body**

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

- **Cellular level of organization**

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

- **Tissue level of organization**

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

Unit II

10 hours

- **Integumentary system**

Structure and functions of skin

- **Skeletal system**

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

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

- **Joints**
Structural and functional classification, types of joints movements and its articulation

Unit III

10 hours

- **Body fluids and blood**
- Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.
- **Lymphatic system**
Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV

08 hours

Peripheral nervous system:

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

Origin and functions of spinal and cranial nerves.

- **Special senses**
Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V

07 hours

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

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.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 Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

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

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

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

Course Content:

UNIT-I

10 Hours

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

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

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

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

UNIT-II

10 Hours

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

UNIT-III

10 Hours

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

UNIT-IV

08 Hours

Redox titrations

(a) Concepts of oxidation and reduction

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

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

UNIT-V

07 Hours

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

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following

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

II Preparation and standardization of

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

III Assay of the following compounds along with Standardization of Titrant

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

IV Determination of Normality by electro-analytical methods

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

Recommended Books: (Latest Editions)

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

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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

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

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

Course Content:

UNIT – I

10 Hours

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

UNIT – II

10 Hours

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

UNIT – III**08 Hours**

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

UNIT – IV**08 Hours**

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

UNIT – V**07 Hours**

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

1 . Syrups

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

2. Elixirs

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

3.Linctus

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

4. Solutions

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

5. Suspensions

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

6. Emulsions

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

7. Powders and Granules

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

8. Suppositories

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

8. Semisolids

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

9. Gargles and Mouthwashes

- a) Iodine gargle
- b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

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

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course student shall be able to

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

Course Content:

UNIT I

10 Hours

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

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

UNIT II

10 Hours

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

UNIT III

10 Hours

- **Gastrointestinal agents**

Acidifiers: Ammonium chloride* and Dil. HCl

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

Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

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

UNIT IV

08 Hours

- **Miscellaneous compounds**

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate

Haematinics: Ferrous sulphate*, Ferrous gluconate

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

Astringents: Zinc Sulphate, Potash Alum

UNIT V

07 Hours

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

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I Limit tests for following ions

Limit test for Chlorides and Sulphates

Modified limit test for Chlorides and Sulphates

Limit test for Iron

Limit test for Heavy metals

Limit test for Lead

Limit test for Arsenic

II Identification test

Magnesium hydroxide

Ferrous sulphate

Sodium bicarbonate

Calcium gluconate

Copper sulphate

III Test for purity

Swelling power of Bentonite

Neutralizing capacity of aluminum hydroxide gel

Determination of potassium iodate and iodine in potassium Iodide

IV Preparation of inorganic pharmaceuticals

Boric acid

Potash alum

Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 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

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

Objectives:

Upon completion of the course the student shall be able to

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

Course content:

UNIT – I

07 Hours

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

UNIT – II

07 Hours

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

UNIT – III

07 Hours

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

UNIT – IV

05 Hours

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

04 Hours

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

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

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 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, 2ndEdition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

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

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

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

UNIT I

07 Hours

Living world:

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

Morphology of Flowering plants

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

UNIT II

07 Hours

Body fluids and circulation

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

Digestion and Absorption

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

Breathing and respiration

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

UNIT III

07 Hours

Excretory products and their elimination

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

Neural control and coordination

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

Chemical coordination and regulation

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

Human reproduction

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

UNIT IV

05 Hours

Plants and mineral nutrition:

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

Photosynthesis

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

UNIT V

04 Hours

Plant respiration:Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant 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. Ananthkrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
 - a) Study of Microscope
 - b) Section cutting techniques
 - c) Mounting and staining
 - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root
Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

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

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I

06 Hours

- **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function:**

Real Valued function, Classification of real valued functions,

- **Limits and continuity :**

Introduction, Limit of a function, Definition of limit of a function ($\epsilon - \delta$

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

UNIT –II

06 Hours

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

UNIT – III

06 Hours

- **Calculus**

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n w.r.t x , where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles (**without Proof**), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV

06 Hours

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

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

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

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I

10 hours

- **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit II

06 hours

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

- **Respiratory system** **10 hours**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV

10 hours

- **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit V

09 hours

- **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.

11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

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

Reference Books:

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

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I

07 Hours

- **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II 10 Hours

- **Alkanes*, Alkenes* and Conjugated dienes***

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 versus 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 carbocations.

SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV 10 Hours

- **Carbonyl compounds* (Aldehydes and ketones)**

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V

08 Hours

- **Carboxylic acids***

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- **Aliphatic amines*** - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
 1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
 3. Solubility test
 4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
 5. Melting point/Boiling point of organic compounds
 6. Identification of the unknown compound from the literature using melting point/ boiling point.
 7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
 8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwalia/Chatwal.

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shall be able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I

08 Hours

- **Biomolecules**

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

- **Bioenergetics**

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II

10 Hours

- **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III

10 Hours

- **Lipid metabolism**

- Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV

10 Hours

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V

07 Hours

- **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murray, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

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

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I

10Hours

- **Basic principles of Cell injury and Adaptation:**
Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:**

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit II

10Hours

- **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

- **Respiratory system:** Asthma, Chronic obstructive airways diseases.

- **Renal system:** Acute and chronic renal failure .

Unit II

10Hours

- **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones

- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

- **Gastrointestinal system:** Peptic Ulcer

-

Unit IV

8 Hours

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout

- **Principles of cancer:** classification, etiology and pathogenesis of cancer

- **Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V

7 Hours

- **Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhoea

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)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

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

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I

06 hours

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II

06 hours

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV

06 hours

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V

06 hours

Computers as data analysis in Preclinical development:

Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope:Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

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

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I

10hours

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II

10hours

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III

10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

10 Hours

- **Benzene and its derivatives**

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

10 Hours

- **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids*** -Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III

10 Hours

- **Fats and Oils**
 - a. Fatty acids – reactions.

- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV

08 Hours

- **Polynuclear hydrocarbons:**

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V

07 Hours

- **Cyclo alkanes***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

- I Experiments involving laboratory techniques
- Recrystallization
 - Steam distillation
- II Determination of following oil values (including standardization of reagents)
- Acid value
 - Saponification value
 - Iodine value
- III Preparation of compounds
- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
 - 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
 - Acetanilide by halogenation (Bromination) reaction.
 - 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
 - Benzoic acid from Benzyl chloride by oxidation reaction.
 - Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
 - 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
 - Benzil from Benzoin by oxidation reaction.
 - Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
 - Cinnamic acid from Benzaldehyde by Perkin reaction
 - *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I

10 Hours

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II

10Hours

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III

08 Hours

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV**08Hours**

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V**07 Hours**

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in 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

Scope:

- Study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc..

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

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I

10 Hours

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit II

10 Hours

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III

10 Hours

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

Unit V

07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 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. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

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

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I

10 Hours

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II

10 Hours

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III

08 Hours

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV

08 Hours

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V

07 Hours

- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical 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

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation – To calculate the efficiency of steam distillation.
- III. To determine the overall heat transfer coefficient by heat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
- IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I

10 Hours

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II

10 Hours

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III

10 Hours

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV**8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V**07 Hours****Reactions of synthetic importance**

Metal hydride reduction (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

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

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

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

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

UNIT- I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II

10 Hours

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

10 Hours

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV

08 Hours

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

Miscellaneous:

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

Fluoro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methobarbital. **Hydantoins:**

Phenytoin*, Mephenytoin, Ethotoin **Oxazolindione diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide* **Urea and**

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbiturates: Methohexital sodium*, Thiopental sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, 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, Zomepiac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

II Assay of drugs

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

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

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

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

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I

07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

UNIT-II

10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III

10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT-IV**10Hours**

Micromeritics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V**10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceuticals by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

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

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I

08 hours

1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II

12 Hours

General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III**10 Hours****2. Pharmacology of drugs acting on peripheral nervous system**

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV**08 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

UNIT-V**07 Hours****3. Pharmacology of drugs acting on central nervous system**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

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

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II

10 Hours

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin
Factors influencing cultivation of medicinal plants.
Plant hormones and their applications.
Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III

07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

UNIT IV

10 Hours

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: (i)Tragacanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & 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), 1st 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

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

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

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

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 succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

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, Lorcaïnide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT- IV**08 Hours****Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progesterones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V**07 Hours****Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipiperodon, 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 PharmacyI (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

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

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I

07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

10 Hours

Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III

08 Hours

Capsules:

- a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

10 Hours

Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V

10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP 506 P. Industrial PharmacyI (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

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

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

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

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

UNIT-II

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT-III

10hours

3. Autocoids and related drugs

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

UNIT-IV**08hours****5. Pharmacology of drugs acting on endocrine system**

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V**07hours****5. Pharmacology of drugs acting on endocrine system**

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

6. Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA₂ value of prazosin using rat anococcygeus muscle (by Schild's 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, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

14 Hours

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

06 Hours

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

UNIT-IV

10 Hours

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V

8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

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

Recommended Books: (Latest Editions)

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

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III

10 Hours

- **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

Penalties

- **Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV

08 Hours

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V

07 Hours

- **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

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

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

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

UNIT – I

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

-Lactam antibiotics: Penicillin, Cephalosporins, - Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT – III

10 Hours

Anti-tubercular Agents

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, 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, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

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

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

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

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

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II

10hours

3. Chemotherapy

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

UNIT-III

10hours

3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents

- c. Antifungal agents
- d. Antiviral drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

UNIT-IV

08hours

3. Chemotherapy

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

4. Immunopharmacology

- a. Immunostimulants
- b. Immunosuppressant

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

UNIT-V

07hours

5. Principles of toxicology

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

6. Chronopharmacology

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

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

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

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I

11 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-II

7 Hours

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III

10 Hours

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV

10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V

07 Hours

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I Hours

10

Introduction to Biopharmaceutics

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

UNIT- II Hours

10

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III

10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E , $t_{1/2}$, V_d , AUC , K_a , Cl_t and CL_R - definitions methods of eliminations, understanding of their significance and application

UNIT- IV**08 Hours**

Multicompartment models: Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT- V**07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall International edition,USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Merceel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

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

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

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I

10 Hours

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

Unit II

10 Hours

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
 - i) Interferon
 - ii) Vaccines- hepatitis- B
 - iii) Hormones-Insulin.
- d) Brief introduction to PCR

Unit III

10 Hours

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications
- g) Blood products and Plasma Substitutes.

Unit IV

08Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation: Types of mutation/mutants.

Unit V

07 Hours

- a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b) Large scale production fermenter design and its various controls.
- c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
- d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: 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

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

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

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

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

Course content:

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III

10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV

08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V

07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 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

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

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

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I

10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

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

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III

10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV

08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V

07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

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

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

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

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV**08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V**07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 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

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

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

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

Unit I:

10 Hours

a) Hospital and its organization

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

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

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

Unit II:

10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

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

d) Medication adherence

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

e) Patient medication history interview

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

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III:

10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) information services

Drug

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

c) Patient counseling

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

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

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

Unit IV 8 Hours

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

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

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

c) Over the counter (OTC) sales

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*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

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

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit-III

10 Hours

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

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

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

Unit-IV

08 Hours

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

Unit-V

07 Hours

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

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

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 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. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

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

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB[®], DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content:

Unit-I

10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II

10 Hours

Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression- Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference

Unit-III

10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:

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

Unit-V

7Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

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

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:

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

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

Course content:

Unit I:

10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II:

10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III:

10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV:

08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V:

07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 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

Scope:

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

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

Unit I

10 Hours

Marketing:

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

Pharmaceutical market:

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

Unit II

10 Hours

Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III

10 Hours

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV**10 Hours****Pharmaceutical marketing channels:**

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

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V**10 Hours****Pricing:**

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

Emerging concepts in marketing:

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

Recommended Books: (Latest Editions)

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

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

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

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

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I

10Hours

New Drug Discovery and development

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

Unit II

10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III

10Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV

08Hours

Clinical trials

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

Unit V

07Hours

Regulatory Concepts

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

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 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

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

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I

10 Hours

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II

10 hours

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Unit III

10 Hours

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

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

Communication in pharmacovigilance

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

Unit IV

8 Hours

Safety data generation

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

ICH Guidelines for Pharmacovigilance

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

Unit V

7 hours

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

Recommended Books (Latest edition):

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

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. <http://www.who/umc.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)

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

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

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

Unit I

10 hours

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms
WHO guidelines for quality control of herbal drugs.
Evaluation of commercial crude drugs intended for use

Unit II

10 hours

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

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

Unit III

10 hours

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV

08 hours

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.
Preparation of documents for new drug application and export registration
GMP requirements and Drugs & Cosmetics Act provisions.

Unit V

07 hours

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

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

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I

10 Hours

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II

10 Hours

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III

10 Hours

Molecular Modeling and virtual screening techniques

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

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

UNIT-IV**08 Hours****Informatics & Methods in drug design**

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V**07 Hours**

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

Recommended Books (Latest Editions)

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

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

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

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I

10Hours

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: History and Summation.
- c) Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II

10 Hours

- a) DNA and the Flow of Molecular Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

Unit III

10 Hours

- a) Proteins: Defined **and** Amino Acids
- b) Protein Structure

- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

Unit IV

08 Hours

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

Unit V

07 Hours

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

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 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. Pepler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I

10Hours

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III

10 Hours

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

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

UNIT IV

08 Hours.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

UNIT V

07 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

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

Antiperspirants and Deodorants- Actives and mechanism of action

References

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3) Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

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

Objectives

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Unit –I	08 Hours
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	10 Hours
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

<p>Unit –III</p> <p>Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics</p>	
<p>Unit –IV</p> <p>Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants</p> <p>Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.</p>	
<p>Research methodology and Bio-statistics</p> <p>Selection of research topic, review of literature, research hypothesis and study design</p> <p>Pre-clinical data analysis and interpretation using Students ‘t’ test and One-way ANOVA. Graphical representation of data</p>	<p>05 Hours</p>

Recommended Books (latest edition):

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

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

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

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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I

10 Hours

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

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

UNIT-II

10 Hours

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

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III

10 Hours

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV

08 Hours

Radio immune assay:Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V

07 Hours

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

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

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3

Tutorial:1

Credit point:4

Scope :

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

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I

07 hours

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

15 hours

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

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

UNIT III

07 hours

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

- b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV

10 hours

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, - Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

UNIT V

06 hours

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 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

Unit-I

10 Hours

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non - ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

Unit-III

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directly compressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products
- v. Excipients for formulation of NDDS

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

Unit-IV

08 Hours

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

Unit-V

07 Hours

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

Recommended Books (Latest editions)

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



PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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23 SEP 2021

✓ To

- a) All institutions approved for D.Pharm Course.
- b) All State Governments (Technical Education and Health Departments) and admission making authorities.
- c) All Examining Authorities.

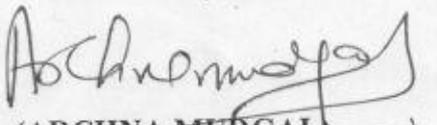
Sub: "Syllabus framed under Regulation 7, List of prescribed equipments and apparatus under Appendix-A of The Education Regulations, 2020 for Diploma Course in Pharmacy."

Sir/Madam

With reference to the subject cited above, it is informed that -

1. With due approval of the Ministry of Health and Family Welfare, Government of India, PCI has notified the Education Regulations, 2020 for Diploma course in Pharmacy in the Gazette of India, Extraordinary No. 435, Part-III, Section-4, dt.16.10.2020.
2. As empowered under regulation 7 and Appendix-A of ER-20, the PCI has framed the syllabus. A copy of the same titled as under is enclosed as **Annexure-I**.
"Syllabus framed under Regulation 7, List of prescribed equipments and apparatus under Appendix-A of The Education Regulations, 2020 for Diploma Course in Pharmacy."
3. It is for implementation and strict compliance from 2021-2022 academic session.

Yours faithfully


(ARCHANA MUDGAL)
Registrar-cum-Secretary



Pharmacy Council of India New Delhi

**“Syllabus framed under Regulation 7,
List of prescribed equipments and
apparatus under Appendix-A of
The Education Regulations, 2020
For Diploma Course in Pharmacy”**

COMMITTEE MEMBERS

S. No.	Name	Affiliation	Role
1.	Dr. B. Suresh	President, Pharmacy Council of India, New Delhi	Ex-Officio
2.	Dr. Shailendra Saraf	Vice President, Pharmacy Council of India, New Delhi	Ex-Officio
3.	Dr. V. Gopal	Member, Pharmacy Council of India, (Puducherry)	Convener
4.	Dr. B. Jayakar	Member, Pharmacy Council of India, (Tamil Nadu)	Member
5.	Sri Kumar Ajay	Member, Pharmacy Council of India, (Bihar)	Member
6.	Dr. H. Lalhlenmawia	Member, Pharmacy Council of India, (Mizoram)	Member
7.	Dr. R. Debnath	Member, Pharmacy Council of India, (West Bengal)	Member
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9.	Dr. Priyashree Sunita	Member, Pharmacy Council of India, (Jharkhand)	Member
10.	Dr. Mannava Radhakrishna Murthy	Member, Pharmacy Council of India, (Andhra Pradesh)	Member
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12.	Shri K.R. Dinesh Kumar	Member, Pharmacy Council of India, (Kerala)	Member
13.	Mrs. Manjiri Sandeep Gharat	Principal I/c., Prin. K.M. Kundnani Pharmacy Polytechnic, Ulhasnagar, Maharashtra	Member
14.	Shri Raj Vaidya	Community Pharmacist, Hindu Pharmacy, Goa	Member
15.	Dr. R.N. Gupta	Professor, Birla Institute of Technology, Ranchi, Jharkhand.	Member
16.	Dr. K.P. Arun	Associate Professor, JSS College of Pharmacy, Ooty, Tamil Nadu	Member
17.	Dr. Neeraj Upmanyu	Professor & Dean, School of Pharmacy & Research, People's University Bhopal, Madhya Pradesh	Special Invitee

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1. Preamble

“Revamping the curriculum, pedagogy, assessment, and student support” is one of the vision statements and recommendations of the National Education Policy (NEP) of Govt. of India for attaining enhanced learning experiences by the students. In light of this, Pharmacy Council of India, the apex body regulating the pharmacy education in the country, committed to revise the education regulations of Diploma in Pharmacy (D.Pharm) program and thus, the ‘Education Regulations 2020’ (ER-2020) has been notified in the Gazette of India in October 2020. This new regulation has given due consideration for the fact that, universally the role of pharmacist has undergone continuous evolution from ‘dispenser of medicines’ to ‘medicine expert’ in the multidisciplinary health care team.

Accordingly, the courses (course means the subject) of the existing education regulations (ER-91) have been revisited, compared with the present and future needs of the society, expectations of the healthcare team and other stakeholders from the pharmacists were assessed, feedback from the experts in the pharmacy and other healthcare professions were sought. Thus, the course of study prescribed in ER-2020 is an amalgamation of all such exercises to arrive at a curriculum structure for D.Pharm that is more relevant to the current practice standards, dynamic to accommodate and address the upcoming changes.

Though the total number of courses across the program remain 21 as that of ER-91, the number of theory courses is reduced from 12 to 11 in the new regulation, while the number of practical courses is increased from 9 to 10. Further, the theory teaching hours across the program have been reduced from 850 to 825, while the practical hours have been increased from 750 to 800 in the new regulation. Three practical courses have been introduced for the first time in ER-2020. Further, about 275 hours have been assigned for the first time in D.Pharm curriculum for ‘Tutorial’ activities. All such changes explicitly reveal that the ER-2020 is intended to provide a little edge to the experiential learning through the practical courses and encourages the small group teaching-learning, self-directed learning, etc. in the tutorial hours.

Introduction of ‘Pharmacotherapeutics’ courses (theory and practical) is one of the revolutionary changes in the new curriculum, that will help the students to hone their knowledge and skills in the area of pharmaceutical care services which will certainly redefine the roles of the D.Pharm qualified pharmacists in both community and hospital settings. Also, the introduction of ‘Social Pharmacy’ courses (theory and practical) will provide insights about the primary and preventive healthcare concepts in the country and the potential roles of pharmacists in such healthcare segments.

In this backdrop, the Council has formulated a Committee which comprised of 16 Members who have rich experiences in various domains such as education, hospital

pharmacy practice, community pharmacy practice, clinical pharmacy practice, administrative and regulatory affairs to design the syllabus for the individual theory and practical courses as per the curriculum framework defined in ER-2020. The Committee with its clear understanding about the philosophy and objectives of the ER-2020, drafted the syllabus for individual theory and practical courses with utmost care to avoid repetitions, redundancy, over/under utilization of hours, etc. Every course is defined with scope, set of course objectives and course outcomes which will help to understand the significance and the expectations of the course from both teachers and students. Lots of scope has been given in the syllabus for the active learning by the students through the assignment topics and field visit activities which will enhance their critical thinking, searching scientific literatures, interpretational skills and communication skills.

According to the ER-2020 curriculum framework, the students do not earn any credits based on the academic hours they spend. However, as per the conventional methodology of credit calculations, the curriculum of ER-2020 shall be deemed equivalent to 80 credits that shall be used for the administrative purposes, wherever necessary.

Further, the 'Competencies for the Indian D.Pharm Holders' based on the knowledge, skill, attitude and value that are essential for the successful practice of the profession have been derived. These competencies have also been mapped with the individual courses of the curriculum based on the expected outcomes of the individual course. Thus, the courses and the competencies are interlaced in such a way that multiple courses contribute to build one competency and one course contributes to build more than one competency, which reveal the strength of the competency mapping.

The Council strongly believes that the ER-2020 regulations, curriculum and syllabus will uplift the knowledge and skills of the students on par with the contemporary and future professional demands and enable them to be a successful practitioner in the chosen field of pharmacy.

By considering the substantial changes and inclusion of advanced and current subject matters in the new syllabus, the Council shall conduct series of meetings, seminars, conferences, workshops, and webinars for the faculty members handling D.Pharm courses and equip them to deliver such new courses / topics more effectively and efficiently.

The Council appreciate all the efforts of the Members for successfully bringing out the Education Regulations 2020, curriculum and syllabus. Also, profound gratitude to all the stakeholders who contributed directly or indirectly in completing this task.

2. Competencies for the Indian D.Pharm Holders

Competency is defined as “A distinct composite of knowledge, skill, attitude and value that is essential to the practice of the profession in real life contexts”.

The candidates who successfully complete the Diploma in Pharmacy (D.Pharm) program of Education Regulations 2020 (ER-2020), from the institutions approved by the Pharmacy Council of India are expected to attain the following professional competencies.

1. Review Prescriptions
2. Dispense Prescription / Non-Prescription Medicines
3. Provide Patient Counselling / Education
4. Hospital and Community Pharmacy Management
5. Expertise on Medications
6. Proficiency on drugs / pharmaceuticals
7. Entrepreneurship and Leadership
8. Deliver Primary and Preventive Healthcare
9. Professional, Ethical and Legal Practice
10. Continuing Professional Development

1. Review Prescriptions: The student should receive and handle prescriptions in a professional manner and be able to check for their completeness and correctness. Also, the prescribers should be contacted for any clarifications and corrections in the prescriptions with suggestions if any.

2. Dispense Prescription / Non-Prescription Medicines: The student should be able to dispense the various scheduled drugs / medicines as per the implications of the Drug & Cosmetics Act and Rules thereunder. Also, the non-prescription medicines (over-the-counter drugs) should be dispensed judiciously to the patients as required.

3. Provide Patient Counselling / Education: The student should be able to effectively counsel / educate the patients / caretakers about the prescription / non-prescription medicines and other health related issues. Effective communication includes using both oral and written communication skills and various communication techniques.

4. Hospital and Community Pharmacy Management: The student should be able to manage the drug distribution system as per the policies and guidelines of the hospital pharmacy, good community pharmacy practice and the recommendations of regulatory agencies. Also, be able to manage the procurement, inventory, and distribution of medicines in hospital / community pharmacy settings.

5. Expertise on Medications: The student should be able to provide an expert opinion on medications to health care professionals on safe and effective medication-use, relevant policies and procedures based on available evidences.

6. Proficiency on Pharmaceutical Formulations: The student should be able to describe the chemistry, characteristics, types, merits and demerits of both drugs and excipients used in pharmaceutical formulations based on her/his knowledge and scientific resources.

7. Entrepreneurship and Leadership: The student should be able to acquire the entrepreneurial skills in the dynamic professional environments. Also, be able to achieve leadership skills through teamwork and sound decision-making skills.

8. Deliver Primary and Preventive Healthcare: The student should be able to contribute to various healthcare programs of the nation including disease prevention initiatives to improve public health. Also contribute to the promotion of national health policies.

9. Professional, Ethical and Legal Practice: The student should be able to deliver professional services in accordance with legal, ethical, and professional guidelines with integrity.

10. Continuing Professional Development: The student should be able to recognize the gaps in the knowledge and skills in the effective delivery of professional services from time to time and be self-motivated to bridge such gaps by attending continuing professional development programs.

3. Competency Mapping with the Courses (Part I, II & III) of Education Regulations 2020

Competencies	Pharmaceutics	Pharmaceutical Chemistry	Pharmacognosy	Human Anatomy & Physiology	Social Pharmacy	Pharmacology	Community Pharmacy & Management	Biochemistry & Clinical Pathology	Pharmacotherapeutics	Hospital & Clinical Pharmacy	Pharmacy Law & Ethics	Practical Training
1. Review the Prescriptions	√	√	√	√		√	√	√	√	√	√	√
2. Dispense Prescription / Non-Prescription Medicines	√	√	√		√	√	√	√	√	√	√	√
3. Provide Patient Counselling / Education	√	√	√	√	√	√	√	√	√	√	√	√
4. Hospital and Community Pharmacy Management					√		√			√	√	√
5. Expertise on Medications	√	√	√	√	√	√	√	√	√	√	√	√
6. Proficiency on Pharmaceutical Formulations	√	√	√			√			√			√
7. Entrepreneurship and Leadership							√			√		√
8. Deliver Primary and Preventive Healthcare				√	√	√	√	√	√	√	√	√
9. Professional, Ethical and Legal Practice					√		√		√	√	√	√
10. Continuing Professional Development	√	√	√		√	√	√		√	√	√	√

4. ER-2020 D.Pharm Syllabus – An Overview

The ER-2020 D.Pharm Syllabus has the following structure in every course. Though the theory and practical courses are not mutually exclusive, as per the Regulations, the theory and practical are to be considered as individual courses.

Scope: These are broader statements on the purpose of the course in the curriculum, key contents of the course that will contribute to the specific knowledge and or skill developments. The teacher is expected to orient the students about the scope of the particular course at the beginning and intermittently.

Course Objectives: The course objectives describe the key topics that are intended by the teacher to be covered in the course. In general, these are more specific than the scope and broader than the course outcomes. The teacher is expected to discuss the objectives of the course with the students and break-down the course objectives into micro levels as objectives of a specific topic / objectives of a specific lecture, etc. Such an exercise shall make the students to understand the significance of the course / topic / lecture and enhance their attention on the course / topic / lecture.

Course Outcomes: The course outcomes are more specific than the course objectives describe that describe the abilities of the students to perform/act, upon successful completion of the course. Hence, conventionally the course outcomes are described with verbs that are measurable or observable actions. The teacher is expected to describe the desired outcomes of the particular course, so that the students shall understand the various assessment criteria, modalities, and parameters. This also serves as a broader guideline for the teachers for preparing the assessment plan. A well-structured assessment plan associated with the course outcomes shall enable to mapping with the professional competencies and their attainment levels that are attributed to the program outcomes.

Theory Courses: The theory courses basically provide concepts and explain the relationships between the concepts. Understanding of the theoretical courses enable the students to identify the problems in real life situation and make a plan for addressing such problems. Also, the theory course helps to understand what is not known and thus is the tool for accumulation of knowledge. The syllabus of the theory courses has been systematically and logically described as different chapters and the minimum number of hours to be spent on teaching are mentioned chapter wise and course wise. The teachers shall further distribute the total hours of any given chapter among the sub-topics as required by the subject matter.

Practical Courses: The practical courses are designed for applying the theoretical knowledge in the given experimental / simulated conditions. The practical courses deepen the understanding of theories, develop the skills, hone professional competencies, provide opportunities to observe, think and analyse problem solving methods. Further, they help to gain experience with the real things in practice. The teachers shall train the students in actual / simulated practical conditions.

Tutorials: The purpose of the tutorial hour is typically to engage the students in smaller groups in order to pay a closer attention on their learning process. This is an opportunity for the students to complete their assignments, develop specific skills, discuss any problems in the study topics in a less formal way. During the tutorial hour, the students shall exchange their ideas within the small group and learn to accept constructive criticism and listen to others. Also, the tutorial hour enables the teachers to closely monitor the progress of the individual student and provide additional academic support to individuals, if necessary.

Assignments: The purpose the assignments are to encourage the students for self-directed learning. Further, the assignments will provoke critical thinking, enhance the skills such as literature search, data mining, data interpretation, report formatting, time-management, and written communication. This is also a mode of self-assessment for the student about the level of understanding of the concepts of a particular course. The teachers shall apply their knowledge and wisdom in choosing the assignment topics at a micro level in alignment with the topics given in the syllabus. The assignments shall be evaluated against a set of criteria. A typical format for the assessment of an assignment is given in Appendix-1.

Field Visits: The purpose of field visits is to provide a real-world experience to the students. The field visits will help them to realize that what they learn within the walls of the classroom / laboratory can help them solve the problems they see in the world around them. Also, this is helpful to the teachers to widen their horizons of knowledge and broadening the scope of the syllabus. Every student shall submit a report describing their objectives, experience, learning points, etc. pertaining to the field trip, in the typical format given in Appendix-2.

Recommended Books: For each course, a list of recommended books is given in the syllabus. The list shall be considered as an important and common resource for the teaching-learning process, but not the complete list. It is always encouraged to use the latest edition of the books specified. Further, the teachers and students are encouraged to explore more primary, secondary, and tertiary resources as required.

Practical Training: The goal of the practical training for the students is to provide a real-time, supervised experience on the professional tasks emphasised in their course of study. Further, it helps them to apply their acquired knowledge and skills in the professional working environment. The practical training intensively prepares the students with adequate competencies and qualifications required for the career opportunity in the future.

Thus, the ER 2020 D.Pharm syllabus is designed to nurture the students in all the three domains of Bloom's Taxonomy viz. cognitive (knowledge), affective (attitude) and psychomotor (skills). Further, it also provides ample of scope to the students for different learning styles viz. visual, auditory and kinaesthetic, i.e., 'see, hear and do'.

The summary of the curriculum, courses and other activities and their metrics across the ER-2020 D.Pharm program (Part I, II & III) are given here.

Criteria	Metrics
Number of subject areas (considering both theory & practical together)	11
Number of theory courses	11
Number of practical courses	10
Number of theory hours	825
Number of practical hours	600
Number of practical training hours	500
Number of tutorial hours	275
Number of course outcomes for theory courses	45
Number of course outcomes for practical courses	40
Number of courses which have given assignments	9
Number of assignment topics given	75
Number of assignments reports each student shall submit	27
Number of courses which have field visit	5
Number of field visit reports each student shall submit	9
Number of professional competencies	10

5. Guidelines for the conduct of theory examinations

Sessional Examinations

There shall be two or more periodic sessional (internal assessment) examinations during each academic year. The duration of the sessional exam shall be 90 minutes. The highest aggregate of any two performances shall form the basis of calculating the sessional marks. The scheme of the question paper for theory sessional examinations shall be as given below.

I. Long Answers (Answer 3 out of 4)	3 x 5 = 15
II. Short Answers (Answer 5 out of 6)	5 x 3 = 15
III. Objective type Answers (Answer all 10 out of 10) (Multiple Choice Questions / Fill-in the Blanks / One word OR one Sentence questions)	10 x 1 = 10

Total = 40 marks

Internal assessment: The marks secured by the students out of the total 40 shall be reduced to 20 in each sessional, and then the internal assessment shall be calculated based on the best two averages for 20 marks.

Final Board / University Examinations

The scheme of the question paper for the theory examinations conducted by the examining authority (Board / University) shall be as given below. The duration of the final examination shall be 3 hours.

I. Long Answers (Answer 6 out of 7)	=	6 x 5 = 30
II. Short Answers (Answer 10 out of 11)	=	10 x 3 = 30
III. Objective type Answers (Answer all 20) (Multiple Choice Questions / Fill-in the Blanks / One word OR one Sentence questions)	=	20 x 1 = 20

Total = 80 marks

6. Guidelines for the conduct of practical examinations

Sessional Examinations

There shall be two or more periodic sessional (internal assessment) practical examinations during each academic year. The duration of the sessional exam shall be three hours. The highest aggregate of any two performances shall form the basis of calculating the sessional marks. The scheme of the question paper for practical sessional examinations shall be as given below.

I. Synopsis	=	10
II. Experiments	=	50*
III. Viva voce	=	10
IV. Practical Record Maintenance	=	10

Total	=	80 marks

* The marks for the experiments shall be divided into various categories, viz. major experiment, minor experiment, spotters, etc. as per the requirement of the course.

Internal assessment: The marks secured by the students out of the total of 80 shall be reduced to 10 in each sessional, and then the internal assessment shall be calculated based on the best two averages for 10 marks from the sessional and other 10 marks shall be awarded as per the details given below.

Actual performance in the sessional examination	=	10 marks
Assignment marks (Average of three)	=	5 marks*
Field Visit Report marks (Average for the reports)	=	5 marks ^{\$}

Total	=	20 marks

*, ^{\$} Only for the courses given with both assignments and field visit/s

Note:

1. For the courses having either assignments or field visit/s, the assessments of assignments or field visit/s shall be done directly for 10 marks and added to the sessional marks.
2. For the courses not having both assignment and field visit, the whole 20 marks shall be calculated from the sessional marks.

Final Board / University Examinations

The scheme of the question paper for the practical examinations conducted by the examining authority (Board / University) shall be as given below. The duration of the final examination shall be 3 hours.

I. Synopsis	=	10
II. Experiments	=	60*
III. Viva voce	=	10

Total	=	80 marks

* The marks for the experiments shall be divided into various categories, viz. major experiment, minor experiment, spotters, etc. as per the requirement of the course.

7. ER-2020 D.Pharm Syllabus – Part I

S. No.	Course Code	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week
1.	ER20-11T	Pharmaceutics – Theory	75	25	3	1
2.	ER20-11P	Pharmaceutics – Practical	75	-	3	-
3.	ER20-12T	Pharmaceutical Chemistry – Theory	75	25	3	1
4.	ER20-12P	Pharmaceutical Chemistry – Practical	75	-	3	-
5.	ER20-13T	Pharmacognosy – Theory	75	25	3	1
6.	ER20-13P	Pharmacognosy – Practical	75	-	3	-
7.	ER20-14T	Human Anatomy & Physiology – Theory	75	25	3	1
8.	ER20-14P	Human Anatomy & Physiology – Practical	75	-	3	-
9.	ER20-15T	Social Pharmacy – Theory	75	25	3	1
10.	ER20-15P	Social Pharmacy – Practical	75	-	3	-

PHARMACEUTICS – THEORY

Course Code: ER20-11T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge and skills on the art and science of formulating and dispensing different pharmaceutical dosage forms.

Course Objectives: This course will discuss the following aspects of pharmaceutical dosage forms

1. Basic concepts, types and need
2. Advantages and disadvantages, methods of preparation / formulation
3. Packaging and labelling requirements
4. Basic quality control tests, concepts of quality assurance and good manufacturing practices

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe about the different dosage forms and their formulation aspects
2. Explain the advantages, disadvantages, and quality control tests of different dosage forms
3. Discuss the importance of quality assurance and good manufacturing practices

Chapter	Topics	Hours
1	<ul style="list-style-type: none">• History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations.• Pharmacy as a career• Pharmacopoeia: Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia	7
2	Packaging materials: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5
3	Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses	3
4	Unit operations: Definition, objectives/applications, principles, construction, and workings of:	9
	Size reduction: hammer mill and ball mill	
	Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves	

	Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer	
	Filtration: Theory of filtration, membrane filter and sintered glass filter	
	Drying: working of fluidized bed dryer and process of freeze drying	
	Extraction: Definition, Classification, method, and applications	
5	Tablets – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi-layered, etc.)	8
	Capsules - hard and soft gelatine capsules	4
	Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution	6
	Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries	8
	Nasal preparations, Ear preparations	2
	Powders and granules - Insufflations, dusting powders, effervescent powders, and effervescent granules	3
	Sterile formulations – Injectables, eye drops and eye ointments	6
	Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	4
6	Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	5
7	Novel drug delivery systems: Introduction, Classification with examples, advantages, and challenges	5

PHARMACEUTICS – PRACTICAL

Course Code: ER20-11P

75 Hours (3 Hours/week)

Scope: This course is designed to train the students in formulating and dispensing common pharmaceutical dosage forms.

Course Objectives: This course will discuss and train the following aspects of preparing and dispensing various pharmaceutical dosage forms

1. Calculation of working formula from the official master formula

2. Formulation of dosage forms based on working formula
3. Appropriate Packaging and labelling requirements
4. Methods of basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Calculate the working formula from the given master formula
2. Formulate the dosage form and dispense in an appropriate container
3. Design the label with the necessary product and patient information
4. Perform the basic quality control tests for the common dosage forms

Practicals

1. Handling and referring the official references: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.
2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labelling
 - **Liquid Oral:** Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution
 - **Emulsion:** Castor oil emulsion, Cod liver oil emulsion
 - **Suspension:** Calamine lotion, Magnesium hydroxide mixture
 - **Ointment:** Simple ointment base, Sulphur ointment
 - **Cream:** Cetrimide cream
 - **Gel:** Sodium alginate gel
 - **Liniment:** Turpentine liniment, White liniment BPC
 - **Dry powder:** Effervescent powder granules, Dusting powder
 - **Sterile Injection:** Normal Saline, Calcium gluconate Injection
 - **Hard Gelatine Capsule:** Tetracycline capsules
 - **Tablet:** Paracetamol tablets
3. Formulation of at least five commonly used cosmetic preparations – e.g. cold cream, shampoo, lotion, toothpaste etc
4. Demonstration on various stages of tablet manufacturing processes
5. Appropriate methods of usage and storage of all dosage forms including special dosage such as different types of inhalers, spacers, insulin pens
6. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices
2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical
3. Overview of various machines / equipments / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.
4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level
5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, alligation, proof spirit, isotonicity

Field Visit

The students shall be taken for an industrial visit to pharmaceutical industries to witness and understand the various processes of manufacturing of any of the common dosage forms viz. tablets, capsules, liquid orals, injectables, etc. Individual reports from each student on their learning experience from the field visit shall be submitted.

PHARMACEUTICAL CHEMISTRY – THEORY

Course Code: ER20-12T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on the chemical structure, storage conditions and medicinal uses of organic and inorganic chemical substances used as drugs and pharmaceuticals. Also, this course discusses the impurities, quality control aspects of chemical substances used in pharmaceuticals.

Course Objectives: This course will discuss the following aspects of the chemical substances used as drugs and pharmaceuticals for various disease conditions

1. Chemical classification, chemical name, chemical structure
2. Pharmacological uses, doses, stability and storage conditions
3. Different types of formulations / dosage form available and their brand names
4. Impurity testing and basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the chemical class, structure and chemical name of the commonly used drugs and pharmaceuticals of both organic and inorganic nature
2. Discuss the pharmacological uses, dosage regimen, stability issues and storage conditions of all such chemical substances commonly used as drugs
3. Describe the quantitative and qualitative analysis, impurity testing of the chemical substances given in the official monographs
4. Identify the dosage form & the brand names of the drugs and pharmaceuticals popular in the marketplace

Chapter	Topic	Hours
1	Introduction to Pharmaceutical chemistry: Scope and objectives Sources and types of errors: Accuracy, precision, significant figures Impurities in Pharmaceuticals: Source and effect of impurities in Pharmacopoeial substances, importance of limit test, Principle and procedures of Limit tests for chlorides, sulphates, iron, heavy metals and arsenic.	8
2	Volumetric analysis: Fundamentals of volumetric analysis, Acid-base titration, non-aqueous titration, precipitation titration, complexometric titration, redox titration Gravimetric analysis: Principle and method.	8

3	<p>Inorganic Pharmaceuticals: Pharmaceutical formulations, market preparations, storage conditions and uses of</p> <ul style="list-style-type: none"> ● Haematinics: Ferrous sulphate, Ferrous fumarate, Ferric ammonium citrate, Ferrous ascorbate, Carbonyl iron ● Gastro-intestinal Agents: Antacids :Aluminium hydroxide gel, Magnesium hydroxide, Magaldrate, Sodium bicarbonate, Calcium Carbonate, Acidifying agents, Adsorbents, Protectives, Cathartics ● Topical agents: Silver Nitrate, Ionic Silver, Chlorhexidine Gluconate, Hydrogen peroxide, Boric acid, Bleaching powder, Potassium permanganate ● Dental products: Calcium carbonate, Sodium fluoride, Denture cleaners, Denture adhesives, Mouth washes ● Medicinal gases: Carbon dioxide, nitrous oxide, oxygen 	7
4	Introduction to nomenclature of organic chemical systems with particular reference to heterocyclic compounds containing up to Three rings	2
<p>Study of the following category of medicinal compounds with respect to classification, chemical name, chemical structure (compounds marked with*) uses, stability and storage conditions, different types of formulations and their popular brand names</p>		
5	<p>Drugs Acting on Central Nervous System</p> <ul style="list-style-type: none"> ● Anaesthetics: Thiopental Sodium*, Ketamine Hydrochloride*, Propofol ● Sedatives and Hypnotics: Diazepam*, Alprazolam*, Nitrazepam, Phenobarbital* ● Antipsychotics: Chlorpromazine Hydrochloride*, Haloperidol*, Risperidone*, Sulpiride*, Olanzapine, Quetiapine, Lurasidone ● Anticonvulsants: Phenytoin*, Carbamazepine*, Clonazepam, Valproic Acid*, Gabapentin*, Topiramate, Vigabatrin, Lamotrigine ● Anti-Depressants: Amitriptyline Hydrochloride*, Imipramine Hydrochloride*, Fluoxetine*, Venlafaxine, Duloxetine, Sertraline, Citalopram, Escitalopram, Fluvoxamine, Paroxetine 	9
6	<p>Drugs Acting on Autonomic Nervous System</p> <ul style="list-style-type: none"> ● Sympathomimetic Agents: <i>Direct Acting:</i> Nor-Epinephrine*, Epinephrine, Phenylephrine, 	9

	<p>Dopamine*, Terbutaline, Salbutamol (Albuterol), Naphazoline*, Tetrahydrozoline. Indirect Acting Agents: Hydroxy Amphetamine, Pseudoephedrine. Agents With Mixed Mechanism: Ephedrine, Metaraminol</p> <ul style="list-style-type: none"> ● Adrenergic Antagonists: Alpha Adrenergic Blockers: Tolazoline, Phentolamine ● Phenoxybenzamine, Prazosin. Beta Adrenergic Blockers: Propranolol*, Atenolol*, Carvedilol ● Cholinergic Drugs and Related Agents: Direct Acting Agents: Acetylcholine*, Carbachol, And Pilocarpine. Cholinesterase Inhibitors: Neostigmine*, Edrophonium Chloride, Tacrine Hydrochloride, Pralidoxime Chloride, Echothiopate Iodide ● Cholinergic Blocking Agents: Atropine Sulphate*, Ipratropium Bromide <p>Synthetic Cholinergic Blocking Agents: Tropicamide, Cyclopentolate Hydrochloride, Clidinium Bromide, Dicyclomine Hydrochloride*</p>	
7	<p>Drugs Acting on Cardiovascular System</p> <ul style="list-style-type: none"> ● Anti-Arrhythmic Drugs: Quinidine Sulphate, Procainamide Hydrochloride, Verapamil, Phenytoin Sodium*, Lidocaine Hydrochloride, Lorcaïnide Hydrochloride, Amiodarone and Sotalol ● Anti-Hypertensive Agents: Propranolol*, Captopril*, Ramipril, Methyldopate Hydrochloride, Clonidine Hydrochloride, Hydralazine Hydrochloride, Nifedipine, ● Antianginal Agents: Isosorbide Dinitrate 	5
8	<p>Diuretics: Acetazolamide, Frusemide*, Bumetanide, Chlorthalidone, Benzthiazide, Metolazone, Xipamide, Spironolactone</p>	2
9	<p>Hypoglycemic Agents: Insulin and Its Preparations, Metformin*, Glibenclamide*, Glimepiride, Pioglitazone, Repaglinide, Gliflozins, Gliptins</p>	3
10	<p>Analgesic And Anti-Inflammatory Agents: Morphine Analogues, Narcotic Antagonists; Nonsteroidal Anti-Inflammatory Agents (NSAIDs) - Aspirin*, Diclofenac, Ibuprofen*, Piroxicam, Celecoxib, Mefenamic Acid, Paracetamol*, Aceclofenac</p>	3
11	<p>Anti-Infective Agents</p> <ul style="list-style-type: none"> ● Antifungal Agents: Amphotericin-B, Griseofulvin, Miconazole, Ketoconazole*, Itraconazole, Fluconazole*, Naftifine Hydrochloride 	8

	<ul style="list-style-type: none"> ● Urinary Tract Anti-Infective Agents: Norfloxacin, Ciprofloxacin, Ofloxacin*, Moxifloxacin, ● Anti-Tubercular Agents: INH*, Ethambutol, Para Amino Salicylic Acid, Pyrazinamide, Rifampicin, Bedaquiline, Delamanid, Pretomanid* ● Antiviral Agents: Amantadine Hydrochloride, Idoxuridine, Acyclovir*, Foscarnet, Zidovudine, Ribavirin, Remdesivir, Favipiravir ● Antimalarials: Quinine Sulphate, Chloroquine Phosphate*, Primaquine Phosphate, Mefloquine*, Cycloguanil, Pyrimethamine, Artemisinin ● Sulfonamides: Sulfanilamide, Sulfadiazine, Sulfamethoxazole, Sulfacetamide*, Mafenide Acetate, Cotrimoxazole, Dapsone* 	
12	Antibiotics: Penicillin G, Amoxicillin*, Cloxacillin, Streptomycin, Tetracyclines: Doxycycline, Minocycline, Macrolides: Erythromycin, Azithromycin, Miscellaneous: Chloramphenicol* Clindamycin	8
13	Anti-Neoplastic Agents: Cyclophosphamide*, Busulfan, Mercaptopurine, Fluorouracil*, Methotrexate, Dactinomycin, Doxorubicin Hydrochloride, Vinblastine Sulphate, Cisplatin*, Dromostanolone Propionate	3

PHARMACEUTICAL CHEMISTRY – PRACTICAL

Course Code: ER20-12P

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic training and hands-on experiences to synthesis chemical substances used as drugs and pharmaceuticals. Also, to perform the quality control tests, impurity testing, test for purity and systematic qualitative analysis of chemical substances used as drugs and pharmaceuticals.

Course Objectives: This course will provide the hands-on experience on the following aspects of chemical substances used as drugs and pharmaceuticals

1. Limit tests and assays of selected chemical substances as per the monograph
2. Volumetric analysis of the chemical substances
3. Basics of preparatory chemistry and their analysis
4. Systematic qualitative analysis for the identification of the chemical drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Perform the limit tests for various inorganic elements and report
2. Prepare standard solutions using the principles of volumetric analysis
3. Test the purity of the selected inorganic and organic compounds against the monograph standards
4. Synthesize the selected chemical substances as per the standard synthetic scheme
5. Perform qualitative tests to systematically identify the unknown chemical substances

Practicals

S. No.	Experiment
1	Limit test for <ul style="list-style-type: none"> • Chlorides; sulphate; Iron; heavy metals
2	Identification tests for Anions and Cations as per Indian Pharmacopoeia
3	Fundamentals of Volumetric analysis Preparation of standard solution and standardization of Sodium Hydroxide, Potassium Permanganate
4	Assay of the following compounds <ul style="list-style-type: none"> • Ferrous sulphate- by redox titration • Calcium gluconate-by complexometric • Sodium chloride-by Modified Volhard's method • Ascorbic acid by iodometry • Ibuprofen by alkalimetry
5	Fundamentals of preparative organic chemistry Determination of Melting point and boiling point of organic compounds
6	Preparation of organic compounds <ul style="list-style-type: none"> • Benzoic acid from Benzamide • Picric acid from Phenol
7	Identification and test for purity of pharmaceuticals Aspirin, Caffeine, Paracetamol, Sulfanilamide
8	Systematic Qualitative analysis experiments (4 substances)

Assignments

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Different monographs and formularies available and their major contents
2. Significance of quality control and quality assurance in pharmaceutical industries
3. Overview on Green Chemistry
4. Various software programs available for computer aided drug discovery
5. Various instrumentations used for characterization and quantification of drug

PHARMACOGNOSY – THEORY

Course Code: ER20-13T

75 Hours (3 Hours/week)

Scope: This course is designed to impart knowledge on the medicinal uses of various drugs of natural origin. Also, the course emphasizes the fundamental concepts in the evaluation of crude drugs, alternative systems of medicine, nutraceuticals, and herbal cosmetics.

Course Objectives: This course will discuss the following aspects of drug substances derived from natural resources.

1. Occurrence, distribution, isolation, identification tests of common phytoconstituents
2. Therapeutic activity and pharmaceutical applications of various natural drug substances and phytoconstituents
3. Biological source, chemical constituents of selected crude drugs and their therapeutic efficacy in common diseases and ailments
4. Basic concepts in quality control of crude drugs and various system of medicines
5. Applications of herbs in health foods and cosmetics

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Identify the important/common crude drugs of natural origin
2. Describe the uses of herbs in nutraceuticals and cosmeceuticals
3. Discuss the principles of alternative system of medicines
4. Describe the importance of quality control of drugs of natural origin

Chapter	Topic	Hours
1	Definition, history, present status and scope of Pharmacognosy	2
2	Classification of drugs: <ul style="list-style-type: none">● Alphabetical● Taxonomical● Morphological● Pharmacological● Chemical● Chemo-taxonomical	4
3	Quality control of crude drugs: <ul style="list-style-type: none">● Different methods of adulteration of crude drugs● Evaluation of crude drugs	6

4	Brief outline of occurrence, distribution, isolation, identification tests, therapeutic activity and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.	6																																						
5	<p>Biological source, chemical constituents and therapeutic efficacy of the following categories of crude drugs.</p> <table border="1" data-bbox="352 445 1289 1693"> <tr> <td data-bbox="352 445 715 488">Laxatives</td> <td data-bbox="715 445 1289 488">Aloe, Castor oil, Ispaghula, Senna</td> </tr> <tr> <td data-bbox="352 488 715 530">Cardiotonic</td> <td data-bbox="715 488 1289 530">Digitalis, Arjuna</td> </tr> <tr> <td data-bbox="352 530 715 663">Carminatives and G.I. regulators</td> <td data-bbox="715 530 1289 663">Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafoetida, Nutmeg, Cinnamon</td> </tr> <tr> <td data-bbox="352 663 715 748">Astringents</td> <td data-bbox="715 663 1289 748">Myrobalan, Black Catechu, Pale Catechu</td> </tr> <tr> <td data-bbox="352 748 715 880">Drugs acting on nervous system</td> <td data-bbox="715 748 1289 880">Hyoscyamus, Belladonna, Ephedra, Opium, Tea leaves, Coffee seeds, Coca</td> </tr> <tr> <td data-bbox="352 880 715 922">Anti-hypertensive</td> <td data-bbox="715 880 1289 922">Rauwolfia</td> </tr> <tr> <td data-bbox="352 922 715 965">Anti-tussive</td> <td data-bbox="715 922 1289 965">Vasaka, Tolu Balsam</td> </tr> <tr> <td data-bbox="352 965 715 1008">Anti-rheumatics</td> <td data-bbox="715 965 1289 1008">Colchicum seed</td> </tr> <tr> <td data-bbox="352 1008 715 1050">Anti-tumour</td> <td data-bbox="715 1008 1289 1050">Vinca, Podophyllum</td> </tr> <tr> <td data-bbox="352 1050 715 1093">Antidiabetics</td> <td data-bbox="715 1050 1289 1093">Pterocarpus, Gymnema</td> </tr> <tr> <td data-bbox="352 1093 715 1135">Diuretics</td> <td data-bbox="715 1093 1289 1135">Gokhru, Punarnava</td> </tr> <tr> <td data-bbox="352 1135 715 1178">Anti-dysenteric</td> <td data-bbox="715 1135 1289 1178">Ipecacuanha</td> </tr> <tr> <td data-bbox="352 1178 715 1263">Antiseptics and disinfectants</td> <td data-bbox="715 1178 1289 1263">Benzoin, Myrrh, Neem, Turmeric</td> </tr> <tr> <td data-bbox="352 1263 715 1305">Antimalarials</td> <td data-bbox="715 1263 1289 1305">Cinchona, Artemisia</td> </tr> <tr> <td data-bbox="352 1305 715 1348">Oxytocic</td> <td data-bbox="715 1305 1289 1348">Ergot</td> </tr> <tr> <td data-bbox="352 1348 715 1391">Vitamins</td> <td data-bbox="715 1348 1289 1391">Cod liver oil, Shark liver oil</td> </tr> <tr> <td data-bbox="352 1391 715 1476">Enzymes</td> <td data-bbox="715 1391 1289 1476">Papaya, Diastase, Pancreatin, Yeast</td> </tr> <tr> <td data-bbox="352 1476 715 1608">Pharmaceutical Aids</td> <td data-bbox="715 1476 1289 1608">Kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelatine</td> </tr> <tr> <td data-bbox="352 1608 715 1693">Miscellaneous</td> <td data-bbox="715 1608 1289 1693">Squill, Galls, Ashwagandha, Tulsi, Guggul</td> </tr> </table>	Laxatives	Aloe, Castor oil, Ispaghula, Senna	Cardiotonic	Digitalis, Arjuna	Carminatives and G.I. regulators	Coriander, Fennel, Cardamom, Ginger, Clove, Black Pepper, Asafoetida, Nutmeg, Cinnamon	Astringents	Myrobalan, Black Catechu, Pale Catechu	Drugs acting on nervous system	Hyoscyamus, Belladonna, Ephedra, Opium, Tea leaves, Coffee seeds, Coca	Anti-hypertensive	Rauwolfia	Anti-tussive	Vasaka, Tolu Balsam	Anti-rheumatics	Colchicum seed	Anti-tumour	Vinca, Podophyllum	Antidiabetics	Pterocarpus, Gymnema	Diuretics	Gokhru, Punarnava	Anti-dysenteric	Ipecacuanha	Antiseptics and disinfectants	Benzoin, Myrrh, Neem, Turmeric	Antimalarials	Cinchona, Artemisia	Oxytocic	Ergot	Vitamins	Cod liver oil, Shark liver oil	Enzymes	Papaya, Diastase, Pancreatin, Yeast	Pharmaceutical Aids	Kaolin, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelatine	Miscellaneous	Squill, Galls, Ashwagandha, Tulsi, Guggul	30
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6	<p>Plant fibres used as surgical dressings: Cotton, silk, wool and regenerated fibres</p> <p>Sutures – Surgical Catgut and Ligatures</p>	3																																						
7	<p>● Basic principles involved in the traditional systems of medicine like: Ayurveda, Siddha, Unani and Homeopathy</p> <p>● Method of preparation of Ayurvedic formulations like: Arista, Asava, Gutika, Taila, Churna, Lehya and Bhasma</p>	8																																						

8	Role of medicinal and aromatic plants in national economy and their export potential	2
9	Herbs as health food: Brief introduction and therapeutic applications of: Nutraceuticals, Antioxidants, Pro-biotics, Pre-biotics, Dietary fibres, Omega-3-fatty acids, Spirulina, Carotenoids, Soya and Garlic	4
10	Introduction to herbal formulations	4
11	Herbal cosmetics: Sources, chemical constituents, commercial preparations, therapeutic and cosmetic uses of: Aloe vera gel, Almond oil, Lavender oil, Olive oil, Rosemary oil, Sandal Wood oil	4
12	Phytochemical investigation of drugs	2

PHARMACOGNOSY – PRACTICAL

Course Code: ER20-13P

75 Hours (3 Hours/week)

Scope: This course is designed to train the students in physical identification, morphological characterization, physical and chemical characterization, and evaluation of commonly used herbal drugs.

Course Objectives: This course will provide hands-on experiences to the students in

1. Identification of the crude drugs based on their morphological characteristics
2. Various characteristic anatomical characteristics of the herbal drugs studied through transverse section
3. Physical and chemical tests to evaluate the crude drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Identify the given crude drugs based on the morphological characteristics
2. Take a transverse section of the given crude drugs
3. Describe the anatomical characteristics of the given crude drug under microscopical conditions
4. Carry out the physical and chemical tests to evaluate the given crude drugs

Practicals

1. Morphological Identification of the following drugs:

Ispaghula, Senna, Coriander, Fennel, Cardamom, Ginger, Nutmeg, Black Pepper, Cinnamon, Clove, Ephedra, Rauwolfia, Gokhru, Punarnava, Cinchona, Agar.

2. Gross anatomical studies (Transverse Section) of the following drugs:

Ajwain, Datura, Cinnamon, Cinchona, Coriander, Ashwagandha, Liquorice, Clove, Curcuma, Nux_vomica, Vasaka

3. Physical and chemical tests for evaluation of any FIVE of the following drugs:

Asafoetida, Benzoin, Pale catechu, Black catechu, Castor oil, Acacia, Tragacanth, Agar, Guar gum, Gelatine.

Assignments

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Market preparations of various dosage forms of Ayurvedic, Unani, Siddha, Homeopathic (Classical and Proprietary), indications, and their labelling requirements
2. Market preparations of various herbal formulations and herbal cosmetics, indications, and their labelling requirements
3. Herb-Drug interactions documented in the literature and their clinical significances

Field Visit

The students shall be taken in groups to a medicinal garden to witness and understand the nature of various medicinal plants discussed in theory and practical courses. Additionally, they shall be taken in groups to the pharmacies of traditional systems of medicines to understand the availability of various dosage forms and their labelling requirements. Individual reports from each student on their learning experience from the field visit shall be submitted.

HUMAN ANATOMY AND PHYSIOLOGY – THEORY

Course Code: ER20-14T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on the structure and functions of the human body. It helps in understanding both homeostasis mechanisms and homeostatic imbalances of various systems of the human body.

Course Objectives: This course will discuss the following:

1. Structure and functions of the various organ systems and organs of the human body
2. Homeostatic mechanisms and their imbalances in the human body
3. Various vital physiological parameters of the human body and their significances

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the various organ systems of the human body
2. Discuss the anatomical features of the important human organs and tissues
3. Explain the homeostatic mechanisms regulating the normal physiology in the human system
4. Discuss the significance of various vital physiological parameters of the human body

Chapter	Topic	Hours
1	Scope of Anatomy and Physiology Definition of various terminologies	2
2	Structure of Cell: Components and its functions	2
3	Tissues of the human body: Epithelial, Connective, Muscular and Nervous tissues – their sub-types and characteristics.	4
4	Osseous system: structure and functions of bones of axial and appendicular skeleton Classification, types and movements of joints, disorders of joints	3 3
5	Haemopoietic system <ul style="list-style-type: none">● Composition and functions of blood● Process of Hemopoiesis● Characteristics and functions of RBCs, WBCs, and platelets● Mechanism of Blood Clotting● Importance of Blood groups	8

6	Lymphatic system <ul style="list-style-type: none"> ● Lymph and lymphatic system, composition, function and its formation. ● Structure and functions of spleen and lymph node. 	3
7	Cardiovascular system <ul style="list-style-type: none"> ● Anatomy and Physiology of heart ● Blood vessels and circulation (Pulmonary, coronary and systemic circulation) ● Cardiac cycle and Heart sounds, Basics of ECG ● Blood pressure and its regulation 	8
8	Respiratory system <ul style="list-style-type: none"> ● Anatomy of respiratory organs and their functions. ● Regulation, and Mechanism of respiration. ● Respiratory volumes and capacities – definitions 	4
9	Digestive system <ul style="list-style-type: none"> ● Anatomy and Physiology of the GIT ● Anatomy and functions of accessory glands ● Physiology of digestion and absorption 	8
10	Skeletal muscles <ul style="list-style-type: none"> ● Histology ● Physiology of muscle contraction ● Disorder of skeletal muscles 	2
11	Nervous system <ul style="list-style-type: none"> ● Classification of nervous system ● Anatomy and physiology of cerebrum, cerebellum, mid brain ● Function of hypothalamus, medulla oblongata and basal ganglia ● Spinal cord-structure and reflexes ● Names and functions of cranial nerves. ● Anatomy and physiology of sympathetic and parasympathetic nervous system (ANS) 	8
12	Sense organs - Anatomy and physiology of <ul style="list-style-type: none"> ● Eye ● Ear ● Skin ● Tongue ● Nose 	6
13	Urinary system <ul style="list-style-type: none"> ● Anatomy and physiology of urinary system ● Physiology of urine formation ● Renin - angiotensin system ● Clearance tests and micturition 	4

14	Endocrine system (Hormones and their functions) <ul style="list-style-type: none"> ● Pituitary gland ● Adrenal gland ● Thyroid and parathyroid gland ● Pancreas and gonads 	6
15	Reproductive system <ul style="list-style-type: none"> ● Anatomy of male and female reproductive system ● Physiology of menstruation ● Spermatogenesis and Oogenesis ● Pregnancy and parturition 	4

HUMAN ANATOMY AND PHYSIOLOGY – PRACTICAL

Course Code: ER20-14P

75 Hours (3 Hours/week)

Scope: This course is designed to train the students and instil the skills for carrying out basic physiological monitoring of various systems and functions.

Course Objectives: This course will provide hands-on experience in the following:

1. General blood collection techniques and carrying out various haematological assessments and interpreting the results
2. Recording and monitoring the vital physiological parameters in human subjects and the basic interpretations of the results
3. Microscopic examinations of the various tissues permanently mounted in glass slides
4. Discuss the anatomical and physiological characteristics of various organ systems of the body using models, charts, and other teaching aids

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Perform the haematological tests in human subjects and interpret the results
2. Record, monitor and document the vital physiological parameters of human subjects and interpret the results
3. Describe the anatomical features of the important human tissues under the microscopical conditions
4. Discuss the significance of various anatomical and physiological characteristics of the human body

Practicals

1. Study of compound microscope
2. General techniques for the collection of blood
3. Microscopic examination of Epithelial tissue, Cardiac muscle, Smooth muscle, Skeletal muscle, Connective tissue, and Nervous tissue of ready / pre-prepared slides.
4. Study of Human Skeleton-Axial skeleton and appendicular skeleton
5. Determination of
 - a. Blood group
 - b. ESR
 - c. Haemoglobin content of blood
 - d. Bleeding time and Clotting time
6. Determination of WBC count of blood
7. Determination of RBC count of blood
8. Determination of Differential count of blood
9. Recording of Blood Pressure in various postures, different arms, before and after exertion and interpreting the results
10. Recording of Body temperature (using mercury, digital and IR thermometers at various locations), Pulse rate/ Heart rate (at various locations in the body, before and after exertion), Respiratory Rate
11. Recording Pulse Oxygen (before and after exertion)
12. Recording force of air expelled using Peak Flow Meter
13. Measurement of height, weight, and BMI
14. Study of various systems and organs with the help of chart, models, and specimens
 - a) Cardiovascular system
 - b) Respiratory system
 - c) Digestive system
 - d) Urinary system
 - e) Endocrine system
 - f) Reproductive system
 - g) Nervous system
 - h) Eye
 - i) Ear
 - j) Skin

SOCIAL PHARMACY – THEORY

Course Code: ER20-15T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on public health, epidemiology, preventive care, and other social health related concepts. Also, to emphasize the roles of pharmacists in the public health programs.

Course Objectives: This course will discuss about basic concepts of

1. Public health and national health programs
2. Preventive healthcare
3. Food and nutrition related health issues
4. Health education and health promotion
5. General roles and responsibilities of pharmacists in public health

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Discuss about roles of pharmacists in the various national health programs
2. Describe various sources of health hazards and disease preventive measures
3. Discuss the healthcare issues associated with food and nutritional substances
4. Describe the general roles and responsibilities of pharmacists in public health

Chapter	Topic	Hours
1	Introduction to Social Pharmacy <ul style="list-style-type: none">• Definition and Scope. Social Pharmacy as a discipline and its scope in improving the public health. Role of Pharmacists in Public Health. (2)• Concept of Health -WHO Definition, various dimensions, determinants, and health indicators. (3)• National Health Policy – Indian perspective (1)• Public and Private Health System in India, National Health Mission (2)• Introduction to Millennium Development Goals, Sustainable Development Goals, FIP Development Goals (1)	9
2	Preventive healthcare – Role of Pharmacists in the following <ul style="list-style-type: none">• Demography and Family Planning (3)• Mother and child health, importance of breastfeeding, ill effects of infant milk substitutes and bottle feeding (2)• Overview of Vaccines, types of immunity and immunization (4)	18

	<ul style="list-style-type: none"> • Effect of Environment on Health – Water pollution, importance of safe drinking water, waterborne diseases, air pollution, noise pollution, sewage and solid waste disposal, occupational illnesses, Environmental pollution due to pharmaceuticals (7) • Psychosocial Pharmacy: Drugs of misuse and abuse – psychotropics, narcotics, alcohol, tobacco products. Social Impact of these habits on social health and productivity and suicidal behaviours (2) 	
3	<p>Nutrition and Health</p> <ul style="list-style-type: none"> • Basics of nutrition – Macronutrients and Micronutrients (3) • Importance of water and fibres in diet (1) • Balanced diet, Malnutrition, nutrition deficiency diseases, ill effects of junk foods, calorific and nutritive values of various foods, fortification of food (3) • Introduction to food safety, adulteration of foods, effects of artificial ripening, use of pesticides, genetically modified foods (1) • Dietary supplements, nutraceuticals, food supplements – indications, benefits, Drug-Food Interactions (2) 	10
4	<p>Introduction to Microbiology and common microorganisms (3)</p> <p>Epidemiology: Introduction to epidemiology, and its applications. Understanding of terms such as epidemic, pandemic, endemic, mode of transmission, outbreak, quarantine, isolation, incubation period, contact tracing, morbidity, mortality, . (2)</p> <p>Causative agents, epidemiology and clinical presentations and Role of Pharmacists in educating the public in prevention of the following communicable diseases:</p> <ul style="list-style-type: none"> • Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1, SARS, MERS, COVID-19), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis, Ebola (7) • Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrheal diseases, typhoid, amebiasis, worm infestations, food poisoning (7) 	28

	<ul style="list-style-type: none"> • Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya (4) • Surface infections – trachoma, tetanus, leprosy (2) • STDs, HIV/AIDS (3) 	
5	Introduction to health systems and all ongoing National Health programs in India, their objectives, functioning, outcome, and the role of pharmacists.	8
6	Pharmacoeconomics – Introduction, basic terminologies, importance of pharmacoeconomics	2

SOCIAL PHARMACY – PRACTICAL

Course Code: ER20-15P

75 Hours (3 Hours/week)

Scope: This course is designed to provide simulated experience in various public health and social pharmacy activities.

Course Objectives: This course will train the students on various roles of pharmacists in public health and social pharmacy activities in the following areas:

1. National immunization programs
2. Reproductive and child health programs
3. Food and nutrition related health programs
4. Health education and promotion
5. General roles and responsibilities of the pharmacists in public health
6. First Aid for various emergency conditions including basic life support and cardiopulmonary resuscitation

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the roles and responsibilities of pharmacists in various National health programs
2. Design promotional materials for public health awareness
3. Describe various health hazards including microbial sources
4. Advice on preventive measures for various diseases
5. Provide first aid for various emergency conditions

Note: Demonstration / Hands-on experience / preparation of charts / models / promotional materials / role plays / enacting / e-brochures / e-flyers / podcasts / video podcasts / any other innovative activities to understand the concept of various elements of social pharmacy listed here. (At least one activity to be carried out for each one of the following):

Practicals

1. National immunization schedule for children, adult vaccine schedule, Vaccines which are not included in the National Immunization Program.
2. RCH – reproductive and child health – nutritional aspects, relevant national health programmes.
3. Family planning devices
4. Microscopical observation of different microbes (readymade slides)
5. Oral Health and Hygiene
6. Personal hygiene and etiquettes – hand washing techniques, Cough and sneeze etiquettes.
7. Various types of masks, PPE gear, wearing/using them, and disposal.
8. Menstrual hygiene, products used
9. First Aid – Theory, basics, demonstration, hands on training, audio-visuals, and practice, BSL (Basic Life Support) Systems [SCA - Sudden Cardiac Arrest, FBAO - Foreign Body Airway Obstruction, CPR, Defibrillation (using AED) (Includes CPR techniques, First Responder).
10. Emergency treatment for all medical emergency cases viz. snake bite, dog bite, insecticide poisoning, fractures, burns, epilepsy etc.
11. Role of Pharmacist in Disaster Management.
12. Marketed preparations of disinfectants, antiseptics, fumigating agents, antilarval agents, mosquito repellents, etc.
13. Health Communication: Audio / Video podcasts, Images, Power Point Slides, Short Films, etc. in regional language(s) for mass communication / education / Awareness on 5 different communicable diseases, their signs and symptoms, and prevention.
14. Water purification techniques, use of water testing kit, calculation of Content/percentage of KMnO_4 , bleaching powder to be used for wells/tanks
15. Counselling children on junk foods, balanced diets – using Information, Education and Communication (IEC), counselling, etc. (Simulation Experiments).
16. Preparation of various charts on nutrition, sources of various nutrients from Locally available foods, calculation of caloric needs of different groups (e.g. child, mother, sedentary lifestyle, etc.). Chart of glycemic index of foods.
17. Tobacco cessation, counselling, identifying various tobacco containing products through charts/pictures

Assignment

The students shall be asked to submit the written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. An overview of Women's Health Issues
2. Study the labels of various packed foods to understand their nutritional contents
3. Breastfeeding counselling, guidance – using Information, Education and Communication (IEC)
4. Information about the organizations working on de-addiction services in the region (city / district, etc.)
5. Role of a pharmacist in disaster management – A case study
6. Overview on the National Tuberculosis Elimination Programme (NTEP)
7. Drug disposal systems in the country, at industry level and citizen level
8. Various Prebiotics or Probiotics (dietary and market products)
9. Emergency preparedness: Study of local Government structure with respect to Fire, Police departments, health department
10. Prepare poster/presentation for general public on any one of the Health Days. e.g. Day, AIDS Day, Handwashing Day, ORS day, World Diabetes Day, World Heart Day, etc.
11. List of home medicines, their storage, safe handling, and disposal of unused medicines
12. Responsible Use of Medicines: From Purchase to Disposal
13. Collection of newspaper clips (minimum 5) relevant to any one topic and its submission in an organized form with collective summary based on the news items
14. Read a minimum of one article relevant to any theory topic, from Pharma /Science/ or other Periodicals and prepare summary of it for submission
15. Potential roles of pharmacists in rural India

Field Visits

The students shall be taken in groups to visit any THREE of the following facilities to witness and understand the activities of such centres/facilities from the perspectives of the topics discussed in theory and/or practical courses. Individual reports from each student on their learning experience from the field visits shall be submitted.

1. Garbage Treatment Plant
2. Sewage Treatment Plant
3. Bio-medical Waste Treatment Plant
4. Effluent Treatment Plant
5. Water purification plant
6. Orphanage / Elderly-Care-Home / School and or Hostel/Home for persons with disabilities
7. Primary health care centre

8. ER-2020 D.Pharm Syllabus – Part II

S. No.	Course Code	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week
1.	ER20-21T	Pharmacology – Theory	75	25	3	1
2.	ER20-21P	Pharmacology – Practical	50	-	2	-
3.	ER20-22T	Community Pharmacy & Management – Theory	75	25	3	1
4.	ER20-22P	Community Pharmacy & Management – Practical	75	-	3	-
5.	ER20-23T	Biochemistry & Clinical Pathology – Theory	75	25	3	1
6.	ER20-23P	Biochemistry & Clinical Pathology – Practical	50	-	2	-
7.	ER20-24T	Pharmacotherapeutics – Theory	75	25	3	1
8.	ER20-24P	Pharmacotherapeutics – Practical	25	-	1	-
9.	ER20-25T	Hospital & Clinical Pharmacy – Theory	75	25	3	1
10.	ER20-25P	Hospital & Clinical Pharmacy – Practical	25	-	1	-
11.	ER20-26T	Pharmacy Law & Ethics	75	25	3	1

PHARMACOLOGY – THEORY

Course Code: ER20-21T

75 Hours (3 Hours/week)

Scope: This course provides basic knowledge about different classes of drugs available for the pharmacotherapy of common diseases. The indications for use, dosage regimen, routes of administration, pharmacokinetics, pharmacodynamics, and contraindications of the drugs discussed in this course are vital for successful professional practice.

Course Objectives: This course will discuss the following:

1. General concepts of pharmacology including pharmacokinetics, pharmacodynamics, routes of administration, etc.
2. Pharmacological classification and indications of drugs
3. Dosage regimen, mechanisms of action, contraindications of drugs
4. Common adverse effects of drugs

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the basic concepts of pharmacokinetics and pharmacodynamics
2. Enlist the various classes and drugs of choices for any given disease condition
3. Advise the dosage regimen, route of administration and contraindications for a given drug
4. Describe the common adverse drug reactions

Chapter	Topic	Hours
1	General Pharmacology <ul style="list-style-type: none">• Introduction and scope of Pharmacology• Various routes of drug administration - advantages and disadvantages• Drug absorption - definition, types, factors affecting drug absorption• Bioavailability and the factors affecting bioavailability• Drug distribution - definition, factors affecting drug distribution• Biotransformation of drugs - Definition, types of biotransformation reactions, factors influencing drug metabolisms• Excretion of drugs - Definition, routes of drug excretion• General mechanisms of drug action and factors modifying drug action	10

2	<p>Drugs Acting on the Peripheral Nervous System</p> <ul style="list-style-type: none"> • Steps involved in neurohumoral transmission • Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> a) Cholinergic drugs b) Anti-Cholinergic drugs c) Adrenergic drugs d) Anti-adrenergic drugs e) Neuromuscular blocking agents f) Drugs used in Myasthenia gravis g) Local anaesthetic agents h) Non-Steroidal Anti-Inflammatory drugs (NSAIDs) 	11
3	<p>Drugs Acting on the Eye</p> <p>Definition, classification, pharmacological actions, dose, indications and contraindications of</p> <ul style="list-style-type: none"> • Miotics • Mydriatics • Drugs used in Glaucoma 	2
4	<p>Drugs Acting on the Central Nervous System</p> <p>Definition, classification, pharmacological actions, dose, indications, and contraindications of</p> <ul style="list-style-type: none"> • General anaesthetics • Hypnotics and sedatives • Anti-Convulsant drugs • Anti-anxiety drugs • Anti-depressant drugs • Anti-psychotics • Nootropic agents • Centrally acting muscle relaxants • Opioid analgesics 	8
5	<p>Drugs Acting on the Cardiovascular System</p> <p>Definition, classification, pharmacological actions, dose, indications, and contraindications of</p> <ul style="list-style-type: none"> • Anti-hypertensive drugs • Anti-anginal drugs • Anti-arrhythmic drugs • Drugs used in atherosclerosis and Congestive heart failure • Drug therapy for shock 	6

6	Drugs Acting on Blood and Blood Forming Organs Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> • Hematinic agents • Anti-coagulants • Anti-platelet agents • Thrombolytic drugs 	4
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> • Bronchodilators • Expectorants • Anti-tussive agents • Mucolytic agents 	2
8	Drugs Acting on the Gastro Intestinal Tract Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> • Anti-ulcer drugs • Anti-emetics • Laxatives and purgatives • Anti-diarrheal drugs 	5
9	Drugs Acting on the Kidney Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> • Diuretics • Anti-Diuretics 	2
10	Hormones and Hormone Antagonists Physiological and pathological role and clinical uses of <ul style="list-style-type: none"> • Thyroid hormones • Anti-thyroid drugs • Parathormone • Calcitonin • Vitamin D • Insulin • Oral hypoglycemic agents • Estrogen • Progesterone • Oxytocin • Corticosteroids 	8

11	Autocoids <ul style="list-style-type: none"> • Physiological role of Histamine, 5 HT and Prostaglandins • Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists 	3
12	Chemotherapeutic Agents: Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes: <ul style="list-style-type: none"> • Penicillins • Cephalosporins • Aminoglycosides • Fluoroquinolones • Macrolides • Tetracyclines • Sulphonamides • Anti-tubercular drugs • Anti-fungal drugs • Anti-viral drugs • Anti-amoebic agents • Anthelmintics • Anti-malarial agents • Anti-neoplastic agents 	12
13	Biologicals Definition, types, and indications of biological agents with examples	2

PHARMACOLOGY – PRACTICAL

Course Code: ER20-21P

50 Hours (2 Hours/week)

Scope: This course provides the basic understanding about the uses, mechanisms of actions, dose dependent responses of drugs in simulated virtual animal models and experimental conditions.

Course Objectives: This course will demonstrate / provide hands-on experience in the virtual platform using appropriate software on the following

1. Study of pharmacological effects of drugs like local anaesthetics, mydriatic and mitotic on rabbit eye
2. Screening the effects of various drugs acting in the central nervous system
3. Study of drug effects on isolated organs / tissues
4. Study of pyrogen testing on rabbit

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Study and report the local anaesthetic, mydriatic and mitotic effects of the given drug on the rabbit eye
2. Choose appropriate animal experiment model to study the effects of the given drugs acting on the central nervous system and submit the report
3. Perform the effects of given tissues (simulated) on isolated organs / tissues and interpret the results
4. Interpret the dose dependent responses of drugs in various animal experiment models

Practicals

Introduction to the following topics pertaining to the experimental pharmacology have to be discussed and documented in the practical manuals.

1. Introduction to experimental pharmacology
2. Study of laboratory animals
(a) Mice; (b) Rats; (c) Guinea pigs; (d) Rabbits
3. Commonly used instruments in experimental pharmacology
4. Different routes of administration of drugs in animals
5. Types of pre-clinical experiments: In-Vivo, In-Vitro, Ex-Vivo, etc.
6. Techniques of blood collection from animals

Experiments

Note: Animals shall not be used for doing / demonstrating any of the experiments given. The given experiments shall be carried-out / demonstrated as the case may be, ONLY with the use of software program(s) such as 'Ex Pharm' or any other suitable software

1. Study of local anaesthetics on rabbit eye
2. Study of Mydriatic effect on rabbit eye
3. Study of Miotic effect on rabbit eye
4. Effect of analgesics using Analgesiometer
5. Study of analgesic activity by writhing test
6. Screening of anti-convulsant using Electro Convulsiometer
7. Screening of Muscle relaxants using Rota-Rod apparatus
8. Screening of CNS stimulants and depressants using Actophotometer
9. Study of anxiolytic activity using elevated plus maze method
10. Study of effect of drugs (any 2) on isolated heart
11. Effect of drugs on ciliary motility on frog's buccal cavity
12. Pyrogen testing by rabbit method

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Introduction to Allergy Testing
2. Introduction to Toxicity Studies
3. Drug Facts Labels of US FDA
4. Pre-clinical studies in new drug development
5. Medicines and meals: Before or After food
6. Pre-clinical studies in new drug development
7. Drugs available as paediatric formulations
8. Drug information apps

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T

75 Hours (3 Hours/week)

Scope: The course is designed to impart basic knowledge and skills to provide various pharmaceutical care services to patients and general practitioners in the community setup.

Course Objectives: This course will discuss the following:

1. Establishing and running a community pharmacy and its legal requirements
2. Professional aspects of handling and filling prescriptions
3. Patient counselling on diseases, prescription and or non-prescription medicines
4. Scope for performing basic health screening in community pharmacy settings

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the establishment, legal requirements, and effective administration of a community pharmacy
2. Professionally handle prescriptions and dispense medications
3. Counsel patients about the disease, prescription and or non-prescription medicines
4. Perform basic health screening on patients and interpret the reports in the community pharmacy settings

Chapter	Topic	Hours
1	Community Pharmacy Practice – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	Prescription and prescription handling <ul style="list-style-type: none">• Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage• Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them	7

4	Communication skills <ul style="list-style-type: none"> • Definition, types of communication skills • Interactions with professionals and patients • Verbal communication skills (one-to-one, over the telephone) • Written communication skills • Body language • Patient interview techniques 	6
5	Patient counselling <ul style="list-style-type: none"> • Definition and benefits of patient counselling • Stages of patient counselling - Introduction, counselling content, counselling process, and closing the counselling session • Barriers to effective counseling - Types and strategies to overcome the barriers • Patient counselling points for chronic diseases/disorders - Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS • Patient Package Inserts - Definition, importance and benefits, Scenarios of PPI use in India and other countries • Patient Information leaflets - Definition and uses 	10
6	Medication Adherence Definition, factors influencing non-adherence, strategies to overcome non-adherence	2
7	Health Screening Services in Community Pharmacy Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	5
9	Over The Counter (OTC) Medications <ul style="list-style-type: none"> • Definition, need and role of Pharmacists in OTC medication dispensing • OTC medications in India, counseling for OTC products • Self-medication and role of pharmacists in promoting the safe practices during self-medication • Responding to symptoms, minor ailments, and advice for self-care in conditions such as - Pain management, Cough, Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat, Skin disorders, Oral health (mouth ulcers, dental pain, gum swelling) 	15

10	<p>Community Pharmacy Management</p> <ul style="list-style-type: none"> • Legal requirements to set up a community pharmacy • Site selection requirements • Pharmacy designs and interiors • Vendor selection and ordering • Procurement, inventory control methods, and inventory management • Financial planning and management • Accountancy in community pharmacy – Day book, Cash book • Introduction to pharmacy operation softwares – usefulness and availability • Customer Relation Management (CRM) • Audits in Pharmacies • SOP of Pharmacy Management • Introduction to Digital Health, mHealth and Online pharmacies 	25
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COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Code: ER20-22P

75 Hours (3 Hours/week)

Scope: The course is designed to train the students and improve professional skills to provide various pharmaceutical care services in community pharmacy.

Course Objectives: This course will train the students in the following

1. Professional handling and filling prescriptions
2. Patient counselling on diseases and minor ailments
3. Patient counselling on prescription and / or non-prescription medicines
4. Preparation of counselling materials such as patient information leaflets
5. Performing basic health screening tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Handle and fill prescriptions in a professional manner
2. Counsel patients on various diseases and minor ailments
3. Counsel patients on prescription and or non-prescription medicines
4. Design and prepare patient information leaflets
5. Perform basic health screening tests

Practicals

Note: The following practicals shall be carried out in the model community pharmacy with appropriate simulated scenarios and materials. Students shall be trained through role plays wherever necessary. The activities of the students shall be assessed / evaluated using a structured objective assessment form.

1. Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)
2. Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
3. Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
4. Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity)
 - Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement
5. Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease)
 - Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
6. Providing counselling to simulated patients for the following minor ailments (any three)
 - Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
- 7 Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
- 8 Use of Community Pharmacy Software and digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)

2. List out the various abbreviations, short forms used in prescriptions and their interpretation
3. Patient Information Leaflet for a given chronic disease / disorder
4. Patient Information Leaflet for prescription / non-prescription medicines
5. Preparation of window / shelf display materials for the model community pharmacy
6. Overview of Software available for retail pharmacy management including billing, inventory, etc.
7. Dosage / Medication Reminder Aids
8. Overview on the operations and marketing strategies of various online pharmacies
9. Overview on the common fixed dose combinations
10. Overview on the medications requiring special storage conditions
11. Role of Community Pharmacists in preventing Antimicrobial Resistance
12. Jan Aushadhi and other Generic Medicine initiatives in India
13. Global Overview of Online Pharmacies
14. Community Pharmacy Practice Standards: Global Vs. Indian Scenario
15. Overview of pharmacy associations in India

Field Visit

The students shall be taken in groups to visit community pharmacies and medicine distributors to understand and witness the professional activities of the community pharmacists, and supply chain logistics. Individual reports from each student on their learning experience from the field visit shall be submitted.

BIOCHEMISTRY & CLINICAL PATHOLOGY – THEORY

Course Code: ER20-23T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on the study of structure and functions of biomolecules and the chemical processes associated with living cells in normal and abnormal states. The course also emphasizes on the clinical pathology of blood and urine.

Course Objectives: This course will discuss the following at the fundamental level

1. Structure and functions of biomolecules
2. Catalytic activity, diagnostic and therapeutic importance of enzymes
3. Metabolic pathways of biomolecules in health and illness (metabolic disorders)
4. Biochemical principles of organ function tests and their clinical significance
5. Qualitative and quantitative determination of biomolecules / metabolites in the biological sample
6. Clinical pathology of blood and urine

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the functions of biomolecules
2. Discuss the various functions of enzymes in the human system
3. Explain the metabolic pathways of biomolecules in both physiological and pathological conditions
4. Describe the principles of organ function tests and their clinical significances
5. Determine the biomolecules / metabolites in the given biological samples, both qualitatively and quantitatively
6. Describe the clinical pathology of blood and urine

Chapter	Topic	Hours
1	Introduction to biochemistry: Scope of biochemistry in pharmacy; Cell and its biochemical organization.	2
2	Carbohydrates <ul style="list-style-type: none">• Definition, classification with examples, chemical properties• Monosaccharides - Structure of glucose, fructose, and galactose• Disaccharides - structure of maltose, lactose, and sucrose• Polysaccharides - chemical nature of starch and glycogen• Qualitative tests and biological role of carbohydrates	5

3	<p>Proteins</p> <ul style="list-style-type: none"> • Definition, classification of proteins based on composition and solubility with examples • Definition, classification of amino acids based on chemical nature and nutritional requirements with examples • Structure of proteins (four levels of organization of protein structure) • Qualitative tests and biological role of proteins and amino acids • Diseases related to malnutrition of proteins. 	5
4	<p>Lipids</p> <ul style="list-style-type: none"> • Definition, classification with examples • Structure and properties of triglycerides (oils and fats) • Fatty acid classification - Based on chemical and nutritional requirements with examples • Structure and functions of cholesterol in the body • Lipoproteins - types, composition and functions in the body • Qualitative tests and functions of lipids 	5
5	<p>Nucleic acids</p> <ul style="list-style-type: none"> • Definition, purine and pyrimidine bases • Components of nucleosides and nucleotides with examples • Structure of DNA (Watson and Crick model), RNA and their functions 	4
6	<p>Enzymes</p> <ul style="list-style-type: none"> • Definition, properties and IUB and MB classification • Factors affecting enzyme activity • Mechanism of action of enzymes, Enzyme inhibitors • Therapeutic and pharmaceutical importance of enzymes 	5
7	<p>Vitamins</p> <ul style="list-style-type: none"> • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins 	6
8	<p>Metabolism (Study of cycle/pathways without chemical structures)</p> <ul style="list-style-type: none"> • Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose 	20

	<p>level. Diseases related to abnormal metabolism of Carbohydrates</p> <ul style="list-style-type: none"> • Metabolism of lipids: Lipolysis, β-oxidation of Fatty acid (Palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as Ketoacidosis, Fatty liver, Hypercholesterolemia • Metabolism of Amino acids (Proteins): General reactions of amino acids and its significance— Transamination, deamination, Urea cycle and decarboxylation. Diseases related to abnormal metabolism of amino acids, Disorders of ammonia metabolism, phenylketonuria, alkaptonuria and Jaundice. • Biological oxidation: Electron transport chain and Oxidative phosphorylation 	
9	Minerals: Types, Functions, Deficiency diseases, recommended dietary requirements	05
10	<p>Water and Electrolytes</p> <ul style="list-style-type: none"> • Distribution, functions of water in the body • Water turnover and balance • Electrolyte composition of the body fluids, Dietary intake of electrolyte and Electrolyte balance • Dehydration, causes of dehydration and oral rehydration therapy 	05
11	Introduction to Biotechnology	01
12	<p>Organ function tests</p> <ul style="list-style-type: none"> • Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances • Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances • Lipid profile tests and its clinical significances 	06
13	<p>Introduction to Pathology of Blood and Urine</p> <ul style="list-style-type: none"> • Lymphocytes and Platelets, their role in health and disease • Erythrocytes - Abnormal cells and their significance • Normal and Abnormal constituents of Urine and their significance 	06

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P

50 Hours (2 Hours/week)

Scope: This course is designed to train the students in the qualitative testing of various biomolecules and testing of biological samples for determination of normal and abnormal constituents

Course Objectives: This course will train and provide hands-on experiences on the following

1. Qualitative determination of biomolecules / metabolites in simulated biological samples
2. Determination of normal and abnormal constituents of simulated blood and urine samples

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Qualitatively determine the biomolecules / metabolites in the given biological samples
2. Determine the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

Practicals

1. Qualitative analysis of carbohydrates (4 experiments)
2. Qualitative analysis of Proteins and amino acids (4 experiments)
3. Qualitative analysis of lipids (2 experiments)
4. Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
5. Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
6. Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
7. Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

The students shall be asked to submit written assignments on Various Pathology Lab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

PHARMACOTHERAPEUTICS - THEORY

Course Code: ER20-24T

75 Hours (3 Hours/week)

Scope: This course is designed to impart basic knowledge on etiopathogenesis of common diseases and their management along with quality use of medicines.

Course Objectives: This course will discuss about

1. Etiopathogenesis of selected common diseases and evidence-based medicine therapy
2. Importance of individualized therapeutic plans based on diagnosis
3. Basic methods for assessing the clinical outcomes of drug therapy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Help assessing the subjective and objective parameters of patients in common disease conditions
2. Assist other healthcare providers to analyse drug related problems and provide therapeutic interventions
3. Participate in planning the rational medicine therapy for common diseases
4. Design and deliver discharge counselling for patients

Chapter	Topic	Hours
1	Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs)	8
2	Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of the diseases associated with	
	(a) Cardiovascular System <ul style="list-style-type: none">• Hypertension• Angina and Myocardial infarction• Hyperlipidaemia• Congestive Heart Failure	8
	(b) Respiratory System <ul style="list-style-type: none">• Asthma• COPD	4
	(c) Endocrine System <ul style="list-style-type: none">• Diabetes• Thyroid disorders - Hypo and Hyperthyroidism	5
	(d) Central Nervous System <ul style="list-style-type: none">• Epilepsy	8

<ul style="list-style-type: none"> • Parkinson's disease • Alzheimer's disease • Stroke • Migraine 	
(e) Gastro Intestinal Disorders <ul style="list-style-type: none"> • Gastro oesophageal reflux disease • Peptic Ulcer Disease • Alcoholic liver disease • Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis) 	8
(f) Haematological disorders <ul style="list-style-type: none"> • Iron deficiency anaemia • Megaloblastic anaemia 	4
(g) Infectious diseases <ul style="list-style-type: none"> • Tuberculosis • Pneumonia • Urinary tract infections • Hepatitis • Gonorrhoea and Syphilis • Malaria • HIV and Opportunistic infections • Viral Infections (SARS, CoV2) 	12
(h) Musculoskeletal disorders <ul style="list-style-type: none"> • Rheumatoid arthritis • Osteoarthritis 	3
(i) Dermatology <ul style="list-style-type: none"> • Psoriasis • Scabies • Eczema 	3
(j) Psychiatric Disorders <ul style="list-style-type: none"> • Depression • Anxiety • Psychosis 	4
(k) Ophthalmology <ul style="list-style-type: none"> • Conjunctivitis (bacterial and viral) • Glaucoma 	2
(l) Anti-microbial Resistance	2
(m) Women's Health <ul style="list-style-type: none"> • Polycystic Ovary Syndrome • Dysmenorrhea • Premenstrual Syndrome 	4

PHARMACOTHERAPEUTICS – PRACTICAL

Course Code: ER20-24P

25 Hours (1 Hour/week)

Scope: This course is designed to train the students in the basic skills required to support the pharmaceutical care services for selected common disease conditions.

Course Objectives: This course will train the students on

1. How to prepare a SOAP (Subjective, Objective, Assessment and Plan) note for clinical cases of selected common diseases
2. Patient counselling techniques/methods for common disease conditions

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Write SOAP (Subjective, Objective, Assessment and Plan) notes for the given clinical cases of selected common diseases
2. Counsel the patients about the disease conditions, uses of drugs, methods of handling and administration of drugs, life-style modifications, and monitoring parameters.

Practicals

I. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions.

1. Hypertension
2. Angina Pectoris
3. Myocardial Infarction
4. Hyperlipidaemia
5. Rheumatoid arthritis
6. Asthma
7. COPD
8. Diabetes
9. Epilepsy
10. Stroke
11. Depression
12. Tuberculosis
13. Anaemia (any one type as covered in theory)
14. Viral infection (any one type as covered in theory)
15. Dermatological conditions (any one condition as covered in theory)

- II. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios. The students are expected to provide counselling on disease condition, medications, life-style modifications, monitoring parameters, etc. and the same shall be documented. (Minimum 5 cases)

- III. Simulated cases to enable dose calculation of selected drugs in paediatrics, and geriatrics under various pathological conditions. (Minimum 4 cases)

HOSPITAL AND CLINICAL PHARMACY – THEORY

Course Code: ER20-25T

75 Hours (3 Hours/week)

Scope: This course is designed to impart fundamental knowledge and professional skills required for facilitating various hospital and clinical pharmacy services.

Course Objectives: This course will discuss and train the students in the following

1. Hospital and Hospital Pharmacy organization and set-ups
2. Basics of hospital pharmacy services including the procurement, supply chain, storage of medicines and medical supplies
3. Basics of clinical pharmacy including introduction to comprehensive pharmaceutical care services
4. Basic interpretations of common laboratory results used in clinical diagnosis towards optimizing the drug therapy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Explain about the basic concepts of hospital pharmacy administration
2. Manage the supply chain and distribution of medicines within the hospital settings
3. Assist the other healthcare providers in monitoring drug therapy and address drug related problems
4. Interpret common lab investigation reports for optimizing drug therapy

S. No.	Topic	Hours
1	Hospital Pharmacy <ul style="list-style-type: none">• Definition, scope, national and international scenario• Organisational structure• Professional responsibilities, Qualification and experience requirements, job specifications, work-load requirements and inter professional relationships• Good Pharmacy Practice (GPP) in hospital• Hospital Pharmacy Standards (FIP Basel Statements, AHSP)• Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	6
2	Different Committees in the Hospital <ul style="list-style-type: none">• Pharmacy and Therapeutics Committee - Objectives, Composition, and functions• Hospital Formulary - Definition, procedure for development and use of hospital formulary	4

	<ul style="list-style-type: none"> • Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance 	
4	Supply Chain and Inventory Control <ul style="list-style-type: none"> • Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics • Procedures of Drug Purchases – Drug selection, short term, long term, and tender/e-tender process, quotations, etc. • Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc. • Inventory Management of Central Drug Store – Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms) • FEFO, FIFO methods • Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs • Documentation - purchase and inventory 	14
5	Drug distribution <ul style="list-style-type: none"> • Drug distribution (in- patients and out - patients) – Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method. • Distribution of drugs to ICCU/ICU/NICU/Emergency wards. • Automated drug dispensing systems and devices • Distribution of Narcotic and Psychotropic substances and their storage 	7
6	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	4
7	Radio Pharmaceuticals - Storage, dispensing and disposal of radiopharmaceuticals	2
8	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy	2
9	Clinical Pharmacy: Definition, scope, and development - in India and other countries Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc.	12

	<p>Daily activities of clinical pharmacists: Definition, goal, and procedure of</p> <ul style="list-style-type: none"> • Ward round participation • Treatment Chart Review • Adverse drug reaction monitoring • Drug information and poisons information • Medication history • Patient counselling • Interprofessional collaboration <p>Pharmaceutical care: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care</p> <p>Medication Therapy Management, Home Medication Review</p>	
10	<p>Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results</p> <ul style="list-style-type: none"> • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Pulmonary Function Tests 	10
11	<p>Poisoning: Types of poisoning: Clinical manifestations and Antidotes</p> <p>Drugs and Poison Information Centre and their services – Definition, Requirements, Information resources with examples, and their advantages and disadvantages</p>	6
12	<p>Pharmacovigilance</p> <ul style="list-style-type: none"> • Definition, aim and scope • Overview of Pharmacovigilance 	2
13	<p>Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP</p> <p>Drug Interactions: Definition, types, clinical significance of drug interactions</p>	6

HOSPITAL AND CLINICAL PHARMACY – PRACTICAL

Course Code: ER20-25P

25 Hours (1 Hour / Week)

Scope: This course is designed to train the students to assist other healthcare providers in the basic services of hospital and clinical pharmacy.

Course Objectives: This course will train the students with hands-on experiences, simulated clinical case studies in the following:

1. Methods to systematically approach and respond to drug information queries
2. How to interpret common laboratory reports to understand the need for optimizing dosage regimens
3. How to report suspected adverse drug reactions to the concerned authorities
4. Uses and methods of handling various medical/surgical aids and devices
5. How to interpret drug-drug interactions in the treatment of common diseases.

Course Outcomes: Upon completion of the course, the students will be able to

1. Professionally handle and answer the drug information queries
2. Interpret the common laboratory reports
3. Report suspected adverse drug reactions using standard procedures
4. Understand the uses and methods of handling various medical/surgical aids and devices
5. Interpret and report the drug-drug interactions in common diseases for optimizing the drug therapy

Note: Few of the experiments of Hospital and Clinical Pharmacy practical course listed here require adequate numbers of desktop computers with internet connectivity, adequate drug information resources including reference books, different types of surgical dressings and other medical devices and accessories. Various charts, models, exhibits pertaining to the experiments shall also be displayed in the laboratory.

Practicals

1. Systematic approach to drug information queries using primary / secondary / tertiary resources of information (2 cases)
2. Interpretation of laboratory reports to optimize the drug therapy in a given clinical case (2 cases)
3. Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
4. Demonstration / simulated / hands-on experience on the identification, types, use / application /administration of
 - Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.

- Different types of bandages such as sterile gauze, cotton, crepe bandages, etc.
 - Needles, syringes, catheters, IV set, urine bag, RYLE's tube, urine pots, colostomy bags, oxygen masks, etc.
5. Case studies on drug-drug interactions (any 2 cases)
 6. Wound dressing (simulated cases and role play –minimum 2 cases)
 7. Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)
 8. Use of Hospital Pharmacy Software and various digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Typical profile of a drug to be included in the hospital formulary
2. Brief layout and various services of the Central Sterile Supplies Department (CSSD)
3. Various types of sterilizers and sterilization techniques used in hospitals
4. Fumigation and pesticide control in hospitals
5. Role of Pharmacists in Transition of Care: Discharge cards, post hospitalization care, medicine reconciliation activities in developed countries
6. Total parenteral nutrition and IV admixtures and their compatibility issues
7. Concept of electronic health records
8. Invasive and Non-invasive diagnostic tests - HRCT, MRI, Sonography, 2D ECHO, X-rays, Mammography, ECG, EMG, EEG
9. Home Diagnostic Kits - Pregnancy Test, COVID testing etc
10. Measures to be taken in hospitals to minimize Antimicrobial Resistance
11. Role and responsibilities of a pharmacist in public hospital in rural parts of the country
12. Safe waste disposal of hospital waste

Field Visit

The students shall be taken in groups to visit a Government / private healthcare facility to understand and witness the various hospital and clinical pharmacy services provided. Individual reports from each student on their learning experience from the field visit shall be submitted.

PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T

75 Hours (3 Hours/week)

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

Course Objectives: This course will discuss the following

1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Chapter	Topics	Hours
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	Pharmacy Act-1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties. Pharmacy Practice Regulations 2015	5
3	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 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.	23

	<p>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.</p> <p>Study of schedule C and C1, G, H, H1, K, P, M, N, and X.</p> <p>Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.</p>	
4	<p>Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.</p>	2
5	<p>Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.</p>	2
6	<p>Prevention of Cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, 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.</p>	2
7	<p>Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons</p>	2
8	<p>FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements</p>	2

9	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, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	5
10	Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.	5
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	2
12	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	1
13	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices	3
14	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	7
15	Blood bank – basic requirements and functions	2
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	2
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	2
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	2
19	Introduction to the Consumer Protection Act	1
20	Introduction to the Disaster Management Act	1
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	2

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines

9. Appendices

No	Appendix Document
1.	A typical format for the assessment of an Assignment
2.	A typical format for the assessment of a Field Visit Report
3.	List of instruments and equipment required for the conduct of D.Pharm program as per ER-2020

Appendix – 1

A typical format for the assessment of an Assignment

Name of the College:

Name of the Student:	
Academic Year of the Student:	
Name of the Subject:	
Title of the Assignment:	
Date on which the Assignment was given:	
Date on which the Assignment was submitted:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Directions: For evaluation, enter rating of the student utilizing the following scale:

5 – Excellent; 4 - Very Good; 3 – Good; 2 – Satisfactory; 1 - Poor

Assessment Criteria	Score	Comments if any
a. Relevance with the content		
b. Use of resource material		
c. Organization & mechanical accuracy		
d. Cohesion & coherence		
e. Language proficiency & Timely submission		
Total Score		

Signature of the Student with Date:

Note: Subject teacher should try to cover all assignments mentioned in the list for each practical subject by assigning the topics to the students. Students should be encouraged to submit an assignment (in a format decided by the Institute) and encouraged to present assignments (at least any one assignment per subject) in the class.

Appendix – 2

A typical format for the assessment of a Field Visit Report

Name of the College:

Name of the Student:	
Academic Year of the Student:	
Name of the Subject:	
Name & full address of the organization visited:	
Date and Duration of Visit:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Objectives set for the field visit: (give 2 – 4 objectives one by one)
Prior preparation of the student for the field visit: (minimum 100 words)
Describe the general experiences during the field visit: (minimum 100 words)
Learning points: Describe what theoretical concept that is correlated during the field visit: (minimum 300 words)

Appendix – 3

List of Instruments and Equipment required for the Conduct of D.Pharm program as per ER-2020

As per ER 2020 regulation;

At least four laboratories specified below should be provided for:

1. Pharmaceutics Lab.
2. Pharm. Chemistry Lab.
3. Physiology, Pharmacology and Pharmacognosy Lab.
4. Biochemistry, Clinical Pathology, Hospital and Clinical Pharmacy Lab.

The institutions shall provide “Model Pharmacy” as per following details

Model Pharmacy	No.	Area
<u>Essential:</u> Running Model Community Pharmacy	01	80 Sq. Mts. (Including 10 Sq. mt. for Drug Information Centre & 10 Sq. mt. for Patient Counselling)
<u>Desirable:</u> Drug Model Store		

NOTE: Wherever animal experimentations are prescribed in the curriculum, the required knowledge and skill should be imparted by using computer assisted modules. Animal hold area shall be as per the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines.

Practical of Social Pharmacy, Pharmacotherapeutics can be conducted in any one of the laboratories by making necessary provisions.

Department wise List of Minimum Equipment required for D.Pharm
(For a practical batch of 20 students)

1. Physiology, Pharmacology and Pharmacognosy Lab.

S. No.	Name	Minimum required Nos. for DPharm 60 intake
1	Microscopes	20
2	Haemocytometer with Micropipettes	20
3	Sahli's haemoglobinometers	20
4	Sphygmomanometers	5
5	Stethoscopes	10
6	Human Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands
7	Models for various organs	One model of each organ system
8	Specimen for various organs and systems	One model for each organ system
9	Human Skeleton and bones	One set of skeleton and one spare bone
10	Different Contraceptive Devices and Models	One set of each device
11	Digital Balance (10 mg Sensitivity)	1
12	Computer with LCD	1
13	Licensed Software packages for Physiological & Pharmacological experiment	1
14	IR Thermometer	2
15	Refrigerator	1
16	First aid equipment	Adequate number
17	Stop watch	20
18	Dummy Inhalers and Nebulizer	1
19	Pharmacotherapeutic charts for various diseases & disorders	Adequate number
20	Surgical devices and Sutures	Adequate number
21	Digital BP Instrument	5
22	Mercury Thermometer	10
23	Digital Thermometer	10
24	Pulse Oximeter	5
25	ESR Apparatus (Westergren and Wintrobe)	10
26	Peak Flow meter	10
27	Stadiometer	2
28	Adult Weighing Scale (150 kg)	5
29	Glucometer	10
30	Projection microscope	1
31	Permanent slide set of plants and charts for Pharmacognosy Lab	Adequate number
32	Drug information resources	Adequate number
33	Various types of PPE Kits,	Adequate number

34	Charts /displays/ AVs on tobacco control, glycemic index of foods, nutrition, reproductive health	Adequate number
35	Menstrual hygiene products	Adequate number
36	Display for various disinfectants, mosquito repellents etc	Adequate number
37	Water Testing Kit	Adequate number
38	Permanent slide of different microbes	Adequate number

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

2. Pharmaceutical Chemistry/ Biochemistry, Clinical Pathology

S. No.	Name	Minimum required Nos. for DPharm 60 intake
1	Hot plates	5
2	Hot Air Oven	1
3	Refrigerator	1
4	Analytical Balances for demonstration	1
5	Digital balance 10mg sensitivity	5
6	Magnetic Stirrers with Thermostat	10
7	Vacuum Pump	1
8	Digital pH meter	1
9	Wall Mounted Water Distillation Unit	2
10	Nessler's Cylinders	40
11	Digital Melting Point Apparatus	2
12	Thieles Tube	20
13	Digital Colorimeter	2
14	Thermostatic Water Bath	1

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

3. Pharmaceutics

S. No.	Name	Minimum required Nos. for DPharm 60 intake
1	Digital balance (10mg)	5
2	Microscopes	10
3	Autoclave	1
4	Vacuum Pump	1
5	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 54, 60, 80, 85, 100, 120	10 sets
6	Tablet dissolution test apparatus IP (Digital single/double Unit)	1
7	Magnetic stirrer, 500ml and 1 litter capacity with speed control	5

8	Digital pH meter	1
9	Capsule Counter	2
10	Hot Plate	2
11	Distillation Unit	1
12	Tablet counter – small size	2
13	Hot air oven	1
14	Electric water bath unit	2
15	Stalagmometer	5
16	Desiccator	5
17	Buchner Funnels (Medium)	10
18	Filtration assembly with Vacuum Pump	1
19	Andreasen's Pipette	5
20	Ointment slab	20
21	Ointment spatula	20
22	Pestle and mortar porcelain	20
23	Refrigerator	1
24	Micrometre slide Eyepiece	5
25	Micrometre slide Stage	5
26	Viscometer Ostwald/Brookfield	1
27	Stop watch	1
28	Sintered glass filter with vacuum	4

NOTE: Aseptic cabinet or area should be provided as per Appendix A of ER 2020 Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

Machine Room

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake
1	Capsule filling machine	1
2	Automated Single Station Tablet punching machine	1
3	Tablet disintegration test apparatus IP (Digital Single/Double unit)	1
4	Monsanto's hardness tester	2
5	Pfizer type hardness tester	2
6	Friability test apparatus (Digital Single/Double unit)	1
7	Sieve shaker with sieve set	1
8	Ointment filling machine	1
9	All-purpose equipment with all accessories	1
10	Bottle washing Machine	1
11	Bottle Sealing Machine	1
12	Liquid Filling Machine	1
13	Ampoule washing machine	1
14	Ampoule filling and sealing machine (Jet Burner)	1

15	Clarity test apparatus	1
16	Collapsible tube – Filling and Sealing	1
17	Liquid Mixer	1

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

4. Hospital and Clinical Pharmacy Lab

S. No.	Name	Minimum required Nos for D.Pharm 60 intake
1	Orthopaedical & Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc	Adequate Number
2	Different Types of bandages such as sterile gauze, cotton, crepe bandages, roll bandage etc	Adequate Number
3	Mannequins for CPR-1 (with indication Signals)	2
4	Mannequins for injection IV Arm	2
5	Variety of Needles	20
6	Variety of Syringes	20
7	Variety of catheters	5
8	IV set	20
9	Urine Bag	2
10	RYLE's tube	2
11	Urine pots	2
12	Colostomy bags	2
13	Oxygen masks	10
14	Inventory Software for Retail Pharmacy	1

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department

5. Model Pharmacy

S. No.	Name	Minimum required Nos. for D.Pharm 60 intake (
1	<ul style="list-style-type: none"> • Empty cartons of variety medicines (across variety dosage forms) • Various name plates indicating different parts of Pharmacy, • Proper arrangement of medicines, shelves, racks, drawers • Box/area for expiry medicines, • Display windows, shelves • Computer • Refrigerator • Designated patient counselling area, • Patient Information Leaflets/Cards • Patient waiting area, • Drug Information books • Health information display, • Various devices for screening services (B.P. monitor, glucometer etc) • Height and body weight chart • Dummy devices (eg. Inhalers) • Display of pharmacist registration, license and other licenses • Display of name of owner • Inspection book, • Lock and key arrangement for Schedule X and NDPS medicines, • Bill book (dummy) , Computer stationary for bill printing 	Adequate
2	Computers: hospital and community pharmacy management software	1

APPENDIX 4

Subject wise list of Recommended Books (Latest Edition)

Pharmaceutics

1. History of Pharmacy in India by Dr. Harikishan Singh
2. Indian Pharmacopoeia, Govt. of India Publication
3. A Text book of Pharmaceuticals Formulation by B.M. Mithal, Vallabh Prakashan.
4. Bentleys' Text book of Pharmaceutics, Editor E.A. Rawlins, Elsevier Int.,
5. The Theory and Practice of Industrial Pharmacy. Leon Lachman, Herbert Lieberman and Joseph Kanig, Editors, Lea and Febiger, Philadelphia. Varghese Publishing House
6. Responsible Use of Medicines: A Layman's Handbook, www.ipapharma.org / publications

Pharmaceutical Chemistry

1. Medicinal & Pharmaceutical chemistry by Harikishan Singh and VK Kapoor
2. Wilson and Griswold's Text book of Organic Medicinal and pharmaceutical Chemistry
3. Practical Organic Chemistry by Mann and Saunders.
4. Practical Pharmaceutical Chemistry, Volume- I & II by Beckett and J. B. Stenlake
5. Indian Pharmacopoeia
6. Vogel's text book of Practical Organic Chemistry

Pharmacognosy

1. Text book of Pharmacognosy by C. K. Kokate, S. B. Gokhale, A.P. Purohit, Nirali Prakashan
2. Text book of Pharmacognosy by C.S. Shah and J. S. Qadry, CBS Publishers & Distributors Pvt. Ltd.
3. Text Book of Pharmacognosy by T. E. Wallis. CBS Publishers & Distributors Pvt. Ltd.
4. Study of crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
5. Powder crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
6. Anatomy of crude drugs by M. A. Iyengar, Manipal Press Ltd, Manipal
7. Augmented Text Book of Homeopathic Pharmacy by Dr. D D Banerjee, B Jain Publishers (P) Ltd

Human Anatomy and Physiology

1. Human Physiology by C. C. Chatterjee
2. Human Anatomy and Physiology by S. Chaudhary and A. Chaudhary
3. Derasari and Gandhi's elements of Human Anatomy, Physiology and Health Education
4. S.R. Kale and R.R. Kale, Textbook of Practical Anatomy and Physiology
5. Ross and Wilson Anatomy and Physiology in Health and illness
6. Human Anatomy and Physiology by Tortora Gerard J
7. Fundamentals of Medical Physiology by K. Sambulingam and P Sambulingam
8. Ranade V.G. Text Book of Practical Physiology
9. Goyal R.K., Natvar M.P. and Shah S.A., Practical Anatomy, Physiology and Biochemistry, Experimental Physiology

Social Pharmacy

1. Social Pharmacy – Innovation and development. Geoff Harding, Sarah Nettleton and Kevin Taylor. The Pharmaceutical Press.
2. Text Book of Community Pharmacy Practice. RPSGB Publication
3. Community Pharmacy Handbook- Jonathan Waterfield
4. S Khurana, P Suresh and R Kalsi. Health Education & Community Pharmacy. S Vikas & Co
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