



Uttar Pradesh University of Medical Sciences,
Saifai, Etawah, Uttar Pradesh, India, 206130

Faculty of Pharmacy

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, recommended by Pharmacy Council of India, New Delhi]

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VISION

Faculty of pharmacy is serving with the revelation to come out as the superlative pharmacy college of Uttar Pradesh and to realize acknowledgment at national or international level for excellence in eminence pharmacy education and research. The faculty of this university is steadfast to work towards new ideas and innovations in pharmaceutical sciences and to motivate students in to world class pharmacy professionals with real to serve the interests of the nation and its people in a competitive global scenario.

MISSION

1. To develop Pharmacy professionals as conscientious citizens of a society with ethical values.
2. Patient centered service.
3. Community oriented research and strong community relationship.
4. Meet the regional, national and global pharmacy health care educational needs.
5. Inter organizational linkage.
6. To nurture the future Pharmacist with focused approach for Academic /Research excellence / Industries and overall development.

FAQs

1. (A) What will be the minimum qualification for admission in B. Pharm (First Year)?

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.M /P.C.B) as optional subjects individually.

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

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

2. What will be the duration of the course?

- ❖ Eight semesters (four academic years for B. Pharm)
- ❖ Six semesters (three academic years for lateral entry students in B. Pharm)

3. What will be the medium of instruction and examinations?

English

4. How much working days should be in each semester?

Each semester shall consist of not less than 100 working days.

5. How much attendance is compulsory for progress?

At least 80% attendance (in theory and practical separately) is compulsory in each semester. A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff.

6. What criteria should be followed for credit assignment?

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For Theory and Laboratory courses- Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. One (01) credit assigned for lecture and tutorial hours and half (1/2) credit 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. How many minimum credits are required for getting B. Pharm degree?

The minimum credit points required for award of a B. Pharm. degree is 208.

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. What will be the pattern for course of study?

The course of study for B. Pharm shall include Semester Wise Theory & Practical.

9. What will be the pattern for examinations or assessments?

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university. Two (02) sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college.

10. Is Industrial training is compulsory?

Every candidate shall be required to work for at least 150 hours spread over four weeks in Pharmaceutical Industry or Hospital after the semester VI and before the commencement of Semester VII.

11. What will be the 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.

12. What are the job opportunities after completion of the course?

Pharmacy graduates have a wide range of career opportunities available to them. /

A. Industrial Pharmacy:

The pharmaceutical industry produces active drug substances, chemicals, prescription and non-prescription drugs, and all other health products. Pharmacists do such things as marketing, research and product development, quality control, sales and administration.

B. Hospital Pharmacy:

The knowledge and clinical skills that contemporary pharmacist possesses make this individual an authoritative source of drug information for physicians, nurses, and patients.

C. Community Pharmacy/ Retail Pharmacy:

This is a more familiar practice setting for the pharmacists and people probably visit the community pharmacy more often than they do other health care team.

D. Veterinary Pharmacy:

The Pharmacist towing this line is focused on the treatment given to animals. A veterinary pharmacist should have a grounded knowledge of the basic care given to animals. He should be able to provide the necessary medication to animals and livestock.

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E. Social/Administrative Pharmacy:

This practice involves research and analysis in various areas of the health sector including how to improve public health care, making necessary drugs available and affordable among others.

F. Pharmacy Journalism:

This is an adventurous field for the pharmacist who is looking for a not-so-ordinary job. This area involves being inquisitive and having a spark for writing.

G. The Academia:

Pharmacists here are interested in training the next generation of pharmacists. They are involved with teaching, research, public service and patient care.

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

6. Attendance and progress

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

7. Program/Course credit structure

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

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)

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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 Pharmacy I- Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II- Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial Pharmacy I – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
Total		27	5	26

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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 Pharmacy II – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
Total		28	5	24

* Non University Examination (NUE)

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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 Herbs			
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

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.

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.

Duties of the Program Committee:

- ✓ Periodically reviewing the progress of the classes.
- ✓ Discussing the problems concerning curriculum, syllabus and the conduct of classes.
- ✓ 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.
- ✓ Communicating its recommendation to the Head of the institution on academic matters.
- ✓ The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessional exam (Internal Assessment) and before the endsemester exam.

11. Examinations/Assessments

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

11.1. End semester examinations

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

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

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I – Theory	10	15	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	Physical Pharmaceutics I –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		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	Total Marks	
			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	Total Marks	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial Pharmacy I – 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 and Phytochemistry 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 Pharmacy I – 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 Marks	Duration	Marks	Duration	
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology – Theory	10	15	1 Hr	75	3 Hrs	100
BP606T	Quality Assurance – Theory	10	15	1 Hr	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	35	4 Hrs	50
Total		75	120	18 Hrs	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 Marks	Sessional Duration	Total	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							
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbs – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
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							
BP812ET	Dietary Supplements And Nutraceuticals – Theory							
BP813ET	Pharmaceutical Product Development – Theory							
BP814PW	Project Work					150	4 Hrs	150
Total		40	60	4 Hrs	100	450	16 Hrs	550

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)	=	05 x 2 = 10
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10
	Total =	30 marks

For subjects having Non-University Examination

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

Question paper pattern for practical sessional examination

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. End semester examinations

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

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Table-XIII: Tentative schedule of End semester examinations

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

**Question paper pattern for End semester theory examination
For 75 marks paper**

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

For 50 marks paper

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

15. 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:

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

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

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

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

19. Cumulative Grade Point Average (CGPA)

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

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

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

20. Declaration of class

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

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.

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Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
Total	75 Marks

Evaluation of Presentation:

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

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

22. Industrial training (Desirable)

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

23. Practice School

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

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

24. Award of Ranks

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

25. Award of degree

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

26. Duration for completion of the program of study

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

27. Re-admission after break of study

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

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

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CHAPTER - II: SYLLABUS

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Semester I

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Course name- HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

Course code- BP101T

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.

Course outcomes:

CO1: Explain the gross morphology, structure and functions of various organs of the human body.

CO2: Describe the various homeostatic mechanisms and their imbalances.

CO3: Identify the various tissues and organs of different systems of human body

CO4: Perform the various experiments related to special senses and nervous system.

CO5: 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

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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, Reticuloendothelial 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

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BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

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

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam, Jaypee Brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee Brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee Brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

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

Course name- PHARMACEUTICAL ANALYSIS (Theory)
Course code- BP102T

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

45 Hours

Course outcomes:

CO1: Understand the principles of volumetric and electro chemical analysis

CO2: Illustrate various volumetric and electro chemical titrations

CO3: Develop analytical skills

CO4: Understanding the method of drug analysis

CO5: Develop the knowledge of students for industrial level

Course Content:

UNIT-I

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

10 Hours

Different techniques of analysis

Methods of expressing concentration

Primary and secondary standards

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

Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

UNIT-II

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

10 Hours

Non aqueous titration: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III

Precipitation titrations: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

10 Hours

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

Concepts of oxidation and reduction

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

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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, Latest Edition

Course name- PHARMACEUTICS-I (Theory)

Course code- BP103T

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.

Course outcomes:

CO1: Outline the history of profession of pharmacy

CO2: Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations

CO3: Understand the professional way of handling the prescription

CO4: Formulate various conventional dosage forms

CO5: Understand the stability of 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 and 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 dosages forms

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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 (Mandle's 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

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Recommended Books (Latest Edition)

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 (Latest Edition)
5. British pharmacopoeia. (Latest Edition)
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.

Course name- PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

Course code- BP104T

45 Hours

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

Course outcomes:

- CO1:** Recall the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- CO2:** Understand the medicinal and pharmaceutical importance of inorganic compounds
- CO3:** Understand about properties of inorganic compounds
- CO4:** Understand the medicinal uses of inorganic compounds
- CO5:** Explain about radio-pharmaceuticals

Course Content:

UNIT I

10 Hours

Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate
General methods of preparation, assay for the compounds superscripted with asterisk (*), properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II

10 Hours

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

UNIT III

10 Hours

Gastrointestinal agents

Acidifiers: Ammonium chloride* and Dil. HCl
Antacid: Ideal properties of antacids, combinations of antacids, Sodium bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture
Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite
Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV

08 Hours

Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride*.
Emetics: Copper sulphate*, Sodium potassium tartarate
Haematinics: Ferrous sulphate*, Ferrous gluconate
Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite
Astringents: Zinc Sulphate, Potash Alum

UNIT V

07 Hours

Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of α , β , γ 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

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

Identification test

Magnesium hydroxide Ferrous sulphate
Sodium bicarbonate Calcium gluconate
Copper sulphate

Test for purity

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

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 (Latest Edition)

Course name-COMMUNICATION SKILLS (Theory)

Course code- BP105T

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.

Course outcomes:

CO1: Demonstration of Verbal and Non-Verbal Communication

CO2: Plan about team management as a team player

CO3: Develop interview skills

CO4: Develop Leadership qualities and essentials

CO5: Illustrate the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation

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

Course name –REMEDIAL BIOLOGY (Theory)

Course code-BP 106RBT

30 Hours

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

Course outcomes-

1. Recall the classification and salient features of five kingdoms of life
2. Understand the basic components of anatomy & physiology of plant
3. Understand the basic components of anatomy & physiology of animals
With 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 & Dicotyledons.

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

L *Am* *SP* *pur* *lp*

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

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

Introduction to experiments in biology

Study of Microscope

- ✓ Section cutting techniques
- ✓ Mounting and staining
- ✓ Permanent slide preparation
- ✓ Study of cell and its inclusions

Study of Stem, Root, Leaf, seed, fruit, flower and their modifications

Detailed study of frog by using computer models

Microscopic study and identification of tissues pertinent to Stem, Root, Leaf, seed, fruit and flower

Identification of bones

Determination of blood group

Determination of blood pressure

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

Course name- REMEDIAL MATHEMATICS (Theory)
Course code-BP 106RMT

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.

Course outcomes-

- 1) Explain the theory and their application in Pharmacy
- 2) Solve the different types of problems by applying theory
- 3) Find 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 of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

UNIT – III

06 Hours

Calculus

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

UNIT – IV

06 Hours

Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

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

Integration:

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

UNIT-V

06 Hours

Differential Equations : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**

Laplace Transform : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

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

Semester II

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Course name- HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

Course code- BP 201T

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.

Course outcomes:

CO1: Explain the gross morphology, structure and functions of various organs of the human body.

CO2: Illustrate the various homeostatic mechanisms and their imbalances.

CO3: Explain the various tissues and organs of different systems of human body.

CO4: Assess the hematological tests like blood cell counts, haemoglobin estimation, bleeding /clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.

CO5: Interpretation of coordinated working pattern of different organs of each system

CO6: Elaborate 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

10 hours

Respiratory system

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

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and

resuscitation methods.

Urinary system

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

Unit IV

Endocrine system

10 hours

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

Reproductive system

09 hours

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 & WilkinsCo, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH,U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee 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

Course name- PHARMACEUTICAL ORGANIC CHEMISTRY -I (Theory)

Course code- BP202T

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.

Course outcomes:

CO1: Demonstration of the structure, name and the type of isomerism of the organic compound

CO2: Explain the reaction, name the reaction and orientation of reactions

CO3: Develop the knowledge about reactivity /stability of compounds

CO4: Applying the knowledge for identification of organic compound

CO5: Relate the properties of organic compounds and their interactions

Course Content:

1. General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained
2. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I

Classification, nomenclature and isomerism

07 Hours

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds (upto 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, Saytzeff's 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)**4Hours / week**

1. Systematic qualitative analysis of unknown organic compounds
2. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
3. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
4. Solubility test
5. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
6. Melting point/Boiling point of organic compounds
7. Identification of the unknown compound from the literature using melting point/boiling point.
8. Preparation of the derivatives and confirmation of the unknown compound by melting point/boiling point.
9. Minimum 5 unknown organic compounds to be analysed systematically.
10. Preparation of suitable solid derivatives from organic compounds
11. 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.
- Reaction and reaction mechanism by Ahluwalia/Chatwal

Course name- BIOCHEMISTRY (Theory)

Course code- BP203 T

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.

Course Outcomes:

- CO1: Demonstrate the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
CO2: Explain the metabolism of nutrient molecules in physiological and pathological conditions.
CO3: Outline the genetic organization of mammalian
CO4: Explain the genome and role in characters determination
CO5: Compare functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I

Biomolecules

08 Hours

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

Carbohydrate metabolism

10 Hours

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance

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

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers level

UNIT III

Lipid metabolism

10 Hours

β -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)
Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

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

Amino acid metabolism

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

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

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

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV

10 Hours

Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V

07 Hours

Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

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

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes - Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

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

Recommended Books (Latest Editions)

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

Course name- PATHOPHYSIOLOGY (THEORY)

Course code-BP 204T

45 Hours

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.

Course Outcomes:

CO1: Explanation of the etiology and pathogenesis of the selected disease states;

CO2: Outline the signs and symptoms of the diseases;

CO3: Illustration of the complications of the diseases.

CO4: Understand the pathophysiological mechanisms

CO5: Explanation of the pathology of various conditions with reference to its pharmacological applications

Course content

10 Hours

Unit I

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

10 Hours

Unit II

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

10 Hours

Unit II

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 liverdisease

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

Principles of cancer: classification, etiology and pathogenesis of cancer

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

Principles of Cancer: Classification, etiology and pathogenesis of Cancer

Unit V

7 Hours

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171(Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

Course name- COMPUTER APPLICATIONS IN PHARMACY (Theory)

Course code- BP205 T

30 Hrs (2 Hrs/Week)

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

Course Outcomes:

CO1: Demonstration of the various types of application of computers in pharmacy

CO2: Demonstration the various types of databases

CO3: Illustration of various applications of data bases in pharmacy

CO4: Explanation about the data storage

CO5: Explanation about application in pharmacy management

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 system and software: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

06 hours

UNIT –II

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

06 hours

UNIT – III

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

06 hours

UNIT – IV

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

06 hours

UNIT-V

Computers as data analysis in Preclinical development: Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

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

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E. Fassett – Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development – Sean Ekins –
3. Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
4. Bioinformatics (Concept, Skills and Applications) – S.C. Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002 (INDIA)
5. 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

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Course name- ENVIRONMENTAL SCIENCES (Theory)

Course code- BP 206 T

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.

Course outcomes:

- CO1:** Create the awareness about environmental problems among learners.
- CO2:** Develop basic knowledge about the environment and its allied problems.
- CO3:** Develop an attitude of concern for the environment.
- CO4:** Develop motivation in learner to participate in environment protection and environment improvement.
- CO5:** Apply skills to help the concerned individuals in identifying and solving environmental problems.
- CO6:** Build enthusiasm in students 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

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.P. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p

Course name- PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)
Course code- BP301T

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.

Course Outcomes:

- CO1:** Name the structure, name and the type of isomerism of the organic compound
CO2: Demonstrate the reaction, name the reaction and orientation of reactions
CO3: Explain for reactivity/stability of compounds,
CO4: Develop organic compounds
CO5: Explain the Chemistry of fats and oils

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

Benzene and its derivatives

10 Hours

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
Reactions of benzene- nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation
Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
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

Fatty acids reaction Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

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:

Synthesis, reactions

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

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BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

1. Experiments involving laboratory techniques
2. Recrystallization
3. Steam distillation
4. Determination of following oil values (including standardization of reagents)
5. Acid value
6. Saponification value
7. Iodine value

Preparation of compounds

1. Benzanilide/Phenyl acylation reaction. benzoate/Acetanilide from Aniline/Phenol/Aniline by
2. 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/Acetanilide by halogenation (Bromination) reaction.
3. 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid /Nitro benzene by nitration reaction.
4. Benzoic acid from Benzyl chloride by oxidation reaction.
5. Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
6. 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
7. Benzil from Benzoin by oxidation reaction.
8. Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
9. Cinnamic acid from Benzaldehyde by Perkin reaction
10. *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.

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.

Course Outcomes:

- CO1: Demonstrate various physicochemical properties of drug molecules in the designing the dosage forms
- CO2: Explain the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- CO3: Demonstrate use of physicochemical properties in the formulation development and
- CO4: Explain the physical evaluation of dosage forms.
- CO5: Illustrate the stability with relation to physical properties

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

08 Hours

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

UNIT-V

07 Hours

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

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 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 to3, 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

**Course name- PHARMACEUTICAL MICROBIOLOGY
(Theory)**

45Hours

Course code-BP 303 T

Scope:

Study of all categories of microorganisms especially for the production of alcoholantibiotics, vaccines, vitamins enzymes etc.

Course Outcomes:

- CO1:** Illustrate methods of identification, cultivation and preservation of various micro organisms
- CO2:** Discuss the importance and implementation of sterilization in pharmaceutical processing and industry
- CO3:** Discuss sterility testing of pharmaceutical products.
- CO4:** Name out microbiological standardization of Pharmaceuticals.
- CO5:** Explain the prevention against microbes

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, B and USP.

Unit IV

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.

08 Hours**Unit V**

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.

07Hours**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. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.

Course name- PHARMACEUTICAL ENGINEERING (Theory)

Course code- BP 304 T

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.

Course Outcomes:

- CO1:** Discuss about various unit operations used in Pharmaceutical industries.
- CO2:** Discuss the material handling techniques.
- CO3:** Elaborate various processes involved in pharmaceutical manufacturing process.
- CO4:** Discuss various test to prevent environmental pollution.
- CO5:** Discuss significance of plant layout design for optimum use of resources.
- CO6:** Summarise 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, Airseparator, 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

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic

- and logarithmic probability plots.
9. 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.
 10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
 11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity)
 12. To study the effect of time on the Rate of Crystallization.
 13. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

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Course name- PHARMACEUTICAL ORGANIC CHEMISTRY -III (Theory)

Course code- BP401T

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.

Course Outcomes:

CO1: Discuss the methods of preparation and properties of organic compounds

CO2: Explain the stereo chemical aspects of organic compounds and stereo chemical reactions

CO3: Discuss the medicinal uses and other applications of organic compounds

CO4: Illustrate the stereo-chemical aspects of organic compounds

CO5: Define the uses 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

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

Course name- MEDICINAL CHEMISTRY – I (Theory)

Course code- BP402T

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.

Course Outcomes:

CO1: Explain the chemistry of drugs with respect to their pharmacological activity

CO2: Explain the drug metabolic pathways, adverse effect and therapeutic value of drugs

CO3: Discuss the Structural Activity Relationship (SAR) of different class of drugs

CO4: Discuss the chemical synthesis of some drugs

CO5: Describe the metabolism of drugs in humans

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, Proteinbinding, 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, Isoflurophate, 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

Sedatives and Hypnotics:

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

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

Miscellaneous:

Amides & imides: Glutethimide.

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

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.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methobarbital.

Hydantoin: Phenytoin*, Mephenytoin, Ethotoin

Oxazolidinone diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT - V

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

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

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

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

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406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

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

Assay of drugs

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

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.

Course name- PHYSICAL PHARMACEUTICS-II (Theory)

Course code- BP 403 T

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.

Course Outcomes:

CO1: Discussion about various physicochemical properties of drug molecules in the designing the dosage forms

CO2: Describe the principles of chemical kinetics & to use them for stability testing

CO3: Explanation about the determination of expiry date of formulations

CO4: Demonstration about use of physicochemical properties in the formulation development

CO5: Discussion about the 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.

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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

P 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

- Determination of particle size, particle size distribution using sieving method
- Determination of particle size, particle size distribution using Microscopic method
- Determination of bulk density, true density and porosity
- Determine the angle of repose and influence of lubricant on angle of repose
- Determination of viscosity of liquid using Ostwald's viscometer
- Determination sedimentation volume with effect of different suspending agent
- Determination sedimentation volume with effect of different concentration of single suspending agent
- Determination of viscosity of semisolid by using Brookfield viscometer
- Determination of reaction rate constant first order.
- Determination of reaction rate constant second order
- 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.

Course name- PHARMACOLOGY-I (Theory)

Course code- BP 404 T

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.

Course Outcomes:

CO1: Discussion about the pharmacological actions of different categories of drugs

CO2: Explain the mechanism of drug action at organ system/ sub cellular/ macro molecular levels.

CO3: Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.

CO4: Findout the effect of drugs on animals by simulated experiments

CO5: Describe correlation of pharmacology with other biomedical sciences

Course Content:

08 hours

UNIT-I

1. General Pharmacology

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.
Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

12 Hours

UNIT-II

General Pharmacology

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.

Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

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

Pharmacology of drugs acting on peripheral nervous system

10 Hours

Organization and function of ANS.

Neurohumoral transmission, co-transmission and classification of neurotransmitters.

Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

Local anesthetic agents.

Drugs used in myasthenia gravis and glaucoma

UNIT-IV

Pharmacology of drugs acting on central nervous system

08 Hours

Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

General anesthetics and pre-anesthetics.

Sedatives, hypnotics and centrally acting muscle relaxants.

Anti-epileptics

Alcohols and disulfiram

UNIT-V

Pharmacology of drugs acting on central nervous system

07 Hours

Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

Drugs used in Parkinsons disease and Alzheimer's disease.

CNS stimulants and nootropics.

Opioid analgesics and antagonists

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 stereotypy 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 McGraw-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,

Course name- PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)
Course code- BP 405 T

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.

Course Outcomes:

- CO1:** Discussion about the techniques in the cultivation and production of crude drugs
- CO2:** Describe the crude drugs, their uses and chemical nature
- CO3:** Explanation about the evaluation techniques for the herbal drugs
- CO4:** Explanation about the microscopic and morphological evaluation of crude drugs
- CO5:** Discussion about the medicinal properties of herbal drugs

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy:

Definition, history, scope and development of Pharmacognosy

Sources of Drugs – Plants, Animals, Marine & Tissue culture

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 serotaxonomical 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 piecemicrometer
- 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, 1st edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

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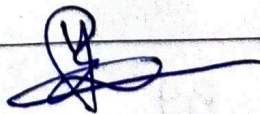
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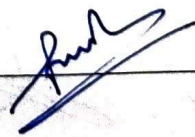
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Course name- MEDICINAL CHEMISTRY – II (Theory)

Course code- BP501T

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.

Course Outcomes:

CO1: Discussion about the chemistry of drugs with respect to their pharmacological activity

CO2: Explain the drug metabolic pathways, adverse effect and therapeutic value of drugs

CO3: Discussion about the Structural Activity Relationship (SAR) of different class of drugs

CO4: Elaboration of chemical synthesis of some drugs

CO5: Describe the metabolism of drugs in humans

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 human body

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: Meclorothamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT - II

10 Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics:

Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

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, Oestrone, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

UNIT - V

07 Hours

Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives: Cocaine, Hexylcaine, 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. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

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Course name- Industrial PharmacyI (Theory)

Course code-BP 502 T

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.

Course Outcomes:

CO1: Discussion about the various pharmaceutical dosage forms and their manufacturing techniques.

CO2: Explain about various considerations in development of pharmaceutical dosage forms

CO3: Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

UNIT-I

07 Hours

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

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

b. **Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization
BCS classification of drugs & its significant

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

UNIT-II

10 Hours

Tablets:

Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

Quality control tests: In process and finished product tests

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

UNIT-III

08 Hours

Capsules:

a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for

manufacture of pellets

UNIT-IV

10 Hours

Parenteral Products:

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

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

UNIT-V

10 Hours

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

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

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

BP 506 P. Industrial Pharmacy I (Practical)

4 Hours/week

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, 5th edition, 2005
- 9) Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

Course name- PHARMACOLOGY-II (Theory)

Course code-BP503T

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.

Course Outcomes:

CO1: Explain the mechanism of drug action and its relevance in the treatment of different diseases

CO2: Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments

CO3: Demonstrate the various receptor actions using isolated tissue preparation

CO4: Explanation about correlation of pharmacology with related medical sciences

Course Content:

UNIT-I

Pharmacology of drugs acting on cardio vascular system

10hours

- 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

Pharmacology of drugs acting on cardio vascular system

10hours

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

Pharmacology of drugs acting on urinary system

- e. Diuretics
- f. Anti-diuretics.

UNIT-III

Autocoids and related drugs

10hours

- g. Introduction to autacoids and classification
- h. Histamine, 5-HT and their antagonists.
- i. Prostaglandins, Thromboxanes and Leukotrienes.
- j. Angiotensin, Bradykinin and Substance P.
- k. Non-steroidal anti-inflammatory agents
- l. Anti-gout drugs
- m. Antirheumatic drugs

UNIT-IV

08hours

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

Pharmacology of drugs acting on endocrine system

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

Bioassay

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

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BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

- 1) Introduction to *in-vitro* pharmacology and physiological salt solutions.
- 2) Effect of drugs on isolated frog heart.
- 3) Effect of drugs on blood pressure and heart rate of dog.
- 4) Study of diuretic activity of drugs using rats/mice.
- 5) DRC of acetylcholine using frog rectus abdominis muscle.
- 6) Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
- 7) Bioassay of histamine using guinea pig ileum by matching method.
- 8) Bioassay of oxytocin using rat uterine horn by interpolation method.
- 9) Bioassay of serotonin using rat fundus strip by three point bioassay.
- 10) Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
- 11) Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schild's plot method).
- 12) Determination of PD_2 value using guinea pig ileum.
- 13) Effect of spasmogens and spasmolytics using rabbit jejunum.
- 14) Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
- 15) Analgesic activity of drug using central and peripheral methods

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

Recommended Books (Latest Editions)

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

Course name- PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

Course code- BP504 T

45Hours Scope: The main purpose of subject is to impart the students the knowledge of how these 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

Course Outcomes:

CO1: Tell about the modern extraction techniques, characterization and identification of the herbal drugs and phyto constituents

CO2: Demonstration about the preparation and development of herbal formulation.

CO3: Explanation about the herbal drug interactions

CO4: Discussion about isolation and identification of phyto constituents

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

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.

- 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
- 3) Caffeine - from tea dust.
- 4) Diosgenin from Dioscorea
- 5) Atropine from Belladonna
- 6) Sennosides from Senna
- 7) Separation of sugars by Paper chromatography
- 8) TLC of herbal extract
- 9) Distillation of volatile oils and detection of phytoconstituents by TLC
- 10) 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, 11nd 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.

Course name- PHARMACEUTICAL JURISPRUDENCE (Theory)

Course code-BP 505 T

45 Hours

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

Course Outcomes:

CO1: Explanation about Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.

CO2: Discussion about various Indian pharmaceutical Acts and Laws

CO3: Describe about The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO4: Explain 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

Study of Salient Features of Drugs and Magic Remedies Act and its rules: 08 Hours
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

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee 07 Hours

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

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Course name- **MEDICINAL CHEMISTRY – III (Theory)**

Course code- **BP601T**

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.

Course Outcomes:

- CO1:** Discussion about the importance of drug design and different techniques of drug design.
CO2: Discussion about the chemistry of drugs with respect to their biological activity.
CO3: Impart the knowledge about the metabolism, adverse effects and therapeutic value of drugs.
CO4: Describe the knowledge about the importance of SAR of drugs.

Course Content:

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

UNIT – I

10 Hours

Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 Hours

Antibiotics

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

Macrolide: Erythromycin, Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT - III

10 Hours

Anti-tubercular Agents

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

Antitubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*,

Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin,

Saquinavir, Indinavir, Ritonavir.

UNIT - IV

08 Hours

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole 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,

Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT - V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

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

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

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.

Course name- PHARMACOLOGY-III (Theory)

Course code- BP602 T

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.

Course Outcomes:

CO1: Explain the mechanism of drug action and its relevance in the treatment of different infectious diseases

CO2: Compare and the principles of toxicology and treatment of various poisonings and

CO3: Describe correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I

10hours

Pharmacology of drugs acting on Respiratory system

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

Pharmacology of drugs acting on the Gastrointestinal Tract

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

UNIT-II

10hours

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

Chemotherapy

- a) Antitubercular agents
- b) Antileprotic agents
- c) Antifungal agents
- d) Antiviral drugs
- e) Anthelmintics

- f) Antimalarial drugs
- g) Antiamoebic agents

UNIT-IV

08hours

Chemotherapy

- a) Urinary tract infections and sexually transmitted diseases.
- b) Chemotherapy of malignancy.

Immunopharmacology

- a) Immunostimulants
- b) Immunosuppressant
- c) Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

07hours

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, Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

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

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

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

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

Course name- HERBAL DRUG TECHNOLOGY (Theory)

Course code-BP 603 T

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

Course Outcomes:

- CO1:** Explanation about raw material as source of herbal drugs from cultivation to herbal drug product
CO2: Describe about the WHO and ICH guide lines for evaluation of herbal drugs
CO3: Discussion about the herbal cosmetics, natural sweeteners, nutraceuticals
CO4: Discussion about patenting of herbal drugs, GMP

Course content:

UNIT-I

Herbs as raw materials

11 Hours

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

Nutraceuticals

7 Hours

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.

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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.

Course name- BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

Course code-BP 604 T

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.

Course Outcomes:

- CO1:** Explanation about the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- CO2:** Discussion about plasma drug concentration- time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- CO3:** Discussion about the concepts of bioavailability and bioequivalence of drug products and their significance.
- CO4:** Illustration about various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I

10Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes,

Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

10 Hours

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

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

UNIT- III

10 Hours

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

UNIT- IV**08 Hours**

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

UNIT- V**07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.
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. Brahmanekar 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 Thomas, N. Tozen, Lea and Febiger, 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 Inn, New York and Basel, 1987.
- 12) Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

Course name- PHARMACEUTICAL BIOTECHNOLOGY (Theory)

Course code- BP 605 T

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.

Course Outcomes:

CO1: Tells about the importance of Immobilized enzymes in Pharmaceutical Industries

CO2: Discussion about Genetic engineering applications in relation to production of pharmaceuticals

CO3: Discussion about Importance of Mono clonal antibodies in Industries

CO4: Appraise the use of micro organisms in fermentation technology

Course content

Unit I

10 Hours

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

Unit II

10 Hours

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

Unit III

10 Hours

Types of immunity- humoral immunity, cellular immunity

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

Unit IV**08Hours**

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

Unit V**07 Hours**

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

Recommended Books (Latest edition):

- 1) B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- 2) RA Goldshy et. al., : Kuby Immunology.
- 3) J.W. Goding: Monoclonal Antibodies.
- 4) J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
- 5) Zaborsky: Immobilized Enzymes, CRC Press, 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

Course name- PHARMACEUTICAL QUALITY ASSURANCE (Theory)

Course code- BP606T

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.

Course Outcomes:

CO1: Explanation about the cGMP aspects in a pharmaceutical industry

CO2: Appraise the importance of documentation

CO3: Discussion about the scope of quality certifications applicable to pharmaceutical industries

CO4: Describe about 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 Dekker Series
- 9) ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

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Course name- INSTRUMENTAL METHODS OF ANALYSIS (Theory)

Course code- BP701T

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.

Course Outcomes:

- CO1:** Discussion about the interaction of matter with electro magnetic radiations and its applications in drug analysis
CO2: Explanation about the chromatographic separation and analysis of drugs.
CO3: Develop quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT -I

UV Visible spectroscopy

- 10 Hours

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

IR spectroscopy

10 Hours

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

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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

Course name- INDUSTRIAL PHARMACY-II (Theory)

Course code- BP 702 T

45 Hours

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

Course Outcomes:

CO1: Explanation about the process of pilot plant and scale up of pharmaceutical dosage forms

CO2: Discussion about the process of technology transfer from lab scale to commercial batch

CO3: Discussion about different Laws and Acts that regulate pharmaceutical industry

CO4: Describe 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>.

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Course name- PHARMACY PRACTICE (Theory)

Course code- BP 703T

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.

Course Outcomes:

- CO1:** Impart the knowledge about various drug distribution methods in a hospital
CO2: Appraise the pharmacy stores management and inventory control
CO3: Examine the drug therapy of patient through medication chart review and clinical Review
CO4: Appraise the concept of Rational drug therapy.

Unit I:

10 Hours

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.

Hospital pharmacy and its organization

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

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.

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

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.

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.

Therapeutic drug monitoring

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

Medication adherence

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

Patient medication history interview

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

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III:

10 Hours

Pharmacy and therapeutic committee

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

Drug information services

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

Patient counseling

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

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.

Prescribed medication order and communication skills

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

Unit IV

8 Hours

Budget preparation and implementation

Budget preparation and implementation

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.

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

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

Investigational use of drugs

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

Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

- a) Merchant S.H. and Dr. J.S. Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakashan; 2001.
- b) 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.
- c) William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
- d) Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
- e) Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
- f) 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)

Course name- NOVEL DRUG DELIVERY SYSTEMS (Theory)

Course code- BP 704T

45 Hours

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

Course Outcomes:

CO1: Discussion about various approaches for development of novel drug delivery systems.

CO2: Describe the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates, Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations. **10 Hours**

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

Unit-II

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications **10 Hours**

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

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches **10 Hours**

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

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications **08 Hours**

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

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Course name- BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

Course code- BP801T

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.

Course Outcomes:

CO1: Impart the knowledge about the operation of M.S.Excel ,SPSS R, and MINITAB[®], DoE (Design of Experiment)

CO2: Discussion about the various statistical techniques to solve statistical problems

CO3: Appraise 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

Blocking and confounding system for Two-level factorials

8 Hours

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

Design and Analysis of experiments:

7Hours

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 Pannerselvam, Learning Private Limited, R.
4. Design and Analysis of Experiments –Wiley Students Edition, Douglas and C. Montgomery

**Course name- SOCIAL AND PREVENTIVE
PHARMACY**

Course code- BP 802T

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.

Course Outcomes:

CO1: Assume high consciousness / realization of current issues related to health and pharmaceutical problems with in the country and world wide.

CO2: Discuss critical way of thinking based on current health care development.

CO3: Explain 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

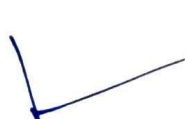
Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

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

Course name- PHARMA MARKETING MANAGEMENT (Theory)

Course code- BP803ET

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 Outcomes:

- CO1:** Describe the concept of pharmaceutical marketing
- CO2:** Discuss the concept of product management in pharmaceutical industry
- CO3:** Discuss the various component of promotion of pharmaceutical products
- CO4:** Explain the different pharmaceutical marketing channels
- CO5:** Discuss the role market research.

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.

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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, Indian Context, Macmilan India, New Delhi.
- 7) Shanker, Ravi: Service Marketing, Excel Books, New Delhi
- 8) Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

Course name- PHARMACEUTICAL REGULATORY SCIENCE (Theory)

Course code- BP804 ET

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.

Course Outcomes:

CO1: Impart knowledge about the process of drug discovery and development

CO2: Impart knowledge about the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO3: Discuss 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

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Course name- PHARMACOVIGILANCE (Theory)

Course code- BP 805T

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.

Course Outcomes:

CO1: Discussion about drug safety monitoring and history and development of pharmacovigilance

CO2: Discuss about National and international scenario of pharmacovigilance

CO3: Describe about methods to generate safety data during preclinical, clinical and post approval phases of drugs' life cycle

CO4: Discussion about Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation

CO11: Impart knowledge about ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning, CIOMS requirements for ADR reporting

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

Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS), **8 Hours**

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

Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK- parameters. **7 hours**

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

Course name- QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Course code- BP 806 ET

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.

Course Outcomes:

CO1: Impart knowledge about WHO guidelines for quality control of herbal drugs

CO2: Impart knowledge about Quality assurance in herbal drug industry

CO3: Explanation about the regulatory approval process and their registration in Indian and international markets

CO4: Appraise 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 intraditional 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)

- a) Pharmacognosy by Trease and Evans
- b) Pharmacognosy by Kokate, Purohit and Gokhale
- c) Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , CarrierPub., 2006.
- d) Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
- e) EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
- f) Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- g) 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.
- h) 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.
- i) WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
- j) WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- k) 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.
- l) WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Course name- COMPUTER AIDED DRUG DESIGN (Theory)

Course code- BP 807 ET

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.

Course Outcomes:

CO1: Design and discovery of lead molecules

CO2: Describe the role of drug design in drug discovery process

CO3: Discuss the concept of QSAR and docking

CO4: Explain various strategies to develop new drug like molecules.

CO5: Impart knowledge about 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

Informatics & Methods in drug design

08 Hours

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

UNIT-V

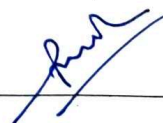
Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

07 Hours

Recommended Books (Latest Editions)

- a) Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
- b) Martin YC. "Quantitative Drug Design" Dekker, New York.
- c) Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- d) Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
- e) Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
- f) Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
- g) Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
- h) Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- i) Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

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Course name- CELL AND MOLECULAR BIOLOGY (Elective subject)

Course code- BP808ET

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.

Course Outcomes:

- CO1:** Summarize cell and molecular biology history.
- CO2:** Summarize cellular functioning and composition.
- CO3:** Describe the chemical foundations of cell biology.
- CO4:** Summarize the DNA properties of cell biology.
- CO5:** Describe protein structure and function.

Unit I

10Hours

Cell and Molecular Biology: Definitions theory and basics and Applications, Cell and Molecular Biology: History and Summation, Properties of cells and cell membrane, Prokaryotic versus Eukaryotic Cellular Reproduction, Chemical Foundations – an Introduction and Reactions (Types)

Unit II

10 Hours

DNA and the Flow of Molecular Informationm DNA Functioning, DNA and RNA, Types of RNA Transcription and Translation

Unit III

10 Hours

Proteins: Defined **and** Amino Acids, Protein Structure, Regularities in Protein Pathways Cellular Processes, Positive Control and significance of Protein Synthesis

Unit IV

08 Hours

Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis, Mitosis and Meiosis Cellular Activities and Checkpoints

Unit V

07 Hours

Cell Signals: Introduction, Receptors for Cell Signals, Signaling Pathways: Overview, Misregulation of Signaling Pathways, Protein-Kinases: Functioning

Recommended Books (latest edition):

- a) W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
- b) Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
- c) Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

- d) Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
- e) Rose: Industrial Microbiology.
- f) Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
- g) Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- h) Pepler: Microbial Technology.
- i) Edward: Fundamentals of Microbiology.
- j) N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- k) Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
- l) B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- m) RA Goldshy et. al., : Kuby Immunology.

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Course name- COSMETIC SCIENCE (Theory)

Course code- BP809ET

45Hours

Course Outcomes:

CO1: Discuss about basic knowledge of Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

CO2: Discuss about Skin: Basic structure and function of skin.

CO3: Discuss about Hair: Basic structure of hair. Hair growth cycle.

CO4: Explain about Oral Cavity: Common problem associated with teeth and gums.

Course Content:

UNIT I

10Hours

Classification of cosmetic and cosmeceutical products

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

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

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

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

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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

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

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Course name- PHARMACOLOGICAL SCREENING METHODS

Course code- BP810 ET

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.

Course Outcomes:

CO1: Appreciate the applications of various commonly used laboratory animals.

CO2: Appreciate and demonstrate the various screening methods used in pre clinical research

CO3: Appreciate and demonstrate the importance of biostatistics and research methodology

CO4: Design and execute a research hypothesis independently

Course Content

Unit –I

10 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

Unit –III

10 hours

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

Unit –IV

10 hours

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, antiaggregatory, coagulants, and anticoagulants

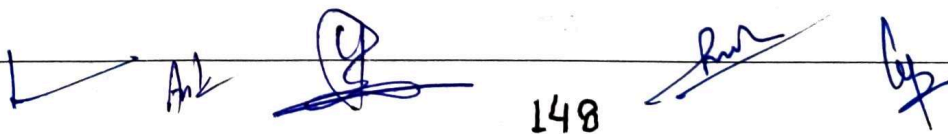
Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

Unit V

05 hours

Research methodology and Bio-statistics

Selection of research topic, review of literature, research hypothesis and study design



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

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

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Course name- ADVANCED INSTRUMENTATION TECHNIQUES

Course code- BP 811 ET

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.

Course Outcomes:

CO1: Discuss about the advanced instruments used and its applications in drug analysis

CO2: Describe the chromatographic separation and analysis of drugs.

CO3: Demonstrate the calibration of various analytical instruments

CO4: Impart knowledge about 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

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UNIT-IV

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 solidphase extraction and liquid-liquid extraction

08 Hours**UNIT-V**

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

07 Hours**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

Course name- DIETARY SUPPLEMENTS AND NUTRACEUTICALS

Course code- BP 812 ET

Scope :

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

Course Outcomes:

- CO1:** Explain the need of supplements by the different group of people to maintain healthy life.
CO2: Discuss the outcome of deficiencies in dietary supplements.
CO3: Appraise the components in dietary supplements and the application.
CO4: Appraise the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I

07 hours

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. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

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

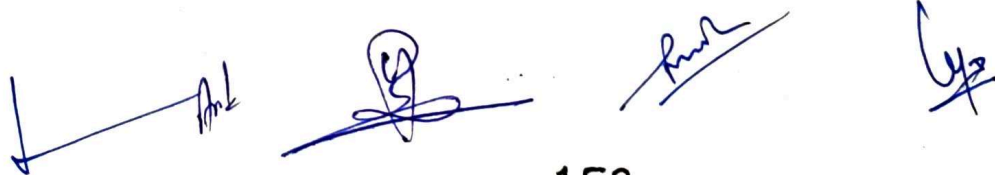
- Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- Sulfides: Diallyl sulfides, Allyl trisulfide.
- Polyphenolics: Resveratrol
- Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- Phyto estrogens : Isoflavones, daidzein, Geestustin, lignans
- Tocopherols
- 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

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.

Dietary fibres and complex carbohydrates as functional food ingredients..



UNIT IV

10 hours

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. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α - Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
Functional foods for chronic disease prevention

UNIT V

06 hours

Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
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) 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

**Course name- Pharmaceutical Product Development
BP 813ET**

45 hours

Scope: This subject covers fundamental knowledge about importance, need and requirements of excipients, optimization techniques and quality control testing in pharmaceutical product development.

Course Outcomes:

CO1: Explain the objective of pharmaceutical product development and quality control of dosage forms

CO2: Discuss about the pharmaceutical excipients of different categories.

CO3: Appraise the optimization techniques in pharmaceutical product development.

Course content

Unit-I

10 Hours

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

Unit-II

10 Hours

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

- a) Solvents and solubilizers
- b) Cyclodextrins and their applications
- c) Non - ionic surfactants and their applications
- d) Polyethylene glycols and sorbitols
- e) Suspending and emulsifying agents
- f) 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

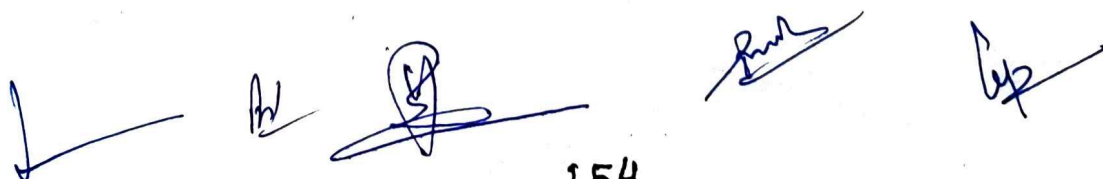
- a) Tablet and capsule excipients
- b) Directly compressible vehicles
- c) Coat materials
- d) Excipients in parenteral and aerosols products
- e) Excipients for formulation of NDDS

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.
- 8) Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
- 9) Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
- 10) Remington – The Science and Practice of Pharmacy, 20th Ed.
- 11) Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
- 12) Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
- 13) Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
- 14) Advanced Review Articles related to the topics.

Course Name- Project Work

BP814PW

Course Outcomes:

CO1: Analyze the recent studies in the field of research

CO2: Examine a research problem and critically categorize relevant papers retrieved from various sources for the study.

CO3: Demonstrate reflective learning skills based on their research work

CO4: Outline and present an overview of the proposed topic of interest, as well as the findings from the investigation of various parameters.

CO5: Evaluate the usefulness of various research methods for the study of a specific problem by selecting one of the options and justifying your choice

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